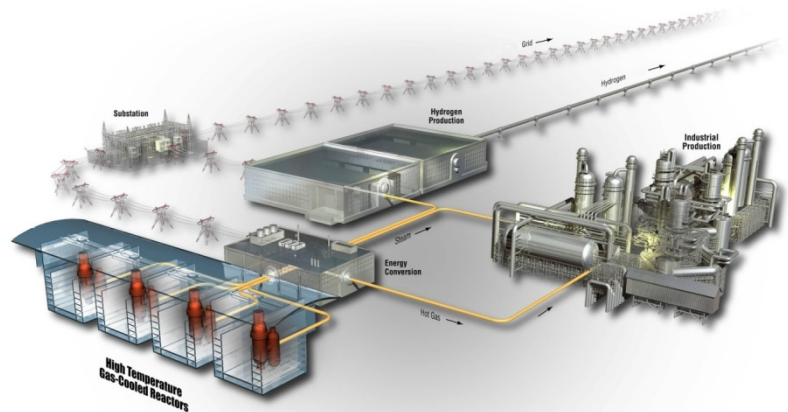


## Quality Assurance Program Plan

Project No. 23843

# Quality Assurance Program Plan for the Next Generation Nuclear Plant Project



Idaho National Laboratory

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NGNP	Plan	eCR Number: 595069
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## REVISION LOG

Rev.	Date	Revision Description
0	10/27/2005	New Document
1	10/31/2006	See DAR 501695
2	03/21/2007	See DAR 506049
3	11/08/2007	<p>See eCR 553043</p> <ul style="list-style-type: none"> <li>• Clarified purpose and scope defining the interface between ATR/RTC and the NGNP project</li> <li>• Deleted the word “developmental” from the first clarification bullet in Requirement 9</li> <li>• Clarified the test control guidance under Requirement 11 and ensured that it does not conflict with test control requirements in LWP-13016</li> <li>• Rewrote the measuring and test equipment clarification to ensure it meets the requirements of LWP-13455 LWP-13016, and NGNP project specific directions for documenting calibration training by defining what is contained on the list of calibration information associated with NGNP work activities</li> <li>• Identified when (timeframe) an ATR work package should be added to NGNP records</li> <li>• Changed MCP-1451 title to R&amp;D Support Services, Work Control Process</li> <li>• Changed LWP-13742 to MCP-13742</li> <li>• Added LWP-1250 to document control section of Matrix</li> <li>• Clarified the need to use both NRC Regulation Guide 1.203 and NQA-1 2000 Subpart 2.7 requirements for the various software programs used and described in NGNP work activities. The change also identified when each of the requirements will be used</li> <li>• Wrote in a deviation for LWP-13012 Scope and Appendix A in the QAPP</li> <li>• Clarified the requirements for QE reviews on the SOW and procurement specification</li> <li>• Clarified the need for NGNP Quality Engineer review of QLD</li> <li>• Changed the Preliminary Project Management Plan (PPMP) reference from INL/EXT-05-00952 to PLN-2489</li> <li>• Deleted duplicate statements on software implementation that are already covered in software implementation procedures</li> <li>• Clarified the statement associated with experiments, tests, and material processing that identified where documentation is to be maintained</li> <li>• Deleted the dual storage requirements for NGNP records</li> <li>• Made numerous editorial changes in document.</li> </ul>

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Rev.	Date	Revision Description
4	5/28/08	<p>(eCR 561363)</p> <ul style="list-style-type: none"> <li>• Deleted the column for affected pages in the revision log since all pages changed in all revisions. This revision log provides sufficient description of the pages since the last version—no revision marking is included.</li> <li>• Added new acronyms/abbreviations to acronym list.</li> <li>• Deleted the discussion of hydrogen production and energy transport in Section 1.2, as this topic is now addressed in Section 1.5.</li> <li>• Revised Section 2 to move the list of applicable documents to Appendix A.</li> <li>• Placed the general clarifications and deviations that were previously just under the Section 3 header to the applicable QA Program element; added subsection numbers to the 18 NQA-1 elements, plus Subsection 3.1.19, for Software QA.</li> <li>• Clarified the review requirements for INL site-wide quality level determinations.</li> <li>• Deleted deviation from LWP-14002 as this INL procedure now adequately addresses provisions for stop work for quality reasons.</li> <li>• Revised applicable sections to recognize the VHTR TDO organization and documents.</li> <li>• Added QA-related information (mostly in Sections 1.3 and 1.5) that was previously covered in the NGNP PPMP in order to make the QAPP stand alone and reflect a consistent approach with the NGNP VHTR TDO QAPP. The NGNP PPMP has been changed accordingly.</li> <li>• Removed the research and development clarifications and deviations from each of the applicable 18 elements in Section 3.1, as they are now covered in the VHTR TDO QAPP. Also removed the R&amp;D-related documents from Appendix A.</li> <li>• Made some editorial and format changes.</li> </ul>
5	06/16/09	<p>eCR 561968</p> <ul style="list-style-type: none"> <li>• Added requirement to Requirement 18 (Section 3.1.18) Audits, that addresses tracking external audit deficiencies</li> <li>• Added requirement to Requirement 18 (Section 3.1.18) Audits, that specifies when external audit deficiencies are to be closed</li> <li>• Moved MCP-13910, “Reviewing and Approving Documents and Records” to ASME NQA-1-2000 7.0, “Control of Purchased Items and Services”</li> <li>• Added responsibility to QA for externally identified issues</li> <li>• Corrected implementing document list</li> <li>• Corrected list formats to delete periods, align grammatical structures, and eliminate single subcategories</li> <li>• Corrected organization chart and requirements graphics</li> <li>• Removed the requirement for QA to sign all Quality Level Determinations</li> <li>• Removed 10 CFR 50 from commitments documents.</li> </ul>
6	12/17/09	<p>eCR 572721</p> <ul style="list-style-type: none"> <li>▪ Deleted reference to LWP-1250 in Appendix A Section 5.0, Instructions Procedures and Drawings.</li> <li>▪ Deleted reference to PLN-2489 in Appendix A Sections 2.0, Quality Assurance Program and 1.0, Organization.</li> <li>▪ Deleted incorrect statement from the Role and Responsibility Section 1.5.9</li> <li>▪ Deleted reference to LWP-13750 in Appendix A Section 18, Audits.</li> <li>▪ Added reference to para 3.1.7.B.5 to para. 3.1.5, 3.1.6</li> <li>▪ Added para 3.1.7.B.5, Non-Vendor Data Managed Documents</li> <li>▪ Deleted reference to LWP-7203 in Appendix A section 4, Procurement Document Control</li> <li>▪ Deleted reference to LWP-7203 in Appendix A section 6. Document Control</li> </ul>

