August 3 , 2010

CCN 221673
NRC Project #0748

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D.C. 20555

SUBJECT: Contract No. DE-AC07-05ID14517 – Next Generation Nuclear Plant Project - Quality Assurance Program Description – NRC Project #0748

Section 641(b) of the Energy Policy Act of 2005 (Public Law 109-58) (EPAct) states that the Next Generation Nuclear Plant (NGNP) Project shall consist of the research, development, design, construction, and operation of a plant, including a nuclear reactor that is based on research and development (R&D) activities supported by the Generation IV Nuclear Energy Systems Initiatives. The NGNP will be a licensed commercial high temperature gas-cooled reactor (HTGR) plant capable of producing electricity and high temperature process heat for a variety of energy intensive industries.

To implement this effort, the NGNP licensing strategy was jointly developed by the Nuclear Regulatory Commission (NRC) and the Department of Energy (DOE) ("NGNP Licensing Strategy – Report to Congress," dated August 2008). The Strategy included recognition of the need for the DOE and NRC to facilitate and coordinate early exchanges of information that relate to the reactor design and the NGNP Combined License (COL) application. Conducting effective early interactions with the NRC is a critical part of the NGNP licensing strategy because the early resolution of issues can significantly impact the preparation of an acceptable license application, the subsequent application review schedule, and the ultimate deployment of the NGNP.

In keeping with that framework, the purpose of this letter is to submit the enclosed document, PDD-172, "Next Generation Nuclear Project Quality Assurance Program Description," (QAPD) for NRC Staff review and feedback, as part of the early licensing phase of the project. The QAPD is the top-level policy document that establishes the Quality Assurance (QA) policy and assigns major functional responsibilities for R&D, design, Early Site Permit (ESP)/COL application/construction/pre-operation and/or operation activities, and decommissioning conducted by or for the NGNP Project. The QAPD describes the methods and establishes QA and administrative control requirements that meet 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The QAPD is based on the requirements and recommendations of NQA-1-2008, 1a-2009, Parts I, II, and III, with the additions and modifications identified in NRC Regulatory Guide 1.28. The NRC has endorsed ASME NQA-1-2008, 1a-2009 as an acceptable method of meeting 10 CFR Part 50, Appendix B criteria.

The NGNP Project's QAPD is believed to be the first program to incorporate the recently endorsed NQA-1 Standard; therefore, we look forward to feedback from the NRC Staff. Following the NRC Staff's review of this submittal, the NGNP Project requests that the NRC provide feedback and documentation of its review in a format that will facilitate resolution of issues that may be identified. The NGNP Project requests that the NRC review be completed, and feedback transmitted, no later than October 29, 2010. This will help facilitate timely resolution of any issues found during the review, as NGNP proceeds through the QAPD implementation process.

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Once we have evaluated and addressed the NRC's feedback, the NGNP Project then intends to update the QAPD (if necessary) and submit it to NRC in the form of a "topical report" transmittal. In this follow-on submittal, we'll request formal NRC review and issuance of a Safety Evaluation Report, after any remaining QAPD content issues have been resolved with the NRC Staff.

If you have any questions regarding this submittal, please contact me at (208) 526-6063 or Jim Kinsey, Director, NGNP Regulatory Affairs at (208) 526-6882.

Sincerely,

Greg Gibbs, Project Director
Next Generation Nuclear Plant Project

JK:DP:CN

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1. PDD-172, Next Generation Nuclear Plant Quality Assurance Program Description

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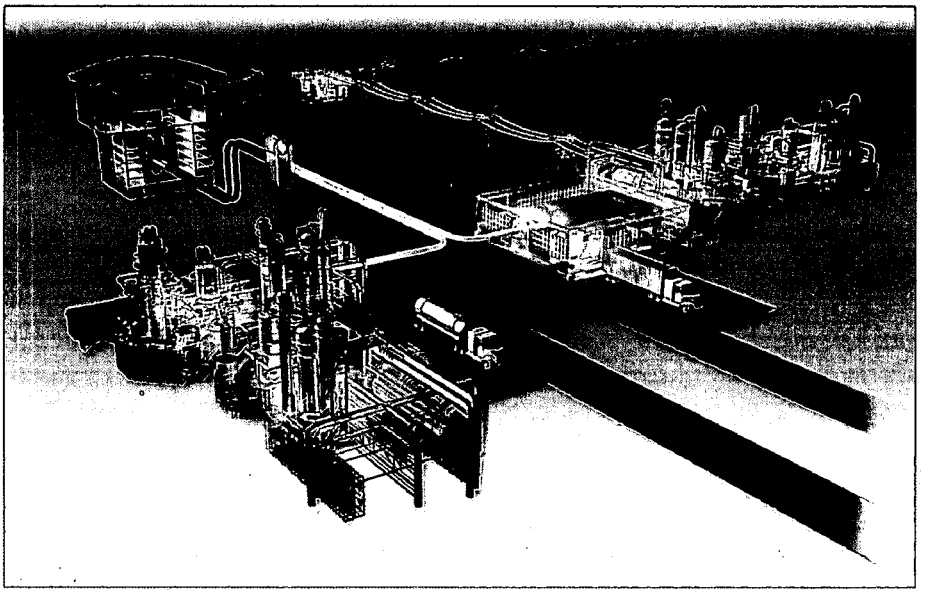
Program Description Document

Next Generation Nuclear Plant Quality Assurance Program Description



The INL is a
U.S. Department of Energy
National Laboratory
operated by
Battelle Energy Alliance

Idaho National Laboratory

POLICY STATEMENT

The Next Generation Nuclear Plant (NGNP) Project manages the services, sciences, and technology provided by Idaho National Laboratory (INL) for the NGNP Project. It is the policy of the NGNP Project to provide high-quality, technically defensible, scientific information and services for the Department of Energy Office of Nuclear Energy while complying with applicable requirements using a graded approach appropriate for the task. The NGNP Project shall perform research and development (R&D) focused on materials, methods, and fuels to support the NGNP design, and shall design, procure, construct, and operate the NGNP nuclear plant in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations, the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, and applicable laws and regulations of the state and local governments.

