September 12, 2012

Mr. Jim Kinsey, Director
Regulatory Affairs
Next Generation Nuclear Plant Project
Idaho National Laboratory
P.O. Box 1625
2525 North Fremont Ave
Idaho Falls, ID 83415

SUBJECT: STAFF ASSESSMENT OF NEXT GENERATION NUCLEAR PLANT QUALITY ASSURANCE PROGRAM DESCRIPTION

Dear Mr. Kinsey:

By letter dated May 19, 2011, the Idaho National Laboratory (INL), submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Program Description Document PDD-172, Revision 3, "Next Generation Nuclear Plant Quality Assurance Program Description," in accordance with the guidance of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants." By letter dated December 21, 2011, INL responded to the NRC staff's request for additional information.

The Next Generation Nuclear Plant (NGNP) Quality Assurance Program Description (QAPD) implements the applicable portions of both Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and American Society of Mechanical Engineers NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," with 1a-2009 Addenda, as endorsed by NRC Regulatory Guide 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction)."

The NGNP QAPD addresses the activities associated with the technology development, design, licensing, construction, pre-operation, operation, and decommissioning phases for a prototype NGNP. However, since INL is not presently an applicant for either a design certification, early site permit, or combined license as described in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," the NRC staff limited its review to the quality assurance activities associated with technology development and high level design activities.

The NRC staff has reviewed the INL submittal and supporting documentation. Based on its review of the portions of the QAPD applicable to the current scope of the NGNP project (i.e., non-applicant activities), the staff has found that the quality assurance program described in the QAPD, as revised by the referenced supplemental letter, meets the criteria of Appendix B to 10 CFR Part 50 and is, therefore, acceptable for use during the technology development and high level design phase of the NGNP project.

The staff's expectation is that either (1) a supplemented QAPD would be submitted by INL should the scope of the NGNP project be expanded to include design and/or construction activities that would warrant INL becoming an applicant in accordance with the guidelines of 10 CFR Part 52; or (2) any future applicant or licensee planning to design and/or construct a

NGNP-type reactor based on INL's current research and development efforts would submit an independent QAPD covering the appropriate scope of activities in accordance with the applicable quality assurance regulations and guidance in place at that time.

The associated staff assessment is enclosed.

Please contact Donald Carlson (Donald.Carlson@nrc.gov, 301-415-0109) if you have questions regarding the enclosed assessment.

Sincerely,

/RA/

Michael E. Mayfield, Director
Division of Advanced Reactors and Rulemaking
Office of New Reactors

Project No.: 0748

Enclosure:
As stated

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STAFF ASSESSMENT BY THE OFFICE OF NEW REACTORS

REGARDING THE IDAHO NATIONAL LABORATORY

PROGRAM DESCRIPTION DOCUMENT PDD-172, REVISION 3,

"NEXT GENERATION NUCLEAR PLANT QUALITY ASSURANCE PROGRAM DESCRIPTION"

1.0 INTRODUCTION

By letter dated May 19, 2011 (Reference 1), the Idaho National Laboratory (INL), submitted for U.S. Nuclear Regulatory Commission (NRC, the Commission) staff review Program Description Document PDD-172, Revision 3, "Next Generation Nuclear Plant Quality Assurance Program Description," in accordance with the guidance of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants" (Reference 2). By letter dated December 21, 2011, INL responded to the NRC staff's request for additional information (Reference 3).

The Next Generation Nuclear Plant (NGNP) Quality Assurance Program Description (QAPD) implements the applicable portions of both Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and American Society of Mechanical Engineers (ASME) NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," with 1a-2009 Addenda (Reference 4), as endorsed by NRC Regulatory Guide (RG) 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction)" (Reference 5), relevant to the project.

The NGNP QAPD addresses the activities associated with the technology development, design, licensing, construction, pre-operation, operation, and decommissioning phases for a NGNP. However, since INL is not presently an applicant for either a design certification (DC), early site permit (ESP), or combined license (COL) as described in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," the NRC staff limited its review to the quality assurance (QA) activities associated with technology development and high level design activities.

As such, the NRC staff's expectation is that either (1) a supplemented QAPD would be submitted by INL should the scope of the NGNP project be expanded to include design and/or construction activities that would warrant INL becoming an applicant in accordance with the guidelines of 10 CFR Part 52; or (2) any future applicant or licensee planning to design and/or construct a NGNP-type reactor based on INL's current research and development efforts would submit an independent QAPD covering the appropriate scope of activities in accordance with the applicable QA regulations and guidance in place at that time.