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Rev.	Date	Revision Description
7	3/31/10	eCR 579289 <ul style="list-style-type: none"> <li>▪ Added references to Appendix A requirement 2, Quality Assurance Program:               <ul style="list-style-type: none"> <li>○ LWP-7205, INL Subcontracted Work</li> <li>○ LWP-7390, Project Management Enterprise</li> <li>○ LWP-21220, Work Management Menu</li> </ul> </li> <li>▪ Added a reference to Appendix A requirement 4, Procurement Document Control:               <ul style="list-style-type: none"> <li>○ LWP-7205, INL Subcontracted Work</li> </ul> </li> <li>▪ Added a reference to Appendix A requirement 5, Instructions Procedures and Drawings:               <ul style="list-style-type: none"> <li>○ LWP-10400, Design Control</li> </ul> </li> </ul>
8	7/09/2010	eCR 582370 <ul style="list-style-type: none"> <li>• Removed section 3.2, “Control of Unqualified Data”. Replaced with section 3.1.20.....“Guidance on Qualification of Existing Data”</li> <li>• Added a reference to Appendix A “INL Implementing Matrix” on “Guidance on Qualification of Existing Data” via MCP-2691</li> <li>• Added code reference ASME NQA-1 2008 and ASME NQA-1a 2009</li> </ul>
9	09/21/10	eCR 583238 <ul style="list-style-type: none"> <li>• Pg 2: Replaced NQA – 1 2008 part 1 reference with NQA-1-2008, 1a 2009 part III reference.</li> <li>• Signature page: Replaced K Perry with P. Mills as VHTR Engineering Director</li> <li>• Pg 21; replaced the title for LWP-13840.</li> </ul>
10	06/28/2011	eCR 593190 <ul style="list-style-type: none"> <li>• Added a background section to explain the change from NQA-1 2000 to 2008 with 2009 addenda and the associated procedures.</li> <li>• Rewrote the purpose statement, breaking it out into three areas.</li> <li>• Added additional regulatory documents.</li> <li>• Modified Figure 1 to show new regulatory drivers</li> <li>• Added Figure 2 for clarification</li> <li>• Modified the organization chart to make it the same as PDD-172</li> <li>• Modified selected R2A2 to match PDD-172</li> <li>• Cleaned up clarifications in Section 3.0</li> <li>• Modified Appendix A to show implementing procedures for either the INL program or the NGNP program</li> </ul>
11	08/02/2011	eCR 595069 <ul style="list-style-type: none"> <li>• Added statement in Section 1.4 to clarify Figure 1 purpose</li> <li>• Revised Figure 1. Requirements and implementation flow down diagram</li> <li>• Added statement in Section 1.4 to clarify Appendix A purpose</li> <li>• Updated organization chart and added reference to expanded organization chart in EDMS</li> </ul>

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**POLICY STATEMENT**

The services, sciences, and technology provided by Idaho National Laboratory (INL) for the Next Generation Nuclear Plant (NGNP) Project are managed under the INL NGNP Project. It is the policy of the INL 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. It is the responsibility of the INL personnel involved in NGNP Project activities to comply with the mandatory requirements of this Quality Assurance Program Plan (QAPP). This QAPP will be executed in accordance with the INL approved directives, procedures, and internal policies, or authorized deviations, clarifications, and unique NGNP Project requirements, as described herein.

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## ACRONYMS

ASME	American Society of Mechanical Engineers
DOE	Department of Energy
eCR	electronic change request
INL	Idaho National Laboratory
HTGR	high temperature gas-cooled reactor
LWP	Laboratory-Wide Procedure
M&O	management and operating
MCP	Management Control Procedure
NGNP	Next Generation Nuclear Plant
NQA-1	American Society of Mechanical Engineers Quality Assurance Requirements for Nuclear Facility Application
NRC	Nuclear Regulatory Commission
PPMP	Preliminary Project Management Plan
QA	quality assurance
QAP	Quality Assurance Program
QAPP	Quality Assurance Program Plan
QE	quality engineer
QL	quality level
R2A2s	roles, responsibilities, authorities, and accountabilities
R&D	research and development
SOW	statement of work
TDO	Technology Development Office
VHTR	Very High Temperature Reactor

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## 1. INTRODUCTION

### 1.1 Background

The objective of the Next Generation Nuclear Plant (NGNP) Project is to sufficiently develop the technology necessary to obtain a Nuclear Regulatory Commission (NRC) license to build and operate the NGNP, a high temperature gas-cooled reactor (HTGR) capable of producing electricity and process heat for industrial applications. The NGNP will be licensed by the NRC and provide the basis for commercialization of a new generation of advanced energy plants that utilize HTGR technology. The general scope of the project is to design, construct, and operate a full-scale prototype HTGR plant, thus establishing the technological basis for expanded commercial applications and infrastructure for the commercialization of this new generation of advanced nuclear plants. PDD-172, "Next Generation Nuclear Plant Quality Assurance Program Description," (QAPD) establishes the quality assurance (QA) policy for the NGNP and assigns major functional responsibilities for NGNP activities conducted by or for the NGNP Project. It describes the methods and establishes QA and administrative control requirements that meet 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

The QA requirements associated with PDD-172 are based on Regulatory Guide 1.28, Rev. 4, June 2010, "Quality Assurance Requirements (Design and Construction)" and on Regulatory Guide 1.33, Rev. 2, February 1978, "Quality Assurance Program Requirements (Operation)." Regulatory Guide 1.28, Rev. 4 states that Part I and Part II requirements of NQA-1-2008, 1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications" provide an adequate basis for complying with the requirements of 10 CFR Part 50, Appendix B, subject to the additions and modifications identified therein. This QAPD is based on the requirements and guidance of American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) NQA-1-2008, 1a-2009, Parts I and II, with specific reference to selected sections of Parts III and IV as identified in this document. This QAPD addresses additions and modifications to the regulatory positions included in Regulatory Guide 1.28, Rev. 4 and NEI 11-XX DRAFT, "Nuclear Generation Quality Assurance Program Description (NG-QAPD)." PLN-3635, NGNP Quality Assurance Program Implementation Plan describes the phased implementation of PDD-172, "Next Generation Nuclear Plant Quality Assurance Program Description."

The QAPD is the policy document that establishes the manner in which quality is to be achieved and presents the NGNP Project's overall philosophy regarding its commitment to achieving and ensuring quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAPD. Phased

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implementation of the QAPD is achieved through a planned, sequential issuance of the implementing documents listed in this plan.