The NGNP Quality Assurance Program (QAP) consists of the Quality Assurance Program Description (QAPD) provided in this document, the Program Requirements Documents, and the associated implementing documents. Together they provide for the control of NGNP Project activities that affect or will affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other DOE requirements and/or NRC guidance lead to the establishment of additional program requirements. The QAPD also applies to the R&D activities that will support the design and licensing of NGNP safety-related SSCs, utilizing a graded approach in applying QA requirements, based on quality levels established through a formal risk determination process.

The NGNP Project begins with R&D activities that support design and licensing of NGNP and develops through Early Site Permit, Combined License, construction, preoperational, and operation phases. Applicable instructions, procedures, and drawings will be developed at each phase to implement the QAPD.

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

Signed

Greg Gibbs

Project Director, Next Generation Nuclear Plant Project

07/26/10

Signatures

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Keith Perry	R&C	7/26/10	NGNP Engineering Director
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R&C – Review and Concurrence
R – Review
A – Approval

REVISION LOG

Rev.	Date	Affected Pages	Revision Description
0	10/01/10	All	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.

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NOTE: ***This document was prepared using the NEI-06-14, Revision 7, Quality Assurance Program Description that was based on NQA-1-1994, as that was the version available for use when the QAPD was issued. As the NEI template is updated to address NQA-1-2008, 1a-2009, this document will be revised to include pertinent changes, exceptions, etc., consistent with the update.***

PART I – INTRODUCTION

1.1 General

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

The NGNP QA Program (QAP) consists of the Quality Assurance Program Description (QAPD), Program Requirements Documents (PRDs) that establish QA requirements based on the ASME NQA-1-2008, 1a-2009 consensus standard, and the procedures that implement the QA requirements.

This QAPD is the top-level policy document that establishes the Quality Assurance (QA) policy and assigns major functional responsibilities for research and development (R&D), design, Early Site Permit (ESP)/Combined Operating License (COL)/construction/pre-operation and/or operation activities, and decommissioning conducted by or for the NGNP Project.

The QAPD describes the methods and establishes QA and administrative control requirements that meet 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." NRC Regulatory Guide 1.28, Quality Assurance Program Criteria, endorses the American Society of Mechanical Engineers (ASME) NQA-1-2008, 1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," subject to identified additions and modifications, as an acceptable method of meeting 10 CFR Part 50, Appendix B criteria. The QAPD is based on the requirements and recommendations of NQA-1-2008, 1a-2009, Parts I, II, and III, with the additions and modifications identified in NRC Regulatory Guide 1.28. As the NGNP is established under the INL M&O contract with DOE, the QAPD also describes the methods and administrative control requirements that meet 10 CFR 830, "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements," DOE Order 414.1C, "Quality Assurance," and DOE Order 226.1A, "Implementation of Department of Energy Oversight Policy."

The QAPD describes the application of the NGNP QAP from initial R&D activities involving materials, methods, and fuels, through the design and licensing including Early Site Permit, Combined Operating License, and through

construction, preoperational, operation and eventual decommissioning activities. R&D activities are conducted in accordance with the guidance in ASME NQA-1-2008, 1a-2009, Part IV, Subpart 4.2, "Guidance on Graded Application of the Nuclear Quality Assurance (NQA) Standard for Research and Development" using a formal graded approach method that ensures defensible data and records commensurate with the proposed application to support licensing of NGNP structures, systems, and components (SSCs) under 10 CFR 50, Appendix B.

Graded application is used only for R&D activities. For non-R&D activities, a formal listing of SSCs, and the basic components of SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public will be developed. Safety-related SSCs will be identified in design documents. The technical aspects of the safety-related SSCs will be considered when determining QAP applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

Implementing procedures and instructions that control NGNP Project activities will be developed prior to commencement of the associated activities at each development phase. Policies establish high-level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all NGNP Project organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

The NGNP QAP includes a comprehensive, integrated Contractor Assurance System (CAS), which is consistent with the hazards and the risks associated with the work performed. The CAS encompasses the activities designed to identify and address program and performance deficiencies, provide opportunities for improvement, provide the means and requirements to report deficiencies to responsible managers and authorities, establish and effectively implement corrective and preventive actions, and share lessons-learned across all aspects of operations.

The NGNP QAP is fully integrated with other INL management systems including the Integrated Safety Management System (ISMS), the Environmental Management System (EMS), and the Integrated Safeguards and Security Management System (ISSMS). All of these management systems function collectively to ensure safe, secure, and compliant work that meets or exceeds the user's requirements or expectations.

Functional responsibilities and levels of authority are identified in roles, responsibilities, accountabilities, and authorities documents (R2A2s), which are developed for each management position and for groups of employees with similar functions. These functional responsibilities and levels of authority support Employee Position Descriptions, which are developed for each employee. 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 QAPD requirements established in accordance with10 CFR Part 50, Appendix B criterion, then NGNP specific procedures are established.