2.0 REGULATORY EVALUATION

The NGNP QAPD applies to the technology development associated with the Very High Temperature Reactor (VHTR) Technology Development Office (TDO), which was created to perform required research and development (R&D) activities in support of the NGNP Project. These R&D activities may be used in the future by either INL or other interested parties to apply for a certified design approval, obtain an NRC license to build and operate a NGNP, obtain an ESP and COL, and/or perform construction, preoperation, operations, and decommissioning activities that may affect the quality and performance of safety-related structures, systems, and components (SSCs).

The Commission's regulatory requirements related to quality assurance programs (QAPs) associated with these activities are set forth in 10 CFR 52.17(a)(1)(xi), 10 CFR 52.47(a)(19), 10 CFR 52.79(a)(25), and Appendix B to 10 CFR Part 50 (Appendix B). However, since INL is not currently an applicant for any of these activities as described in 10 CFR Part 52, only Appendix B applies to the current scope of the NGNP project.

Appendix B to 10 CFR Part 50 establishes QA requirements for the design, fabrication, construction, and testing of SSCs for the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 EVALUATION

In evaluating the adequacy of the NGNP QAPD, the NRC staff utilized the guidance contained in NUREG-0800 Standard Review Plan (SRP), Section 17.5, which provides an outline of an acceptable QAP description for DC, ESP, COL, construction permit (CP), and operating license applicants. Although the staff focused its review efforts on the QA activities associated with technology development and high level design activities for the NGNP project, the SRP guidance was used as applicable to evaluate the acceptability of these activities.

Section 17.5 of the SRP is based on ASME standard NQA-1-1994 Edition, as supplemented by additional regulatory and industry guidance for nuclear operating facilities. ASME standard NQA-1-2008 Edition, upon which the NGNP QAPD is based, incorporates the supplemental guidance into a single document, and is therefore in alignment with Section 17.5 of the SRP. In addition, NQA-1-2008 Edition is endorsed by NRC RG 1.28, Revision 4.

3.1 Quality Assurance Program Overview

Program Description Document PDD-172, Revision 3, provides for the control of INL activities affecting the quality and performance of SSCs related to the NGNP.

3.1.1 Organization

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.A, for providing an organizational description that includes the organizational structure, functional responsibilities,

levels of authority, and interfaces for establishing, executing, and verifying NGNP QAP implementation. The NGNP QAPD establishes independence between the organization performing checking functions related to the QAP and the organization responsible for performing the function. In addition, the NGNP QAPD provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Finally, responsibility and authority for planning, establishing, and implementing an effective overall QAP are clearly described and defined.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 1, Section 100 through Section 300, without further clarifications or exceptions, as applicable to the activities associated with technology development and high level design activities for the NGNP project.

3.1.2 Quality Assurance Program

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.B, for establishing the necessary measures to implement a QAP in order to ensure that the activities relating to the NGNP are in accordance with governing regulations and license requirements. The QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the NGNP, as well as to the managerial and administrative controls to be used to assure that the NGNP complies with applicable regulatory requirements. Examples of NGNP safety-related activities include, but are not limited to, basic, applied, and developmental research, determination of SSC safety class, engineering related to safety-related SSCs, geotechnical investigations, engineering analysis, seismic analysis, meteorological analysis, and document control.

A list or system identifying the SSCs and activities to which the NGNP QAPD applies is maintained for all phases of the project. INL may delegate all or part of the activities for which they are responsible to others, but retains overall responsibility for the effectiveness of the QAP. The NGNP QAPD provides for measures to assess the adequacy of the QAP and to ensure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter. In addition, consistent with SRP Section 17.5, Paragraph II.B.8, the NGNP QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early.

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAP to assure that suitable proficiency is achieved and maintained. The NGNP QAPD provides the minimum training requirements for all personnel responsible for implementation of the NGNP QAP.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 2, Section 100 through Section 500, but requested several clarifications and exceptions. The NRC staff determined that these alternatives to Requirement 2 were outside the scope of the QA activities associated with technology

development and high level design activities for the NGNP project, and therefore did not evaluate them as part of this assessment.