Throughout the phased implementation, the NGNP Project remains in compliance with the Battelle Energy Alliance, LLC (BEA) management and operating (M&O) contract number DE-AC07-051D14517, which requires compliance with 10 CFR 830, Subpart A, "Quality Assurance Requirements," and DOE Order 414.1C, "Quality Assurance." BEA uses the ASME NQA-1-2000 as the baseline.

Currently, NGNP is about half way through the process of implementing PDD-172 and the associated implementing PRDs and MCPs. PLN-3635 identifies which PRDs and MCPs are issued and their state of implementation.

## 1.2 Purpose

Laboratory-Wide Procedure (LWP) LWP-13012 identifies that a Quality Assurance Program Plan (QAPP) may be used to address additional requirements for environmental data. This QAPP therefore serves three purposes:

1. It identifies unique NGNP Project QA requirements, as allowed by Laboratory Wide Procedure (LWP) LWP-13012, "Addressing Program/Project Specific Quality Assurance Requirements."
2. It identifies a set of management controls for NGNP Project systems, structures, and components, and related quality-affecting activities. Implementing these controls will ensure that work supporting the NGNP Project is performed satisfactorily. Work conducted under the NGNP QA program is intended to support eventual licensing of the NGNP reactor design by the NRC.
3. Although the NGNP QAPD is only partially implemented at this time, this QAPP identifies which procedures are used to implement the INL QAP requirements through the use of LWPs and which requirements are implemented using NGNP specific Management Control Procedures (MCP). Note that LWPs are frequently referenced in the MCPs for implementing selected parts of the requirements.

## 1.3 Scope

This QAPP covers all NGNP Project quality-affecting activities performed by NGNP Project personnel (and subcontractors as required by their respective contracts). Management controls are flowed down to the research and development (R&D) activities performed by personnel assigned to the INL Very High Temperature Reactor (VHTR) Technology Development Office (TDO). Quality assurance for NGNP activities conducted by VHTR TDO personnel is

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addressed in Plan PLN-2690, “VHTR Technology Development Office Quality Assurance Program Plan.” Further discussion of the organizational relationship between the NGNP Project and the VHTR TDO is included in Section 1.5 of this QAPP. Quality-affecting activities include those that influence the desired end result, including (but not limited to): siting, design, procurement, fabrication, construction, operation, handling, shipping, receiving, storing, cleaning, and repairing. All INL NGNP work tasks and quality requirements must tier from this QAPP to ensure a consistent QA approach for the project. The NGNP Project requires assurance that all relevant activities will yield NRC licensable designs, data, and other results for facilities, fuels, systems, components, equipment, processes, software, and material. The NGNP Project will identify data-collection requirements and perform periodic reviews of all experimental operating data. NGNP Project activities will conform to established requirements, be traceable to valid data, and be capable of withstanding detailed technical reviews.

#### 1.4 Codes, Standards, and Regulations

Battelle Energy Alliance, LLC (BEA), the INL M&O contractor, is required to comply with DOE Idaho Operations Office Contract number DE-AC07-05ID14517. This contract requires BEA to comply with 10 CFR 830 Subpart A, “Quality Assurance Requirements,” and DOE Order 414.1C, “Quality Assurance.” ASME NQA-1 will be used as the baseline standard for developing and implementing a QAP for INL activities. The INL QAP meets the requirements of 10 CFR 830 Subpart A and DOE Order 414.1C. The NGNP QAPP is based on the INL’s QAP, which implements the requirements of NQA-1 2000 and NRC Regulatory Guide 1.28, Ref 4, which implements NQA-1 2008 with 2009 addenda.

The NGNP falls under the *Energy Reorganization Act of 1974* and is subject to the licensing and related regulatory authority of the NRC as stated in the *Energy Policy Act of 2005*. NRC licensing requirements, 10 CFR 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” apply to this project.

The source documents that contain requirements applicable to the QAPP defined scope of work covered by this plan are listed in Table 1.

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Table 1. QAPP Source Documents.

<b>Regulatory Documents:</b>	
10 CFR 50, Appendix B	Domestic Licensing of Production and Utilization Facilities Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
Regulatory Guide 1.28, Rev. 4	Quality Assurance Program Criteria (Design and Construction)
10 CFR 830 Subpart A	Quality Assurance Requirements
DOE Order 414.1C	Quality Assurance
<b>Commitment Documents:</b>	
ASME NQA-1-2000 Part 1; Part 2, Subpart 2.7; and Part IV, Subpart 4.2	Quality Assurance Requirements for Nuclear Facility Applications
ASME NQA-1-2008, 1a-2009, Parts 1 and 2, Subpart 2.7; Part III, Subpart 3.3; and Part IV, Subpart 4.2	Quality Assurance Requirements for Nuclear Facility Applications
PDD-172	Next Generation Nuclear Plant Quality Assurance Program Description

Figure 1 provides a document hierarchy for requirements flow down and their implementation to accomplish the NGNP Project's mission. Appendix A identifies the implementing NGNP project-specific procedures or INL procedures deemed most appropriate for each applicable NQA-1 element.