1.2 Scope/Applicability

The QAPD applies to the current R&D activities and the future design, ESP, COL, construction, preoperation, operations, and decommissioning activities that may affect the quality and performance of safety-related structures, systems, and components, including, but not limited to:

Designing	Shipping	Startup
Safety related analysis and evaluation	Receiving	Pre-operational activities (including ITAAC)
Siting	Storing	Operating
Software V&V	Constructing	Maintaining
Procuring	Erecting	Repairing
Fabricating	Installing	Modifying
Cleaning	Inspecting	Refueling
Handling	Testing	Training

1.3 Source Documents

1.3.1 Requirements

The NGNP QAP documents and implements the following requirements:

- 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.

- DOE Order 226.1A, "Implementation of Department of Energy Oversight Policy" (CAS Order). This order requires the establishment of a comprehensive, integrated Contractor Assurance System that is consistent with the hazards and the risks associated with the work performed.

1.3.1 Standards

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

- 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."

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

- 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.

1.3.2 Guides

The QA Order 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:

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

- DOE Guide 414.1-1A, *Management Assessment and Independent Assessment.*
- DOE Guide 414.1-3, *Suspect/Counterfeit Items.*
- DOE Guide 414.1-4, *Safety Software*
- ASME NQA-1-2008, 1a-2009, Part III, Subpart 3.3, "Non-mandatory Appendix 3.3: Guidance on Qualification of Existing Data."
- ASME NQA-1-2008, 1a-2009, Part IV, Subpart 4.2, "Graded Approach Application of Quality Assurance Requirements for Research and Development."

1.4 Program Documents

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 PDD (PDD-172) 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.

Also at Tier 2 are LWPs, GDEs, and STDs that are used to implement the QAP at the laboratory level.

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

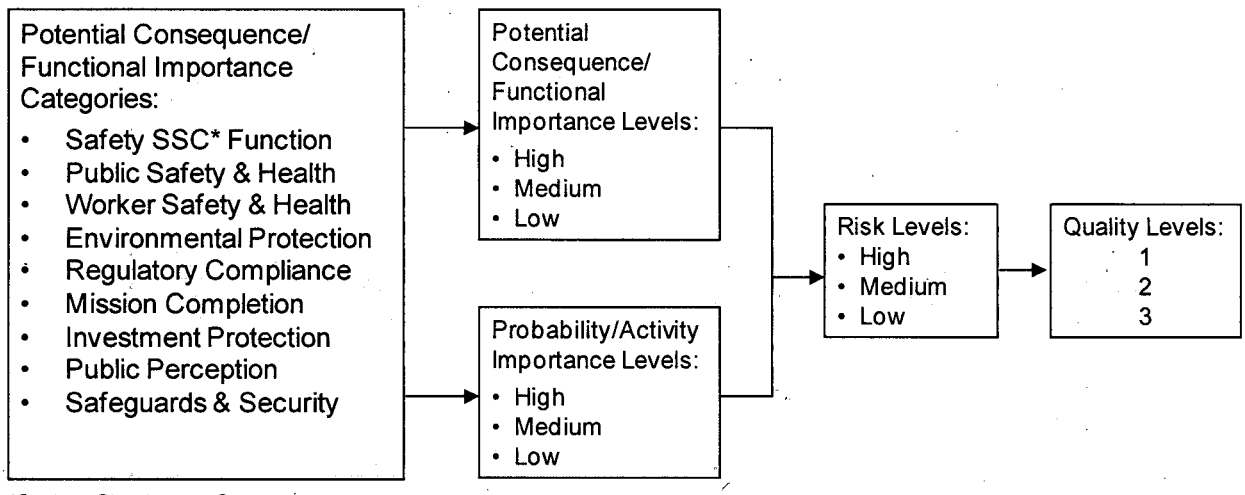
1.5 Program Application

1.5.1 Graded Approach

The NGNP QAP is applied to all R&D items and activities affecting quality using a graded approach. For each item or activity, a quality level

is assigned by using a direct or an indirect risk analysis method. This Quality Level Determination (QLD) process is shown in Figure 1. The direct risk analysis method includes determining the results of failure of the item or activity, the potential consequences of failure, and the probability of failure. The indirect risk analysis is similar to the direct risk analysis but uses the functional importance of the items or activities as a substitute for potential consequences and the relative importance of activities associated with ensuring the function as a substitute for probability. Risks are assigned using Table 1. Items and activities with associated risks of high, medium, and low are assigned Quality Levels of 1, 2, and 3, respectively. The quality levels are recorded in an electronic database that allows document storage and retrievability.

Because the QLD process is critical to correctly applying QA requirements, the determinations are performed only by designated personnel who have been trained and qualified to perform the determinations as Quality Level Analysts. Each determination requires review and concurrence by another qualified Quality Level Analyst (Quality Level Reviewer) and approval by managers who are responsible for the items or activities.



*System, Structure, or Component

Figure 1. Determination of risk and quality level.

Table 1. Risk determination.

Potential Consequence/ Functional Importance	Risk		
High	Medium	High	High
Medium	Low	Medium	High

Low	Low	Low	Medium
Probability/Activity Importance	Low	Medium	High

For each quality level, the depth, extent, and rigor of application of QAP requirements for responsibilities, personnel training and qualification, work processes, design, procurement, inspection and acceptance testing, suspect/counterfeit items prevention, software QA, and documents and records are specified in implementing documents. The depth, extent, and rigor of application of requirements for assessment and quality improvement are based on risk considerations but not quality levels.