3.1.3 Design Control

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.C.1, for establishing the necessary measures to control the design, design verification, and analysis activities of safety-related items and services that are subject to the provisions of the QAP. The NGNP design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces. These provisions ensure that the design inputs (such as design bases, performance and regulatory requirements, and codes and standards) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the NGNP QAPD provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements.

Consistent with SRP Section 17.5, Paragraph II.C.2, the NGNP design processes provide for design verification to ensure that items and activities subject to the provisions of the QAP are suitable for their intended application and consistent with their effect on safety. Design changes are subject to these controls, which include verification measures commensurate with those applied to original plant design. 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. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing.

The NGNP QAPD governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated non safety-related applications. INL and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The QAPD states that the procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

The NGNP QAPD also controls the instrument and equipment set points that could affect nuclear safety in accordance with written instructions. Among other requirements, these written instructions identify the responsibilities and processes for reviewing, approving, and revising set points and set point changes, and ensure that set points and set point changes are consistent with design and accident analysis requirements and assumptions.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 3, Section 100 through Section 900, as well as the standards for computer software contained in NQA-1-2008, with NQA-1a-2009 Addenda, Subpart 2.7, without further clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project. The NGNP QAPD also committed to the requirements for subsurface investigation contained in NQA-1-2008, with NQA-1a-2009 Addenda, Subpart 2.20. However, the NRC staff determined

that this commitment was outside the scope of the QA activities associated with technology development and high level design activities for the NGNP project, and therefore did not evaluate it as part of this assessment.

3.1.4 Procurement Document Control

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QAP requirements are included or referenced in procurement documents.

Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for the procurement of items and services. In addition, procurement document changes are subject to the same degree of control as used in the preparation of the original documents.

To the extent necessary, procurement documents require suppliers to have a documented QAP that is determined to meet the applicable requirements of Appendix B, as appropriate to the circumstances of procurement (or the supplier may work under the NGNP QAP). The scope of procurement includes engineering, design, and testing services, as well as the procurement of safety-related software. No equipment or components are being procured as part of the NGNP project.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 4, Section 100 through Section 400, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project, with the following exceptions and clarifications:

- As an alternative to NQA-1-2008, Requirement 4, Section 300 and Section 400, which require that the technical and QA requirements of procurement documents be reviewed before award of the contract and after procurement document changes, the NGNP QAPD proposes to conduct the QA review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive a QA review.

  The NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents and the associated requirements before awarding the contract and after any change, which meets the intent of NQA-1-2008, Requirement 4, as well as being consistent with SRP Section 17.5, Paragraph II.D. Therefore, the NRC staff concludes that this alternative is acceptable.

- The NGNP QAPD requires that procurement documents for commercial-grade services that will be procured by NGNP for use in safety-related applications contain technical and quality requirements such that the procured service can be appropriately dedicated in accordance with Section 2.7, "Control of Purchased Material, Equipment, and Services," of the NGNP QAPD. This section of the NGNP QAPD commits to implement

the requirements of NQA-1-2008, Part II, Subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services.”

The NRC staff evaluated this proposed alternative and finds it acceptable since it is consistent with NRC staff guidance contained in NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989 (Reference 6) and NRC Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Reference 7), as delineated in SRP Section 17.5, Paragraphs II.U.1.c and II.U.1.d, as well as the guidelines contained in RG 1.28, Revision 4.

The NGNP QAPD requested two additional exceptions to the quality standards described in NQA-1-2008, Requirement 4, Section 100 through Section 400:

- As an alternative to NQA-1-2008, Requirement 4, Section 203, which requires QAP requirements to be specified in procurement documents, the NGNP QAPD proposes that NGNP may require suppliers to have a documented supplier QAP that is determined to meet the applicable requirements of Appendix B, as appropriate to the circumstances of the procurement.

- The NGNP QAPD provides for procurement documents to allow the supplier to work under the NGNP quality assurance program, including implementing procedures, in lieu of the supplier having its own QAP. Appendix B, Criterion IV, "Procurement Document Control," requires that suppliers have a QAP consistent with Appendix B.

The NRC staff determined that these alternatives to Requirement 4 were unnecessary given that NQA-1-2008 already addresses the options for supplier QAPs, and therefore did not evaluate them as part of this assessment.