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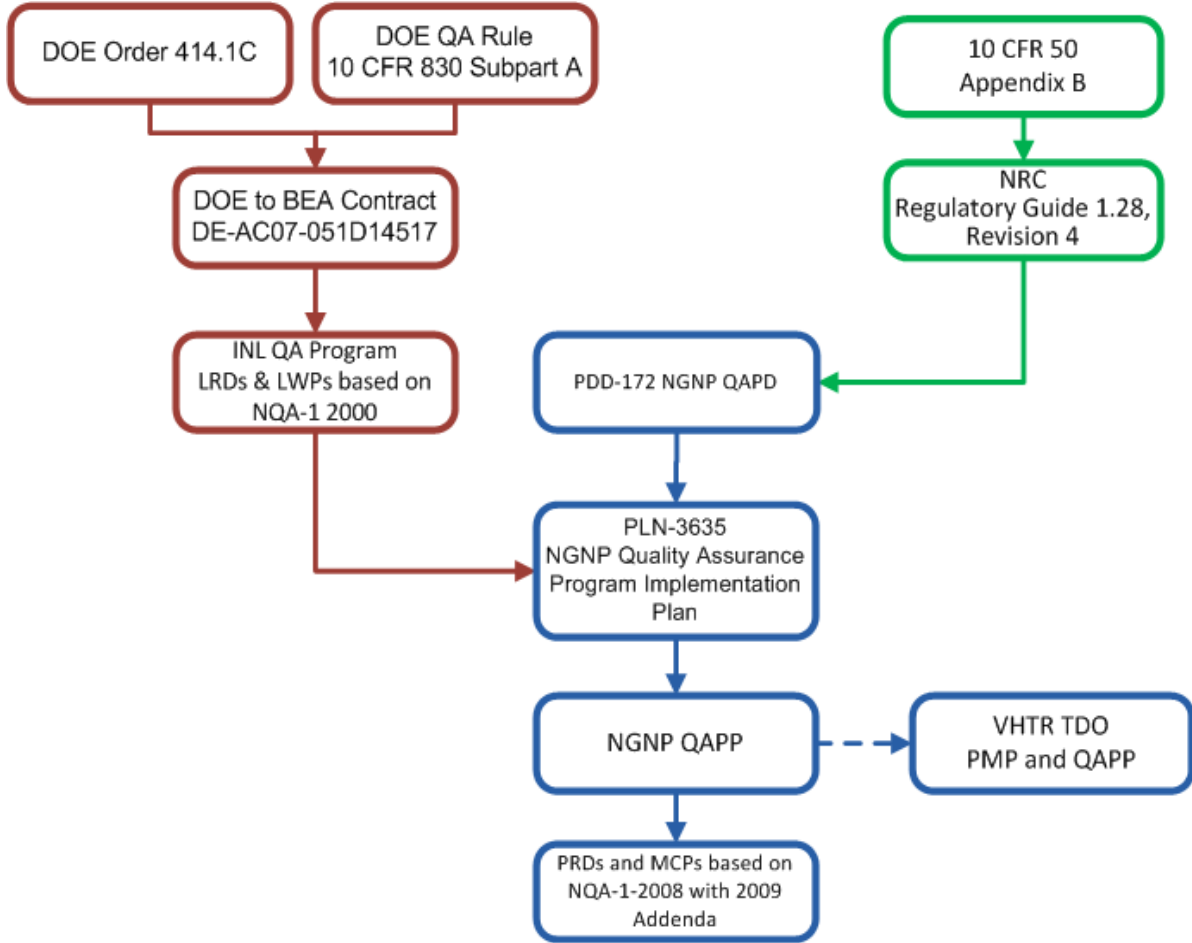


Figure 1. Requirements and implementation flow-down diagram.

Figure 2 shows visually how the NGNP QA program is meeting both DOE and NRC requirements as well as both versions of NQA-1. At present, this is a transitioning target with NGNP implementation of approximately half of the NQA-1 2008, 1a 2009 requirements and all of the NQA-1 2000 requirements. For more information, see PLN-3635, “NGNP Quality Assurance Program Implementation Plan.”



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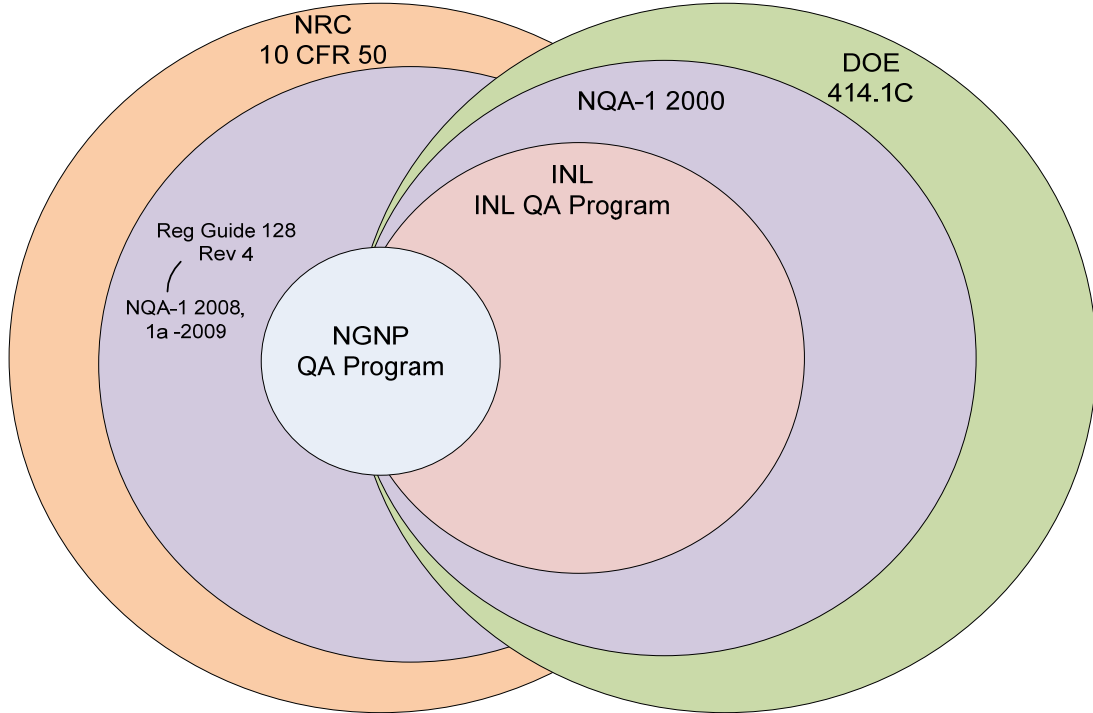


Figure 2. Visual presentation of requirements and how they tie together in the NGNP QA Program.

### 1.5 QAPP Change Control

This QAPP is controlled within the INL Electronic Document Management System (EDMS). It will be reviewed at least annually and revised as necessary. Revisions require review and concurrence of at least INL QA management and the NGNP QA Director (may be the same person), and approval of the NGNP Project Director, or by designated alternates.

### 1.6 Organizational Responsibilities

The management of NGNP programs and activities is provided by the umbrella organization labeled as the NGNP Project. The VHTR TDO is responsible to define the R&D technical work scope (based on functional and operational requirements defined by the NGNP Project) and identify and meet R&D milestones and deliverables within the approved budget for such work scope.

The INL Laboratory Director is responsible for overall management of M&O contractor activities, which include establishing and executing the site-wide QAP. The INL QA Director is responsible for establishing, maintaining, and monitoring the implementation of the overall INL QAP. The NGNP QA Director reports

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administratively (home organization) to the INL QA Director and functionally (work organization) to the NGNP Project Director. 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 QAPP has been established and to verify activities affecting quality. The NGNP Project Director is responsible for establishing overall expectations for effective implementation of this QAPP and for obtaining the desired end result.

The following subsections describe additional roles, responsibilities, authorities, and accountabilities (R2A2s) for individuals performing NGNP Project quality-affecting activities.

The NGNP project organizational structure is shown in Figure 3. The project structure reflected in this organization chart is consistent with that of the NGNP organization chart, which is expanded for clarification of staff assignments and general communication purposes. A current detailed organization chart is maintained on EDMS.