1.6 Program Integration

The NGNP QAP is fully integrated with other INL management systems. In particular, the QAP is integrated with the INL ISMS, the EMS, and the ISSMS. All of these management systems function collectively to ensure safe, secure, and compliant work that meets or exceeds the user's requirements or expectations.

Table 2 shows the QAP elements that are integrated with the elements of ISMS.

Table 2. QAP and ISMS integration.

Guiding Principles (GP) and Core Functions (CF)	QAP Elements
Line Management Responsibilities (GP) Clear Roles and Responsibilities (GP)	Organization Quality Assurance Program
Competence Commensurate with Responsibility (GP)	Quality Assurance Program Personnel Training and Qualification
Define Scope of Work (CF) Balanced Priorities (GP)	Instructions Procedures and Drawings Design Control Procurement Document Control Software QA Control of Purchased Items and Equipment Inspection
Identify and Analyze Hazards (CF) Identification of Safety Standards (GP)	
Develop and Implement Hazard Controls (CF) Hazard Controls Tailored to Work (GP)	

Guiding Principles (GP) and Core Functions (CF)	QAP Elements
Perform Work Within Controls (CF) Operations Authorization (GP)	Test Control Document Control QA Records Identification and Control of Items Control of Special Processes Control of Measuring and Test Equipment Handling, Storage, and Shipping Inspection, Test, and Operating Status Commercial Grade Items and Services Suspect Counterfeit Items Part 21 Reporting
Provide Feedback and Continuous Improvement (CF)	Audits Control of Nonconforming Items Corrective Action Contractor Assurance System Quality Improvement Assessments

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

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 Project is organized and the NGNP Project Organization responsible to establish and implement the NGNP QAP. The organizational structure includes functions for the NGNP including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties

within the scope of the QAPD. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

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 who is 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 size 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 the INL or contracted out to qualified suppliers. The Very High Temperature Reactor (VHTR) – Technology Development Office (TDO) is contracted to perform 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 out to other national laboratories, universities and commercial companies to perform. NGNP QAP requirements are rolled down to the VHTR-TDO through a task baseline agreement. The VHTR TDO roles 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 represents how the NGNP Project implements the applicable organizational requirements of NQA-1-2008, 1a-2009.

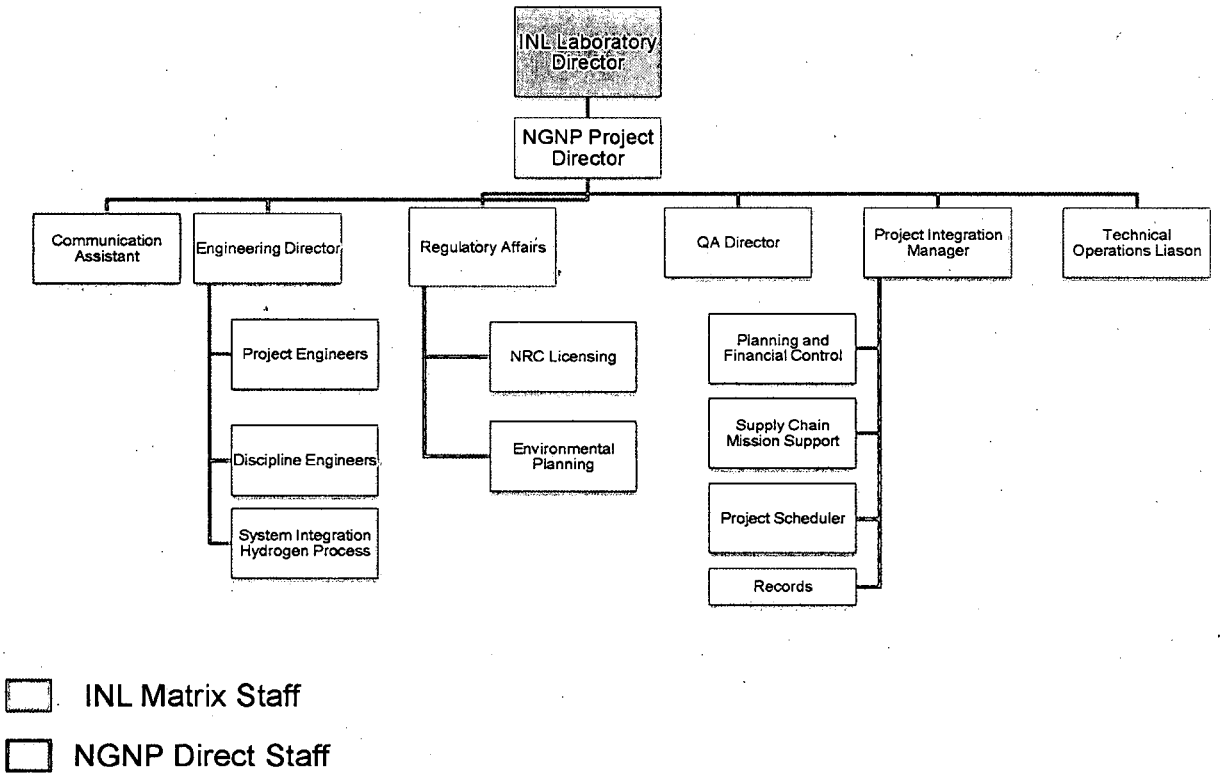


Figure 2. NGNP Organization.