3.1.5 Instructions, Procedures, and Drawings

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, documented 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.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 5, Section 100, without clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.1.6 Document Control

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance of, and changes to documents that specify quality requirements or prescribe how

activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval, unless other organizations are specifically designated. A list of all controlled documents, identifying the current approved revision or date, is maintained so personnel can determine the appropriate document for use.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 6, Section 100 through Section 300, without further clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.1.7 Control of Purchased Material, Equipment, and Services

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services. The QAPD 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 frequency of procurement.

The NGNP QAPD provides measures for evaluating prospective suppliers and selecting only qualified suppliers, as well as auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services. The scope of procurement includes engineering, design and testing services, as well as the procurement of safety-related software. No equipment or components are being procured as part of the NGNP project. Therefore, the controls associated with this section of the NGNP QAPD are limited to applicable services.

The NGNP QAPD also implements controls for the selection, determination of suitability of intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services to ensure they will perform satisfactorily in service. When commercial-grade services are used, the requirements of NQA-1-2008, Part II, Subpart 2.14 are applied.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 7, Section 100 through Section 800, as applicable the QA activities associated with technology development and high level design activities for the NGNP project, with the following clarifications and exceptions:

- The NGNP QAPD proposes that other 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide services to the NGNP project are not required to be evaluated or audited.

  The NRC staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the NIST, and other State and Federal agencies perform work

under acceptable quality programs, and no additional audit or evaluation is required. The NRC staff determined that this exception is acceptable as documented in a letter to the Edwin Hatch Nuclear Power Station on March 20, 2000 (Reference 8).

However, NGNP is still responsible for ensuring that the services procured conform to the applicable Appendix B criteria and other regulatory requirements and commitments. NGNP is also responsible for ensuring that procured services are suitable for the intended application, as well as for documenting the associated evaluation. To this extent and on this basis, the NRC staff finds the proposed alternative acceptable.

- The NGNP QAPD includes provisions consistent with the regulatory guidance provided in SRP Section 17.5, Paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications from a calibration laboratory. The NGNP QAPD proposes not to require procurement source evaluation and selection measures provided each of the following conditions are met:

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

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

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

     1. The calibration laboratory holds a domestic accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement:

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

        ii. American Association for Laboratory Accreditation (A2LA)

        iii. ACLASS Accreditation Services (ACLASS)

        iv. International Accreditation Service (IAS)

        v. Laboratory Accreditation Bureau (L-A-B)

        vi. Other NRC-recognized laboratory accrediting bodies

     2. The accreditation is based on ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

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

The NRC staff has approved the use of commercial-grade calibration laboratories that hold a domestic accreditation approved by certain accrediting bodies. This method for qualifying a calibration supplier and accepting its calibration services is applicable only to dedicating commercial-grade calibration services as defined by 10 CFR Part 21. The current regulatory position regarding the acceptability of procuring commercial-grade calibration services from NRC-recognized calibration laboratories is documented in SRP Section 17.5, Paragraph II.L.8, as well as associated letters to the NRC-recognized laboratories. To this extent and on this basis, the NRC staff finds the proposed alternative acceptable.

- The NGNP QAPD commits to the requirements of the NQA-1a-2009 Addenda, Requirement 7, Section 700, and Subpart 2.14 for establishing commercial-grade requirements. These sections implement controls for the selection, determination of suitability of intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services to ensure they will perform satisfactorily in service. As such, the NRC staff finds the proposed clarification acceptable.

- Although not expected to be necessary during the technology development and high level design phase for the NGNP project, the NGNP QAPD proposes as an alternative to NQA-1a-2009 Addenda, Requirement 7, Section 700, that NGNP assume 10 CFR Part 21 reporting responsibility for all commercial services that NGNP dedicates for use in safety-related applications.

  The purpose of 10 CFR Part 21 states that any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any licensed or regulated facility or activity, who obtains information reasonably indicating: (a) that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards; or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, must immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

  Therefore, the alternative proposed in the NGNP QAPD, which ensures that 10 CFR Part 21 reportability requirements encompass all activities related to the NGNP project, as well as ensuring that commercial-grade dedication activities are accomplished in accordance with the applicable regulatory guidance, continues to meet this requirement and is, therefore, acceptable to the NRC staff.

The NGNP QAPD requested an additional exception to the quality standards described in NQA-1-2008, Requirement 7, Section 100 through Section 800:

- As an alternative to NQA-1-2008, Requirement 7, Section 501, in terms of the requirement that documentary evidence that items conform to procurement requirements shall be available at the facility site prior to installation or use, the NGNP QAPD proposes that documents may be stored in approved electronic media under the applicant's or supplier's control and not physically located at the site, as long as they are accessible from the respective facility.