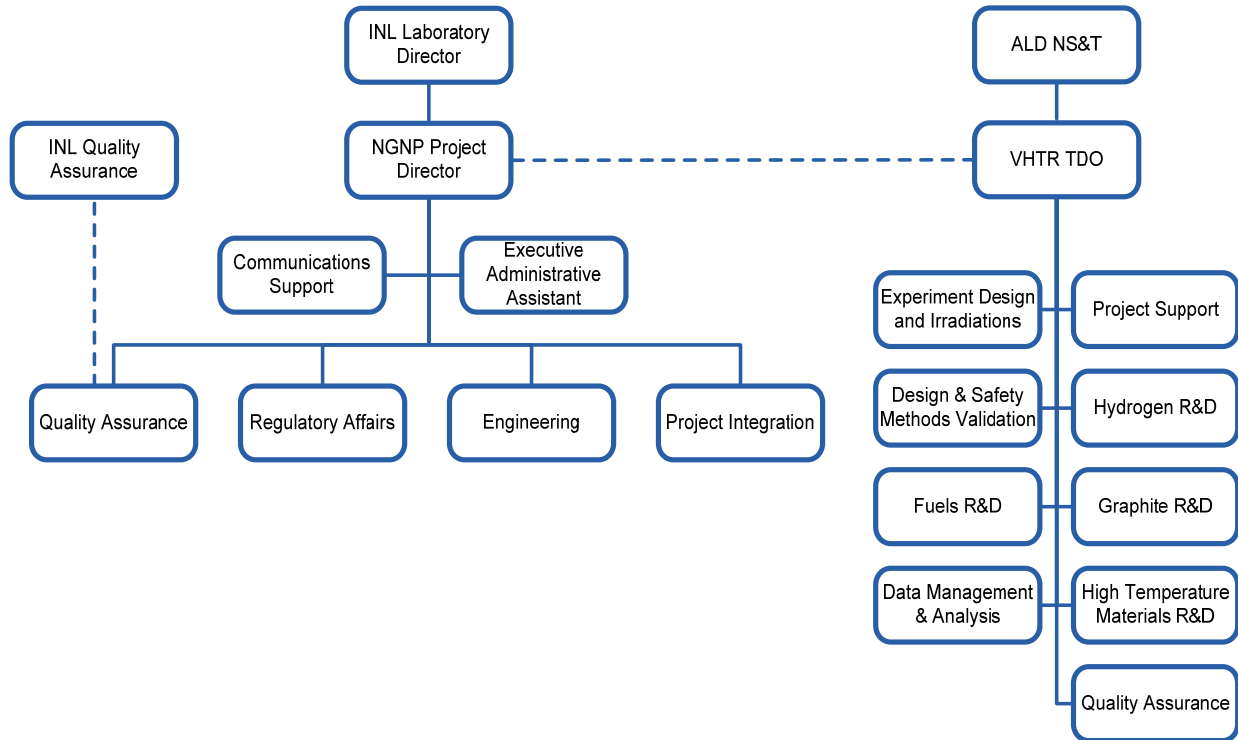


Figure 3. NGNP Project organization chart.

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### 1.6.1 Project Director

#### Roles and Responsibilities

- A. Establishes overall expectations for effective implementation of the QAPP and is responsible for obtaining the desired end result.
- B. Provides overall management for the execution of the NGNP Project.
- C. Leads the cross-functional group of project team members assembled to successfully execute the project objectives established jointly with the customer; the Program Manager; the Deputy for Projects, Nuclear Support, and Production; and the Laboratory Director. The project director must ensure that the project objectives safely meet the NGNP Project requirements and are fulfilled within cost and schedule. These responsibilities span the definition and execution of R&D, design, licensing, construction, testing, operation, and maintenance for the life of the project organization.
- D. Provides overall management direction, defines roles and responsibilities, delegates authorities, and enforces accountabilities for the NGNP Project organization.
- E. Ensures that the appropriate process controls are formally defined for the execution of project work.
- F. Develops and maintains cost and schedule contingencies that are commensurate with acceptable risk levels for the project.
- G. Provides the focal point for both internal and external communication on the project. Responsible for formal correspondence to licensing and regulatory authorities for the NGNP Project.

#### Accountabilities and Authorities

- A. Accountable to the sponsor and the INL Laboratory Director for the overall execution of the NGNP Project within schedule, cost, and quality requirements.
- B. Accountable to the NGNP Project organization to provide leadership and direction.
- C. Authorizes the expenditure of project funds up to the approved authority limit.

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- D. Establishes and approves proposed changes to technical, cost, and schedule baselines within authority limits as defined in project management documents, and endorses other changes affecting the cost, schedule, and technical parameters within the formal project baselines.
- E. Submits formal correspondence to licensing and regulatory authorities for the NGNP Project.
- F. Approves the assignment and reassignment of key project team members.
- G. Manages the project schedule to maximize project efficiency and performance.
- H. Enforces accountability from the NGNP Project organization and the Project Team.

#### **1.6.2 Deputy Project Director**

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

#### **1.6.3 Engineering Director**

##### Roles and Responsibilities

- A. Establishes, in coordination with the NGNP Project Director, the structure, processes, and responsibilities of NGNP Engineering, which includes developing and executing work packages to complete NGNP project milestones.
- B. Responsible for all subcontract and direct NGNP Engineering work.
- C. Supports development of and maintains, in coordination with NGNP Project management and R&D and licensing organizations, the NGNP Project system technical requirements (e.g., preparation of functional and operational requirements and safety research modification).
- D. Provides technical direction, coordination, problem resolution, and oversight of NGNP Project design, R&D, and regulatory

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activities to ensure that the approach, scope, and outcomes of these activities are consistent with the technical requirements (e.g., functional and operational requirements) of the NGNP Project.

- E. Supports the development of the licensing and regulatory strategies.
- F. Ensures that NGNP subcontractor design work is consistent with the project system requirements and licensing strategy.
- G. Provides direct technical oversight of subcontractor activities during the design and engineering activities for the project. This technical oversight includes supporting review and evaluation of original subcontractor proposals to perform design work, and, during the development of the design, performing technical review of deliverables, conducting integrated design reviews, and supporting evaluation of earned value against budget and schedule.
- H. Provides technical support to licensing as required in the interface with the NRC.

Accountabilities and Authorities

- A. Accountable to the NGNP Project Director for:
  - Developing and supervising NGNP Engineering
  - Defining NGNP technical requirements and coordinating and overseeing technical activities within the NGNP project to ensure these activities are consistent with the NGNP technical requirements
  - Complying with QA, procurement, and intellectual property protection requirements as they apply to the NGNP Project.
- B. Coordinates and oversees the schedule and budget for NGNP Engineering activities.
- C. Coordinates and oversees allocated budget.
- D. Coordinates and oversees activities of NGNP Engineering personnel in support of the NGNP Project (e.g., making assignments, reviewing work, and evaluating performance).
- E. Revises Engineering organization responsibilities with NGNP Project Director concurrence.