2.1.1 NGNP Project Director

2.1.1.1 Roles and Responsibilities

- Establishes overall expectations for effective implementation of the NGNP QAP and is responsible for obtaining the desired end result.
- Provides overall management for the execution of the NGNP Project.
- Leads the cross-functional group of project team members assembled to successfully execute the

project objectives established jointly with the customer; the INL Program Manager, the Deputy for Projects Nuclear Support and Production and the 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.

- Provides overall management direction, defines roles and responsibilities, delegates authorities, and enforces accountabilities for the NGNP Project organization.
- Ensures that the appropriate process controls are formally defined for the execution of project work.
- Develops and maintains cost and schedule contingencies that are commensurate with acceptable risk levels for the project.
- 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

- Accountable to the project customer for the overall definition and execution of the project.
- Accountable to the INL Laboratory Director for the overall execution of the NGNP Project within schedule, cost, and quality requirements.
- Accountable to the Deputy for Projects, Nuclear Support, and Production for the conduct of project activities in accordance with the overall policies, processes, and practices for projects at INL.
- Accountable to the NGNP Project organization to provide leadership and direction.

- Authorizes the expenditure of project funds up to the approved authority limit.
- 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.
- Submits formal correspondence to licensing and regulatory authorities for the NGNP Project.
- Approves the assignment and reassignment of key project team members.
- Manages the project schedule to maximize project efficiency and performance.
- 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

- Supports the Project Director in successfully fulfilling the Director's R2A2s.
- Assumes the R2A2s of the NGNP Project Director in the absence of the Director. This assumption of the Project Director R2A2s has 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

- 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.

- Responsible for all subcontract and direct NGNP Engineering work.

- 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).

- Provides technical direction, coordination, problem resolution, and oversight of NGNP Project design, R&D, 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.

- Supports the development of the licensing and regulatory strategies.

- Ensures that NGNP subcontractor design work and R&D activities are consistent with the project system requirements and licensing strategy.

- 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.

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

2.1.3.2 Accountabilities and Authorities

- 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.

- Coordinates and oversees the schedule and budget for NGNP Engineering activities.
- Coordinates and oversees allocated budget.
- Coordinates and oversees activities of NGNP Engineering personnel in support of the NGNP Project (e.g., making assignments, reviewing work, and evaluating performance).
- Revises Engineering organization responsibilities with NGNP Project Director concurrence.

2.1.4 NGNP Project Integration Manager

2.1.4.1 Roles and Responsibilities

- Establishes and maintains an integrated schedule and cost control process for the project's entire scope of work.
- Provides the overall administrative structure for execution of the project, in coordination with the other directors.
- Acts as a liaison between the project and other organizations.
- Manages planning and financial control's resources for the development and maintenance of an integrated schedule and cost control process.
- Ensures proper cost and accounting management of funded work scope.

2.1.4.2 Accountabilities and Authorities

- Accountable to the project organization as the primary point of contact for procurement activities.
- Accountable to the INL Director of Business Management to ensure that Project activities are performed in accordance with INL processes and practices.
- Obtains and assigns personnel, as required, to fulfill responsibilities within the authorized budget.
- Approves purchase requisitions and other procurement actions within authority limits.
- 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

- Coordinates all technical and licensing interfaces with the NRC and environmental/state regulatory agencies.
- Establishes requirements for conduct of work within the NGNP Project organization and its subcontractors necessary to fulfill licensing and regulatory requirements.
- Coordinates with NGNP management to ensure that the licensing strategy is consistent with the technical requirements and that R&D activities are sufficient to support that strategy.
- 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

- 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.
- Accountable (authority delegated from the Project Director) as the licensing contact with the NRC and regulatory agencies.
- Coordinates and oversees the allocated budget.

2.1.6 NGNP Technical Operations Liaison

2.1.6.1 Roles and Responsibilities

- Develops a full understanding of overall work force needs specific to NGNP. Evaluates INL initiatives and industry programs and their potential effectiveness to produce the needed NGNP work.
- Assists the NGNP management team in developing and maintaining a highly productive operational resource base to meet the NGNP mission.

2.1.6.2 Accountabilities and Authorities

- Accountable to the NGNP Project Director for identifying NGNP workforce needs and assisting to meet requirements.

2.1.7 NGNP QA Director

The NGNP QA Director reports to the NGNP Project Director, and is responsible for the development and verification of implementation of the QAPD described in this document. The NGNP QA Director is responsible for assuring compliance with regulatory requirements and procedures through audits and monitoring technical reviews; organization processes to ensure conformance to commitments and licensing document requirements; for ensuring that vendors providing quality services, parts and materials to NGNP are meeting the requirements of 10 CFR 50, Appendix B through NUPIC or NGNP vendor audits. The NGNP QA Director has sufficient independence 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. The QA Director may make recommendations to the NGNP Project management regarding improving the quality of work processes. 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.

2.1.7.1 Roles and Responsibilities

- Serves as QA Director to provide leadership and direction and to integrate and manage the QAPD for the NGNP Project.
- Assists in identifying and interpreting the QA requirements and standards that apply to NGNP activities.
- Verifies that QA processes and systems are developed, implemented, and updated as necessary to support NGNP program needs.
- Assists the NGNP Project Director in developing and maintaining QAPD documentation, including implementing procedures.
- Provides ongoing, timely, and candid communications with NGNP management, participants, and regulating agencies (e.g., NRC and DOE), as appropriate.
- Assesses implementation of NGNP processes and systems and assists in resolving identified issues.
- Assists the NGNP Project Director in coordinating outside audits, and ensures identified issues are entered into INL's issues tracking system.
- Measures, analyzes, and reports QA performance to NGNP Project management.
- Provides and encourages appropriate training, professional development, and leadership opportunities for QA staff.