The NRC staff determined that this alternative to Requirement 7 was outside the scope of the QA activities associated with technology development and high level design activities for the NGNP project, and therefore did not evaluate it as part of this assessment.

3.1.8 Identification and Control of Materials, Parts, and Components

This element is not applicable to the QA activities associated with technology development and high level design activities for the NGNP project, and has therefore not been reviewed or approved by the NRC staff.

3.1.9 Control of Special Processes

This element is not applicable to the QA activities associated with technology development and high level design activities for the NGNP project, and has therefore not been reviewed or approved by the NRC staff.

3.1.10 Inspection

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.J, for establishing the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 10, Section 100 through Section 800, but requested an exception related to the Institute of Electrical and Electronics Engineers (IEEE) 603-1980, “IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Systems.” The NRC staff determined that this alternative to Requirement 10 was outside the scope of the QA activities associated with technology development and high level design activities for the NGNP project, and therefore did not evaluate it as part of this assessment.

3.1.11 Test Control

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.K, for establishing the necessary measures and governing procedures to demonstrate that items subject to the

provisions of the QAPD will perform satisfactorily in service. The programs outlined in the NGNP QAPD also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests.

The NGNP QAPD specifies that tests are performed according to applicable procedures that include, consistent with the effect on safety, (1) instructions and prerequisites to perform the tests, (2) the use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, retesting is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

In establishing provisions to ensure that the computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected outputs are obtained and configuration control maintained, the NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 3, without clarifications or exceptions.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 11, Section 100 through Section 600, without further clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.1.12 Control of Measuring and Test Equipment

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.L, for establishing the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) which provides data to verify that acceptance criteria are met or other information important to the project's success.

The NGNP QAPD provides that the calibration and adjustment of these devices is accomplished through the facility maintenance program to ensure that the facility is operated within design and technical requirements. Appropriate documentation is maintained to indicate the control status, when the next calibration is due, and identify any limitations on use of each M&TE device.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 12, Section 100 through Section 400, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project, with the following clarification:

- The NGNP QAPD clarifies that the out-of-calibration conditions described in NQA-1-2008, Requirement 12, Section 303.2, and the subsequent requirements to evaluate the validity of previous M&TE results, refer to cases where the measuring and test equipment is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration, versus simply overdue for calibration. The latter situation is

addressed by NQA-1-2008, Requirement 12, Section 303, and assumes that an overdue calibration does not automatically equate to an inaccurate measurement or test.

The NRC staff evaluated this proposed alternative and determined that the clarification for out-of-calibration conditions provides for adequate implementation of the intent of NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 12, Section 303.2, as well as being consistent with SRP Section 17.5, Paragraph II.L and Criterion XII of Appendix B, which require that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Therefore, the NRC staff concludes that this alternative is acceptable.

The NGNP QAPD requested an additional exception to the quality standards described in NQA-1-2008, with NQA-1a-2009 Addenda, Requirement 12, Section 100 through Section 400:

- As an alternative to the NQA-1-2008, Requirement 12, Section 303.6, calibration labeling requirements, the NGNP QAPD proposes that 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 when the label will interfere with operation of the device), provided that 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, with NQA-1a-2009 Addenda, Subpart 2.4, Section 7.2.1.

The NRC staff determined that this alternative to Requirement 12 was unnecessary given that NQA-1-2008, with NQA-1a-2009 Addenda, adequately addresses the options for impractical calibration labeling, and therefore did not evaluate it as part of this assessment.

3.1.13 Handling, Storage, and Shipping

This element is not applicable to the QA activities associated with technology development and high level design activities for the NGNP project, and has therefore not been reviewed or approved by the NRC staff.

3.1.14 Inspection, Test, and Operating Status

This element is not applicable to the QA activities associated with technology development and high level design activities for the NGNP project, and has therefore not been reviewed or approved by the NRC staff.

3.1.15 Nonconforming Materials, Parts, or Components

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.O, for establishing the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements, in order to prevent inadvertent use. Controls provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming items, and notification to affected organizations. Controls are also 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. 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.