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#### **1.6.4 Project Integration Manager**

##### Roles and Responsibilities

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

##### Accountabilities and Authorities

- A. Accountable to the project organization as the primary point of contact for procurement activities.
- B. Accountable to the INL Director of Business Management to ensure that Project activities are performed in accordance with INL processes and practices.
- C. Obtains and assign personnel, as required, to fulfill responsibilities within the authorized budget.
- D. Approves purchase requisitions and other procurement actions within authority limits.
- E. Serves as the control account manager of work packages covering assigned scope of responsibilities.

#### **1.6.5 Regulatory Affairs Director**

##### Roles and Responsibilities

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

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

Accountabilities and Authorities

- A. Accountable to the NGNP Project Director to successfully develop and implement the licensing and regulatory strategy for the NGNP prototype and to establish the requirements for the associated work activities within the project, including R&D, design, construction, testing, and operations.
- B. Accountable (authority delegated from the Project Director) as the licensing contact with the NRC and regulatory agencies.
- C. Coordinates and oversees the allocated budget.

**1.6.6 Quality Assurance Director**

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

Roles and Responsibilities

- A. Verifies the development and implementation of this QAPP.
- B. Assures compliance with regulatory requirements and procedures by: audits; monitoring technical reviews and organization processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors who provide quality services, parts, and materials to NGNP are meeting the requirements of 10 CFR 50, Appendix B through vendor audits.
- C. Serves as QA Director to provide leadership and direction and to integrate and manage the QAPP for the NGNP Project.
- D. Assists in identifying and interpreting the QA requirements and standards that apply to NGNP activities.
- E. Verifies that QA processes and systems are developed, implemented, and updated as necessary to support NGNP program needs.

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- F. Assists the NGNP Project Director in developing and maintaining QAPP documentation, including implementing procedures.
- G. Provides ongoing, timely, and candid communications with NGNP management, participants, and regulating agencies (e.g., NRC and DOE), as appropriate.
- H. Assesses implementation of NGNP QA processes and systems and assists in resolving identified issues. The QA Director may make recommendations to the NGNP Project management regarding improving the quality of work processes.
- I. Assists the NGNP Project Director in coordinating outside audits, and ensures identified issues are entered into INL's issues tracking system.
- J. Measures, analyzes, and reports QA performance to NGNP Project and INL QA management.
- K. Provides and encourages appropriate training, professional development, and leadership opportunities for QA staff.

Accountabilities and Authorities

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

**1.6.7 Project Support Personnel**

Roles and Responsibilities

- A. Provides support functions for daily operations of NGNP.
- B. Financial support personnel: Assist program, project, control account, and work package managers in developing and implementing direct or indirect project baselines.
- C. Assist in developing resource-loaded schedules, establishing work breakdown structures as necessary, opening and closing



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

- D. Records and document control personnel: Serve as the NGNP Project representative and direct lead for all document and records management functions
- E. Ensure the documents that specify quality requirements or prescribe activities affecting quality are controlled during preparation, issue, and change such that correct documents are being employed.

Accountabilities and Authorities

- A. Accountable to the 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.

**1.6.8 VHTR TDO Director**

Roles and Responsibilities

- A. Establish, in coordination with the NGNP Director, the structure, processes, and responsibilities of the VHTR TDO, including the development of work packages to complete NGNP R&D project milestones
- B. Oversee the development of technical requirements related to R&D activities
- C. Provide technical direction, coordination, and oversight of TDO R&D activities to ensure that the approach, scope, and outcome of these activities are consistent with technical requirements
- D. Work closely with the NGNP Project Director, Licensing Director and NGNP Engineering Director in the development, assessment, change, and interpretation of technical requirements as specifically addressed by planned and ongoing R&D activities in support of the NGNP

Accountabilities and Authorities

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A. Accountable to the NGNP Director for:

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

B. Authorities:

- Oversee and approve key personnel assignments
- Hold staff and management accountable for performance

### **1.6.9 All Personnel Who Perform Activities for NGNP Project**

#### Roles and Responsibilities

- A. Carry-out work assignments and implement applicable requirements identified in this QAPP as applicable for assigned work.
- B. Comply with applicable policies, standards, and procedures.
- C. Identify opportunities for improvement.
- D. Perform safe, secure, cost effective, and compliant work.

#### Accountabilities and Authorities

- A. Accountable to the NGNP Project and home organization management for carrying out responsibilities in accordance with applicable requirements and expectations, including (but not limited to) those associated with QA, procurement, intellectual

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property and sensitive unclassified information protection, and integrated safety management.

- B. Accountable for identifying and reporting any concerns or problems with the direction, outcome, schedule, or costs associated with completion of subcontractor or NGNP Project activities.
- C. Accountable for identifying and reporting recommendations for revised approaches, directions, or additions to scope that may be required as a result of the outcomes of activities of the subcontractors or the NGNP Project.
- D. Accountable for compliance with laboratory policies, standards, and procedures, including: QA, procurement, intellectual property protection, export control, and integrated safety management requirements, as they apply to the NGNP Project.

## 2. ASSOCIATED PROGRAM DOCUMENTS

NGNP QA program implementing documents are listed in Appendix A of this QAPP. Unique NGNP Project requirements are addressed in Section 3 of this QAPP. QA drivers for this QAPP are addressed in Section 1.3.

## 3. QUALITY PROGRAM ELEMENTS

The NGNP Project will implement all elements of the INL QAP for performing licensed and nonlicensed quality-related activities, except as addressed by authorized deviations and unique NGNP Project QA requirements identified herein.

### 3.1 Quality Assurance Program Specific Deviations and Clarifications and Unique NGNP Project Requirements

#### 3.1.1 Requirement 1.0, Organization

This QAP element will be implemented in accordance with the procedures in Appendix A.

#### 3.1.2 Requirement 2.0, Quality Assurance Program

The NGNP Project QAP is described throughout this QAPP. Requirement 2 will be implemented with the following deviations and clarifications:

- A. *Deviation from LWP-13014, Determining Quality Levels:* NGNP Project work groups will develop a detailed scope of work to support the creation of quality level (QL) determinations. Task

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owners are responsible for the QL determinations for their respective work areas.