2.1.7.2 Accountabilities and Authorities

- Accountable to provide NGNP Project management with leadership and stewardship to achieve success in the NGNP Project's mission.
- Accountable to provide QA staff with leadership, mentoring, training, and necessary resources.
- Obtains and assigns QA staff to support NGNP Project needs.
- Holds the QA staff accountable for performance.
- Resolve quality issues with NGNP management.

2.1.8 Project Support Personnel

2.1.8.1 Roles and Responsibilities

- Provides support functions for daily operations of NGNP.
- Assists program, project, control account, and work package managers in developing and implementing direct or indirect project baselines—financial support personnel.
- Assists 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—financial support personnel.
- Serves as the NGNP Project representative and direct lead for all document and records management functions—records and document control personnel.
- Ensures that the documents which specify quality requirements or prescribe activities affecting quality are controlled during preparation, issue, and change

such that correct documents are being employed—records and document control personnel.

2.1.8.2 Accountabilities and Authorities

- 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 documents, which are developed for each management position and for groups of employees with similar functions, and in Employee Position Descriptions. 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 authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to 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 Quality Assurance Organizational Independence

For the R&D ESP/COL phase, independence shall be maintained between the organization(s) performing the checking (QA and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

2.1.12 NQA-1-2008, 1a-2009 Commitment

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

2.2 Section 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 the QAPD. 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 the QAPD through the audit functions described in Section 2.18.

The objective of the QAPD is to assure that NGNP's R&D activities result in defensible data and records to support the final design and associated SSCs 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 QAPD 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. 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. The QAPD will be implemented in a phased approach commensurate with the development and activities associated with the project phase of the NGNP. Cost and scheduling functions are not to prevent proper implementation of the QAPD.

The QA requirements applied to R&D activities will ensure defensible data and records for use in design and licensing of the NGNP. For the purpose of determining QA Program requirement applicability for R&D activities, the nonmandatory guidance of NQA-1-2008, 1a-2009, Part IV, Subpart 4.2, "Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development," is fully implemented. During the planning for each R&D activity, the Subpart 4.2 guidance is applied to determine NGNP QAP requirement applicability based on the technology lifecycle phase of the R&D; basic, applied, or developmental. Once the program requirement

applicability is determined, the Quality Level Determination process, described in Section 1.5, is applied to determine the level of analysis, extent of documentation, and degree of rigor of process controls to be applied commensurate with the item or quality affecting activity significance, risk, probability of failure, importance to safety, and programmatic mission (end use).

As described in Part III of the QAPD, specific QA program 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, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety. Delegated responsibilities may be performed under a supplier's or principal contractor's QAPD, provided that the supplier or principle contractor has been approved as a supplier in accordance with the QAPD. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principle contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

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

Detailed engineering specifications and construction procedures will be developed to implement the QAPD and Nuclear Steam Supply System NSSS supplier QA programs prior to commencement of preconstruction (ESP) and COL activities. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs during construction of a new 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 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 the QAPD. This includes the activities delineated in Part I, Section 1.1. NGNP personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity and to ascertain that such documents are being used. The 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 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, 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 2 years.

2.2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the NGNP QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a). Changes to the QAPD are evaluated by the NGNP QA Director to ensure that such changes do not degrade previously approved QA controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the ESP and COL application development process. New revisions to the document will be reviewed, at a minimum, by the NGNP QA Director and approved by the NGNP Project Director. As the NGNP Project progresses to the final design, ESP/COL, construction, and operations phases, the applicable parts in this QAPD that are shaded in grey will have the shading removed and the associated requirements will be incorporated and implemented. Any resultant changes to the QAPD will be evaluated and approved by the NGNP QA Director prior to implementation.

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

2.2.6 Personnel Qualifications

Personnel assigned to implement elements of the NGNP QAPD shall be capable of performing their assigned tasks. To this end, NGNP establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the NGNP QAPD to assure that suitable proficiency is achieved and maintained. Research and support staff minimum qualification requirements are established in the INL computer-based training and qualification system, TRAIN. These qualification requirements will be consistent with those delineated in the unit Technical Specifications at the appropriate phase of the project. Other qualification requirements may be established but will not reduce those required by Technical Specifications. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable

NGNP procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the NGNP QAPD elements to be employed. Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training. Records of personnel training and qualification are maintained in the INL computer-based training and qualification system.

The minimum qualifications of the NGNP QA Director are that he/she holds an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing, and maintaining the programs for the 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 Independent Review

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

- Reviews proposed changes to the facility as described in the safety analysis report (SAR). The Independent Review Committee (IRC) also verifies that changes do not adversely

affect safety and if a technical specification change or NRC review is required.

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

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

- Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

- Reviews any matter related to nuclear safety that is requested by the NGNP Project Director.

- Reviews corrective actions for significant conditions adverse to quality.

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

2.2.7.1 Independent Review Committee

- An IRC is assigned independent review responsibilities.

- The independent review committee reports to the NGNP Project Director.

- 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.

- 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.

- Results of the meeting are documented and recorded.

- Consultants and contractors are used for the review of complex problems beyond the expertise of the offsite/onsite IRC.

- 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: 6 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

      - nuclear power plant operations

      - nuclear engineering

      - chemistry and radiochemistry

      - metallurgy

      - nondestructive testing

      - instrumentation and control

      - radiological safety

- mechanical engineering, and electrical engineering.