In addition, the NGNP QAPD provides for establishing the appropriate interfaces between the QAP for identification and control of nonconforming materials or services and the non-quality assurance reporting program in order to satisfy the applicable requirements of 10 CFR Part 21.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 15, Section 100 through Section 400, without further clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.1.16 Corrective Action

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. The NGNP QAPD provides for procedures to ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and quality standards.

The NGNP QAPD also requires personnel to identify known conditions adverse to quality. 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 overall responsibility for the effectiveness of corrective action measures and the corrective action program.

In addition, the NGNP QAPD provides for establishing the appropriate interfaces between the QAP for identification and control of corrective actions, and the non-QA reporting program in order to satisfy the applicable requirements of 10 CFR Part 21.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 15, Section 100, without clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.1.17 Quality Assurance Records

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.Q, for establishing the necessary measures 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.

The NGNP QAPD establishes measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.1 of RG 1.28, Revision 4, and NQA-1-2008, Non-mandatory Appendix 17A-1, Section 200, as applicable for the NGNP project. In all cases where state, local, or other agencies have more restrictive requirements for record retention, the QAPD provides that those requirements will be met.

When using electronic records storage and retrieval systems, the NGNP QAPD provides for compliance with the NRC guidance contained in NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks (Reference 9)," Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media (Reference 10)," and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-1998, "Authentication of Records and Media," TG 15-1998, "Management of Electronic Records," TG 16-1998, "Software Configuration Management and Quality Assurance," and TG 21-1998, "Electronic Records Protection and Restoration."

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 17, Section 100 through Section 800, as well as the regulatory positions contained Regulatory Guide 1.28, Revision 4, without clarifications or exceptions, as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.1.18 Audits

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.R, for establishing the necessary measures and governing procedures to implement audits in order to verify that activities covered by the QAP are performed in conformance with the requirements established. The audit programs are also themselves reviewed for effectiveness as part of the overall NGNP audit process.

The NGNP QAPD provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of program and procedures, as well as to determine if they are meaningful and comply with the overall NGNP QAP. Internal audits are performed (1) with a frequency commensurate with the safety significance of the activity and in a manner which assures that audits of safety-related activities are completed; and/or (2) with a frequency that ensures that an audit of all applicable QAP elements is completed within a period of once per calendar year or at least once during the life of the activity, whichever is shorter.

External audits determine the adequacy of supplier or contractor QAPs. 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 responsibility 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 appropriate NGNP management.

The NGNP QAPD provides for all audit results to be documented and reviewed by responsible management. Management responds to all audit findings and initiates corrective actions where indicated. In addition, where corrective action measures are determined necessary, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means, is conducted to verify the implementation and effectiveness of the assigned corrective actions.

The NGNP QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 18, Section 100 through Section 800, as well as the regulatory positions contained Regulatory Guide 1.28, Revision 4, without clarifications or exceptions as applicable to the QA activities associated with technology development and high level design activities for the NGNP project.

3.2 Non-Safety-Related SSC Quality Control

3.2.1 Non-Safety-Related SSCs - Significant Contributors to Plant Safety

Although not fully applicable during the technology development and high level design phase of the NGNP project, the NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.V.1, for establishing specific program controls to be applied to non safety-related SSCs that are significant contributors to plant safety, but for which Appendix B does not apply.

The NGNP QAPD applies specific controls to such items in a selected manner, targeted toward those characteristics or critical attributes that render the SSC a significant contributor to plant safety, consistent with applicable sections of the NGNP QAP.

The NRC staff has determined that this approach, as described in the NGNP QAPD, is acceptable to maintain alignment with SRP Section 17.5, Paragraph II.V.1.

3.2.2 Non-Safety-Related SSCs Credited for Regulatory Events

This element is not applicable to the QA activities associated with technology development and high level design activities for the NGNP project, and has therefore not been reviewed or approved by the NRC staff.

3.3 Regulatory Commitments

The NGNP QAPD provides a description of the QA requirements that are applicable to all aspects of the NGNP project. However, the scope of the project is currently limited to technology development and other high level activities. The required R&D activities in support of the NGNP project are performed through the VHTR TDO. Therefore, the current scope and applicability of the NGNP QAPD is limited to those quality requirements that support technology development of the VHTR TDO.

The NGNP QAPD follows the guidance of SRP Section 17.5, Paragraph II.U, for establishing QAP commitments. At present, the NGNP QAPD commits to comply with the following NRC Regulatory Guides and other QA standards to supplement and support the overall QAP:

- R G 1.28, Revision 4, "Quality Assurance Program Requirements (Design and Construction)," dated June 2010. RG 1.28 describes a method for complying with the provisions of 10 CFR Part 50 Appendix B with regard to establishing and implementing the requisite QAP for the design of nuclear power plants.