- B. *Clarification on reviews of statements of work (SOW) and procurement specifications:* An NGNP Project quality engineer (QE) must review and concur on NGNP Project QL-1 and QL-2 SOW and procurement specifications. The review and concurrence will be documented. An NGNP Project QE will review QL-3 SOWs and specifications as requested by the cognizant document owner.
- C. *Deviation from requirements of LWP-13012, "Addressing Program/Project Specific Quality Assurance Requirements, Scope and Appendix A":*
- Contrary to the LWP-13012 scope statement, the NGNP Project will use the QAPP to clarify quality requirements to meet project requirements.
  - The NGNP Project will use LWP-13012, Appendix A, "QAPP Format and Content," only as a guide. The NGNP Project QA Director will define the QAPP format and content to meet NQA-1-2000 and NGNP project requirements. Revision numbers of implementing procedures will not be included in Appendix A.

### **3.1.3 Requirement 3.0, Design Control**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

### **3.1.4 Requirement 4.0, Procurement Document Control**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

### **3.1.5 Requirement 5.0, Instructions, Procedures, and Drawings**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A and para. 3.1.7 B.5.

### **3.1.6 Requirement 6.0, Document Control**

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This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A and the following clarification:

- A. For NGNP Project controlled documents, and reports; a table of contents and revision log should be included.

### 3.1.7 Requirement 7.0, Control of Purchased Items and Services

Control of purchased items and services will be implemented per the procedures identified in Appendix A, with the following deviation and clarifications:

- A. *Deviation from TEM-10400-4, "Template for Statement of Work"*: All NGNP SOWs will include:
1. A signature page similar to the one found in TEM-10400-5 for specifications.
  2. A table of contents.
  3. A revision log.
- B. *Clarifications*:
1. Supplier evaluations and selections and the results therefrom are to be documented and are to include one or more of the following:
    - The supplier's history of providing an identical or similar product that performs satisfactorily in actual use, which shall reflect current capability

OR

    - The supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
  2. If an item (not service) will be used in a nuclear facility, the commercial grade dedication process outlined in LWP-13140, "Using Commercial Grade Items in Nuclear Facilities," will be followed. Examples of alternate evaluation processes are:

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- Specialized machining conducted by a vendor with no QAP in place, that would need to be verified by an INL representative on site as it takes place
- OR
- Material, procured from a nonqualified vendor, would be analyzed to verify selected critical characteristics before its use.
3. The specific name, manufacturer, and item attributes, such as chemical/physical and other identifying information, shall be documented for items used in processes that affect the quality of the product.
  4. Non-INL suppliers of fuel and material development and qualification items and services are not required to implement INL-specific documents listed in the appendices, except when specific documents are invoked by procurement action.
  5. The following methods may be used to perform and document reviews and comment resolutions for NGNP Project managed documents that have not been determined to be vendor data:
    - Use of Form 412.13, “Document Management Review Comments and Resolutions.”
    - Use of the electronic “Independent Review” process using the INL eDOCS system. This review can be coordinated via the NGNP Records Coordinator. See Appendix B for procedure details.

### **3.1.8 Requirement 8.0, Identification and Control of Items**

This QA program element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

### **3.1.9 Requirement 9.0, Control of Special Processes**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

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**3.1.10 Requirement 10.0, Inspection**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

**3.1.11 Requirement 11.0, Test Control**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

**3.1.12 Requirement 12.0, Control of Measuring and Test Equipment**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

**3.1.13 Requirement 13.0, Handling, Storage, and Shipping**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

**3.1.14 Requirement 14.0, Inspection, Test, and Operating Status**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

**3.1.15 Requirement 15.0, Control of Nonconforming Items**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

**3.1.16 Requirement 16.0, Corrective Action**

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

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### 3.1.17 Requirement 17.0, Quality Assurance Record

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

### 3.1.18 Requirement 18.0, Audits

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A with the following clarifications:

- A. Verify that all external audits deficiencies identified in the audit report are tracked and resolved using the INL corrective action system.
- B. Periodic assessments will be performed in the year following the audit to verify external audit deficiencies have been closed.
- C. All NGNP Project surveillance and inspection type assessment reports will be checked for the following attributes prior to issuance, as applicable:
  - A clear written scope or extent of review
  - Sample size and extent of conditions
  - Accuracy of language and absence of typos.

### 3.1.19 Subpart 2.7 “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications”

This QAP element will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A.

### 3.1.20 ASME NQA-1 2008 1a 2009, PART III, SUBPART 3.3, NONMANDATORY APPENDIX 3.1 “Guidance on Qualification of Existing Data”

This guidance will be implemented in accordance with NGNP Project and INL requirements per the procedures identified in Appendix A. It provides a means to evaluate data of an indeterminate quality.



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**4. APPENDICES**

Appendix A—NGNP Project Implementing Document Matrix

Appendix B— Independent Review Process

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**Appendix A—  
NGNP Project Implementing Document Matrix**

The NGNP and INL procedures listed in this appendix are those deemed most appropriate for NGNP Project work scope for each NQA-1 requirement. Other INL procedures included as references in the procedures listed in the following table are also applicable to NGNP Project work activities as appropriate. The most current revision of these procedures is applicable to NGNP Project work.

<b>Requirement</b>	<b>INL IMPLEMENTING DOCUMENT NQA-1-2000</b>	<b>NGNP IMPLEMENTING DOCUMENT NQA-1 2008, 1a-2009</b>
1.0, Organization		PRD-349, NGNP Organization MCP-3302, NGNP Organization
2.0, Quality Assurance Program		LST-649, NGNP Definitions and Acronyms PRD-350, NGNP Quality Assurance Program  PRD-351, NGNP Personnel Training and Qualification PRD-352, NGNP Contractor Assurance System MCP-3303, NGNP Quality Assurance Program  MCP-3052, NGNP Personnel Qualification and Certification  MCP-3051, NGNP Audit Personnel Training and Certification  PLN-2690, VHTR TDO QAPP  PLN-3635, NGNP Quality Assurance Program Implementation Plan
3.0, Design Control	LRD-13200, Design Control LWP-10200, Calculations and Analysis LWP-10400, Design Control LWP-10700, Nuclear Materials Experiments Life Cycle Process MCP-13910, Reviewing and Approving Documents and Records STD-10011, Drawing Requirements Standard	Not Currently Issued for design work  PRD-354, NGNP Software Quality Assurance MCP-3058, NGNP Software Quality Assurance