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

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

2.2.8 NQA-1-2008, 1a-2009 Commitment

In establishing qualification and training programs, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 2.

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 the 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 can be related to the design input in sufficient detail to permit verification. Design change processes and the division of responsibilities for design-related activities are detailed in NGNP and supplier procedures. The design control program includes interface controls necessary to control the development,

verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the 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, and the appropriate quality standards applied to the design are identified and documented, and their selection reviewed and approved.

2.3.1 Design Verification

NGNP design processes provide for design verification to ensure that items and activities subject to the provisions of the QAPD are suitable for their intended application 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 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 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, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. 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. The 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:

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

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

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

- 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 Commercial Grade Items and Services

The final design identifies assemblies and/or components that are part of the item being designed. When such an assembly or part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics meet the requirements of ASME NQA-1-2008, 1a-2009a, Part II, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services."

2.3.6 NQA-1-2008, 1a-2009 Commitment

In establishing its program for design control and verification, NGNP commits to compliance with NQA-1-2008, 1a-2009, Basic Requirement 3, the Commercial Grade Items and Services requirements of Part II, Subpart 2.14, the subsurface investigation guidance in Nonmandatory Appendix 2.20, and the requirements for computer software in Part II, Subpart 2.7.

2.4 Procurement Document Control

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

- Where original technical or 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.

- 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 NGNP 's 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-1-2008, 1a-2009 Commitment/Exceptions

In establishing controls for procurement, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 4.

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 the QAPD as described in the QAPD. 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:

A. the written procedure to be present and followed step-by-step while the task is being performed

B. the user to have committed the procedure steps to memory

C. 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, research activities, and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

2.5.3 NQA-1-2008, 1a-2009 Commitment

In establishing procedural controls, NGNP commits to compliance with NQA-1-2008, 1a-2009, Basic 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 assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

- Identification of documents to be controlled and their specified distribution

- A method to identify the correct document (including revision) to be used and control of superseded documents
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents
- Review of documents for adequacy, completeness, and correctness prior to approval and issuance
- A method for providing feedback from users to continually improve procedures and work instructions
- Coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

- Drawings such as design, construction, installation, and as-built drawings
- Engineering calculations
- Design specifications
- Purchase orders and related documents
- Vendor-supplied documents
- Audit, surveillance, and quality verification/inspection procedures
- Inspection and test reports
- Instructions and procedures for activities covered by the QAPD including R&D activities, design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing
- Technical specifications
- Nonconformance reports and corrective action reports.

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

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 station as described in the SAR are screened to identify those that require review by the IRC prior to implementation as described in Part II, Section 2.

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

- Following any modification to a system
- Following an unusual incident, such as an accident, significant operator error, or equipment malfunction
- When procedure discrepancies are found
- Prior to use if not used in the previous two years
- Results of QA audits conducted in accordance with Part II, Section 18.1.

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

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-1-2008, 1a-2009 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 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:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- NGNP shall perform or arrange for annual evaluations of suppliers. NGNP shall document these evaluations and take the following considerations into account:

- The review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions

- Results of previous source verifications, audits, and receiving inspections

- Operating experience of identical or similar products furnished by the same supplier

- - Results of audits from other sources (e.g., ASME or NRC audits) **Note:** In Information Notice (IN) 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," the NRC staff informed applicants and licensees that the NRC recognizes the ASME Accreditation Program and documented QA program that meets the requirements of Appendix B to 10 CFR Part 50. However, recognition of the ASME Accreditation Program applies only to the programmatic aspects of the QA programs. Applicants and licensees or their subcontractors should ensure that the suppliers are effectively implementing their approved QA programs. *(Regulatory Guide 1.28, Rev 4, June 2010)* After award of a contract, NGNP may determine, based on the annual supplier evaluation, that external audits are not necessary for procuring items (a) that are relatively simple and standard in design, manufacturing, and testing and (b) that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. *(Regulatory Guide 1.28, Rev 4, June 2010)*

- NGNP shall either audit its supplier's QA Program on a triennial basis or arrange for such an audit. The triennial period begins when an audit is performed. NGNP may perform an audit when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA Program that has the required scope for purchases placed during the triennial period. If a subsequent contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, NGNP shall conduct an audit of the modified requirements, thus starting a new triennial period. If the supplier is implementing the same QA Program for other customers as that proposed for use on the NGNP's contract, the pre-award survey may serve as the first triennial audit. Therefore, when a pre-award survey is employed as the first triennial audit, it shall satisfy the same audit elements and criteria as those on other triennial audits. *(Regulatory Guide 1.28, Rev 4, June 2010)*

- If other purchasers buy from a single supplier, it is acceptable for NGNP to either perform or arrange for an audit of the supplier on behalf of itself and the other purchaser(s) to reduce the number of external audits of the supplier. The scope of this audit shall satisfy the needs of all purchasers to, and the audit report shall be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit. *(Regulatory Guide 1.28, Rev 4, June 2010)*

- Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the purchaser with appropriate input from the supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to ensure they will perform satisfactorily in service in safety-related applications. When commercial grade items or services are utilized, 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. *(NQA-1-2008, 1a-2009).*

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

2.7.2 NQA-1-2008, 1a-2009 Commitment

In establishing procurement verification controls, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 7, and when commercial grade items or services are utilized, Part II, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services." NGNP also commits to the associated Regulatory Positions in Regulatory Guide 1.28, Rev 4, June 2010.