- ASME NQA-1-2008, and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described above in Sections 3.1.1 through 3.1.18 of this assessment.

- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides, as described in Section 3.1.17 of this assessment.

4.0 CONCLUSION

The NGNP QAPD addresses the activities associated with the technology development, design, licensing, construction, pre-operation, operation, and decommissioning phases for a NGNP. However, since INL is not presently an applicant for either a design certification, early site permit, or combined license as described in 10 CFR Part 52, the NRC staff limited its review to the QA activities associated with technology development and high level design activities.

As such, the NRC staff's expectation is that either (1) a supplemented QAPD would be submitted by INL should the scope of the NGNP project be expanded to include design and/or construction activities that would warrant INL becoming an applicant in accordance with the guidelines of 10 CFR Part 52; or (2) any future applicant or licensee planning to design and/or construct a NGNP-type reactor based on INL's current research and development efforts would submit an independent QAPD covering the appropriate scope of activities in accordance with the applicable QA regulations and guidance in place at that time.

The NGNP QAPD follows the NRC guidance contained within, and conforms to the format of, SRP Section 17.5. The NRC staff used the acceptance criteria of SRP Section 17.5 as the basis for evaluating the acceptability of the NGNP QAP in conformance with the provisions of Appendix B to 10 CFR Part 50. On the basis of its review of the NGNP QAPD, the NRC staff concludes that:

- The NGNP QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the NGNP QAP is applicable.

- The NGNP QAPD adequately provides for organizations and personnel to perform verification and self-assessment functions related to NGNP activities that affect the quality of safety-related nuclear plant SSCs, as well as select non safety-related SSCs, with these organizations and personnel having the authority and independence to conduct activities without undue influence from those directly responsible for costs and schedules.

- The NGNP QAPD adequately applies to activities and items that are important to safety.

- The NGNP QAPD adequately establishes controls that, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, consistent with the criteria contained in SRP Section 17.5, as well as the relevant regulatory guidance.

On the basis of its review, the NRC staff determined that the NGNP QAPD adequately describes the NGNP QAP. Accordingly, the NRC staff concludes that the NGNP QAP complies with the applicable NRC regulations and industry standards and can be used by NGNP for the activities associated with technology development and high level design activities for the NGNP project.

5.0 REFERENCES

1. Letter from Greg Gibbs, Next Generation Nuclear Plant Project, to the NRC Document Control Desk, “Contract No. DE-AC07-05ID14517 - Next Generation Nuclear Plant Project - Quality Assurance Program Description, Revision 3 - Nuclear Regulatory Commission Project #0748,” dated May 19, 2011 (ADAMS Accession No. ML111440219)

2. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," dated March 2007 (ADAMS Accession No. ML063190019)

3. Letter from Greg Gibbs, Next Generation Nuclear Plant Project, to the NRC Document Control Desk, “Contract No. DE-AC07-05ID14517 - Next Generation Nuclear Plant Project Submittal - Response to Nuclear Regulatory Commission Request for Additional Information Letter No. 6 Regarding the Quality Assurance Program Description - NRC Project #0748,” dated December 21, 2011 (ADAMS Accession No. ML11361A390)

4. American Society of Mechanical Engineers (ASME) NQA-1-2008, “Quality Assurance Program Requirements for Nuclear Facilities,” with a2009 Addenda, New York, NY, dated March 14, 2008

5. Regulatory Guide 1.28, Revision 4, “Quality Assurance Program Criteria (Design and Construction), dated June 2010 (ADAMS Accession No. ML100160003)

6. NRC Generic Letter 1989-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989

7. NRC Generic Letter 1991-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991

8. Letter from NRC to Southern Nuclear Operating Company, Edwin I. Hatch Nuclear Power Station, Units 1 and 2, “RE: Approval of Relief Request RR-27, Third 10-Year

Interval Inservice Inspection Program (TAC NOS. MA6163 and MA6164)," dated March 20, 2000 (ADAMS Accession No. ML003693241)

9. NRC Generic Letter 1988-18, "Plant Record Storage on Optical Disks," dated October 20, 1988

10. Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000 (ADAMS Accession No. ML003739359)