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Requirement	INL IMPLEMENTING DOCUMENT NQA-1-2000	NGNP IMPLEMENTING DOCUMENT NQA-1 2008, 1a-2009
4.0, Procurement Document Control	LRD-13300, Procurement Document Control LWP-4001, Material Acquisitions LWP-4002, Service Acquisitions LWP-4003, Using Purchase Cards to Acquire Material and Services LWP-4501, Preparation and Control of Procurement Documents LWP-4502, Flow-down of Standard Procurement Quality Requirements LWP-4503, Supplier Evaluation And Qualification LWP-4504, Supplier Surveillance LWP-4505, External Supplier Audits STD-4507, Standard Procurement Quality Requirements LWP-7205, INL Subcontracted Work	Not Currently Issued
5.0, Instructions Procedures and Drawings	LRD-13100, Work Processes LWP-1201, Document Change LWP-6200, Maintenance Integrated Work Control Process LWP-21220, Work Management Menu MCP-1451, R&D Manufacturing Services Work Management Implementation STD-10011, Drawing Requirements Standard	Not Currently Issued
6.0, Document Control	LRD-13900, Document and Records LWP-1201, Document Management LWP-10200, Calculations and Analysis LWP-11203, Export Licensing and Compliance	Not Currently Issued

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<b>Requirement</b>	<b>INL IMPLEMENTING DOCUMENT NQA-1-2000</b>	<b>NGNP IMPLEMENTING DOCUMENT NQA-1 2008, 1a-2009</b>
7.0, Control of Purchased Items and Services	LRD-13300, Control of Purchased Items and Services LWP-4001, Material Acquisitions LWP-4002, Service Acquisitions LWP-4003, Using Purchase Cards to Acquire Material and Services LWP-4501, Preparation and Control of Procurement Documents LWP-4502, Flow-down of Standard Procurement Quality Requirements LWP-4503, Supplier Evaluation And Qualification LWP-4506, Acceptance of Procured Materials and Services LWP-7203, Vendor Data Process LWP-13140, Using Commercial Grade Items in Nuclear Facilities MCP-13910, Reviewing and Approving Documents and Records	Not Currently Issued
8.0, Identification and Control of Items	LRD-13100, Work Processes LWP-2010, Storing Government Property LWP-4506, Acceptance of Procured Materials and Services LWP-13120, Identification and Controlling Items	Not Currently Issued
9.0, Control of Special Processes	LRD-13100, Work Processes LWP-13110, Controlling Special Processes LWP-13420, Qualifying NDE Equipment and Procedures	Not Currently Issued
10.0, Inspection		PRD-363, NGNP Inspection MCP-3063, NGNP Inspections
11.0, Test Control		PRD-364, NGNP Test Control MCP-3064, NGNP Test Control PRD-354, NGNP Software Quality Assurance MCP-3058, NGNP Software Quality Assurance

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<b>Requirement</b>	<b>INL IMPLEMENTING DOCUMENT NQA-1-2000</b>	<b>NGNP IMPLEMENTING DOCUMENT NQA-1 2008, 1a-2009</b>
12.0, Control of Measuring and Test		PRD-365, NGNP Control of Measuring and Test Equipment MCP-3066, NGNP Control of Measuring and Test Equipment
13.0, Handling, Storage and Shipping	LRD-13100, Work Processes LWP-2010, Storing Government Property LWP-13120, Identification and Controlling Items	Not Currently Issued
14.0, Inspection, Test and Operating Status	LRD-13400, Inspection and Acceptance Testing LWP-13410, Planning, Performing, and Documenting Inspection for Acceptance LWP-13830, Control of Non-conforming Items	Not Currently Issued
15.0, Control of Nonconforming Items		PRD-368, NGNP Control of Nonconforming Items MCP-3060, NGNP Control of Nonconforming Items
16.0, Corrective Action	LRD-13800, Quality Improvement LWP-9301, Event Investigation and Occurrence Reporting LWP-13840, Management Of Issues, Observations, and Noteworthy Practices LWP-13845, Cause Analysis Program LWP-14002, Timeout and Stop Work Authority	Not Currently Issued
17.0, Quality Assurance Records		PRD-372, NGNP Quality Assurance Records MCP-3055, NGNP Records Management Procedure

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Requirement	INL IMPLEMENTING DOCUMENT NQA-1-2000	NGNP IMPLEMENTING DOCUMENT NQA-1 2008, 1a-2009
18.0, Audits	LRD-13700, Assessment LWP-13730, Developing and Maintaining Assurance Portfolios and Schedules LWP-13740, Performing Inspections LWP-13745, Performing Surveillances LWP-13750, Performing Management Assessments LWP-13760, Performing Independent Assessments PDD-13720, Assessment Training and Qualification Program	PRD-373, NGNP Audits PRD-374, NGNP Assessments. MCP-3062, NGNP Quality Assurance Audits.
ASME NQA-1 2000, Subpart 2.7 "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications"		PRD-354, NGNP Software Quality Assurance MCP-3058, NGNP Software Quality Assurance
NQA-1 2008 1a 2009, PART III, SUBPART 3.3, NONMANDATORY APPENDIX 3.1 "Guidance on Qualification of Existing Data"		MCP-2691, Data Qualification

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## Appendix B— Guidance for Independent Review Process

**Purpose:** Provide a process that may be used to review vendor supplied documents.

**Scope:** May be used for vendor supplied documents that do not require review through the Vendor Data Process.

**Introduction:** The Independent Review process is a functioning process found on the EDOCS menu under Document Control, EDOCS. This feature provides a means to review vendor-provided documentation and track comments and resolutions. The following steps are intended to guide you through the review process.

### 1. Procedure

- 1.1 Open “Independent Review” under the EDOCS Menu on the Document Control, EDOCS webpage (you can also access EDOCS through EDMS).
- 1.2 Using the Review process select the desired function:
  - 1.2.1 Reviewer may add and edit comments and concur with changes.
  - 1.2.2 The Review Coordinator may create or edit a review, resolve comments, or analyze existing review requests.

NOTE: There are options to export and import data into Excel, as well as to switch to the Document Review process (eCR Review Menu) on this webpage.

- 1.3 Create or edit a review:
  - 1.3.1 Enter your windows User ID and Password.
  - 1.3.2 To create a review you will need:
    - A description of the purpose for the review
    - List of reviewers
    - An expected due date
    - An electronic copy of the document(s) to be reviewed.
  - 1.3.3 Follow the steps at the top of the page.

NOTE: When attaching material for review, be sure that you select the type of material (step 1) prior to entering the file location (step 2). If this sequence is not followed, the process will crash, requiring you start again from the beginning.

- 1.3.4 Editing a review uses the same steps as creating a review but allows you to change existing data.
- 1.4 Review a document:

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- 1.4.1 Select the document for review. You may need to search on the doc ID in order to be able to select the review.
- 1.4.2 Read the document. From the menu select the appropriate action. To approve the document, select “No Comment.”

2. Reference and Definition

eDOCS INL Database for managing document reviews and changes  
 Independent Review [http://simsprd:8500/pls/sims\\_dar/docreview.nonECRMenu](http://simsprd:8500/pls/sims_dar/docreview.nonECRMenu)