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 that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

2.8.1 NQA-1-2008, 1a-2009 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 that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

2.9.1 NQA-1-2008, 1a-2009 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 operating activities.

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

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information

such as rejection, acceptance, and reinspection 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-1-2008, 1a-2009 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 12 of the QAPD.

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 test, (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 start-up test programs.

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

2.11.1 NQA-1-2008, 1a-2009 Commitment

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

2.11.2 NQA-1-2008, 1a-2009 Commitment for Computer Program Testing

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

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 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-1-2008, 1a-2009 Commitment/Exceptions

In establishing provisions for control of measuring and test equipment, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 12, and Part II, Subpart 2.4 with the following clarification and exception:

> Measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device), provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-2008, 1a-2009, Subpart 2.4, (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 at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

Operators of special handling and lifting equipment are experienced or trained in the use the equipment. During the operational phase, 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-1-2008, 1a-2009 Commitment

In establishing provisions for handling, storage and shipping, NGNP commits to compliance with NQA-1-2008, 1a-2009, Basic Requirement 13. NGNP also commits, during the construction and preoperational phase of the plant, to compliance 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-1-2008, 1a-2009, Subpart 3.2, Appendix 2.1: Only Section 3 precautions are being committed to in accordance with RG 1.37. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels.

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 the inspection, test or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

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

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

2.14.1 NQA-1-2008, 1a-2009 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. 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 identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55, and/or 10 CFR 21 during ESP/COL design and construction, and 10 CFR 21 during operations.

2.15.2 NQA-1-2008, 1a-2009 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-1-2008, 1a-2009 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 test, installation, preoperation, startup, operations, maintenance, modification, decommissioning, and audits and their retention times are defined in appropriate procedures. The records and retention times for design, construction, and initial start-up shall be documented and shall be maintained for their retention periods in accordance with Regulatory Guide 1.28, Revision 4. Retention times for operations phase records are based on construction records that are similar in nature.

NGNP utilizes ASME NQA-1-2008, 1a-2009, Nonmandatory Appendix 17-A1, "Guidance on Quality Assurance Records." Paragraph 200, "List of Lifetime Records," which lists typical lifetime records containing information that meets 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-1-2008, 1a-2009 Commitment/Exceptions

In establishing provisions for records, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 17, and Regulatory Positions stated in Regulatory Guide 1.28, Rev 4, June 2010.

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 requirements established. 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 QA program 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 and record keeping.

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

cognizance of the Quality 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 QAPs.

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 in accordance with approved procedures.

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

Audits of suppliers of safety-related components and/or services are conducted as described in Section 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 such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. (*Regulatory Guide 1.28, Rev 4, June 2010)*

Applicable elements of the NGNP QAP shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the activity being audited shall be performed. The evaluation shall include results of previous QAP audits and the results of audits from other sources, including the nature and frequency of identified deficiencies and any significant changes in personnel, the organization, or the QAP. (*Regulatory Guide 1.28, Rev 4, June 2010)*

During the operations phase, audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are

completed within a period of 2 years. These audits will include, as a minimum, activities in the following areas:

- The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls.
- The performance, training, and qualifications of the NGNP staff.
- The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B.
- 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.
- 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.

Note: For External Audit requirements see Section 2.7

2.18.3 NQA-1-2008, 1a-2009 Commitment

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

3. PART III – NONSAFETY-RELATED SSC QUALITY CONTROL

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 the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

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

NGNP provides documents to direct the performance of activities affecting quality that include but 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

NGNP 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 of Measuring and Test Equipment (M&TE)

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

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 6 months before the submittal date of the application, and will at that time complete Section 3.2 of the QAPD in accordance with the current revision of NEI-06-14.

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. Section 2 provides alternative approaches for satisfying the following NRC guidance:

- Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment that Is Not Safety Related."
- Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment that Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in Regulatory Guide 1.155, Revision 0, August 1988, "Station Blackout."

4. PART IV – REGULATORY COMMITMENTS

This section of the NGNP QAPD will be completed in accordance with the current revision of NEI-06-14A after the NGNP FSAR is completed.

This section identifies the NRC Regulatory Guides (RG) and the other QA standards that have been selected to supplement and support the NGNP QAPD.

NGNP will provide an evaluation of conformance with the guidance in NRC regulatory guides in effect 6 months before the submittal date of the application. That evaluation will 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 NGNP. The section on Regulatory Guides identifies where the NEI template conforms with or provides alternative approaches for satisfying the identified NRC guidance.

5. RECORDS

None

6. DEFINITIONS

Terms used in the QAPD are defined in LST-649

7. 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

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

NEI- 06-14, Revision 7, Nuclear Energy Institute Quality Assurance Program Description, July 2009

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

U.S.N.R.C. Draft Regulatory Guide DG-1215, *Proposed Revision 4 of Regulatory Guide 1.28, dated August 1985.* Quality Assurance Program Requirements (Design and Construction)

U.S.N.R.C. NUREG 0800, Standard Review Plan, Section 17.5,

U.S.N.R.C. Generic Letter 88-18, Plant Record Storage on Optical Disks

DOE Order 414.1C, Quality Assurance

DOE Order 226.1A, Implementation of Department of Energy Oversight Policy

DOE Guide 414.1-2A, Quality Assurance Management System

Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction), Revision 4, dated June 2010

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

DOE Guide 414.1-3, Suspect Counterfeit Items

DOE Guide 414.1-4, Safety Software

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.