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Idaho National Laboratory Advanced Reactor Technologies Quality Assurance Program Plan

Michelle T Sharp

April 2020

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

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Plan

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Idaho National Laboratory Advanced Reactor Technologies Quality Assurance Program Plan

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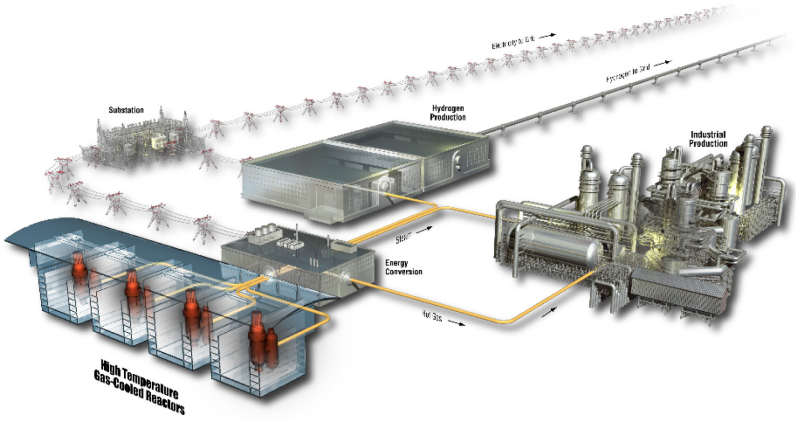

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REVISION LOG

Rev.	Date	Affected Pages	Revision Description
0	04/29/2008	All	New document.
1	06/03/2008	1, 3, 8, 10, 15, and Appendix A	Added PIE to acronym list. Clarified scope statement, included Materials and Fuels Complex facility exemption, and defined quality affecting activities. Revised organization chart. R2A2s did not change as a result of revision. Clarified R2A2s for VHTR TDO Program personnel. Deleted reference to stop work because the stop work procedure now has clear guidance on the stop work process involving QA. Deleted assessment content list because this is now included in assessment procedures and clarified that the QA lead would review surveillances for written content. Added several company procedures to Appendix A, listed procedures in numerical order under each requirement, and added statement on use of revision numbers.
2	06/04/2009	vii, 1, 4-9, 15, 24, 25, and 28	Corrected definition of acronym PIE. Added requirement to Requirement 18, Audits (Section 3.1.18), that specifies when external audit deficiencies are to be closed. Moved MCP-13910, "Reviewing and Approving Documents and Records," to ASME NQA-1-2000 7.0 Control of Purchased Items and Services. Replaced MCP-3630, "I&C Computer System Management," with LWP-10400, "Design Control," and LWP-13620, "Quality Assurance Management System." Revised Section 1.5 to reflect changes in the organization. Revised Section 3 for clarification and deviation statements. Revised/updated INL implementing document matrix. Added a Section 4.0 and Appendix B to document requirements for university contracts with the Center for Advanced Energy Studies. Added narrative to capture externally-identified issues into INL's issue management system. Corrected table of implementation documents.
3	07/22/2009	12, 29, and 30	Added MCP-13910, "Reviewing and Approving Documents and Records," to 7.0 Control of Purchased Items and Services. Removed PLN-1484, "Advanced Gas Reactor Fuel Development and Qualification Program: Project Execution Plan," Section 2. Added word "Material" to document title for PLN-2803 and PLN-2804. Removed LWP-1250, "Electronic Document and Content Management," from Appendix A, Section 5, Instructions Procedures and Drawing.

Rev.	Date	Affected Pages	Revision Description
4	12/07/2009	22 and 15-17	See eCR No. 572738. Clarified statement in Section 3.1.19, Use of Regulatory Guide 1.203. Clarified Para 3.1.7 B regarding management of non-vendor data managed documents and references to Para 3.1.7. Clarified inspection of items modified under service contract, Para 3.1.7 B 6.
5	07/12/2010	4, 22, and 28	See eCR No. 582500. Replaced John Cox with Diane Croson on signature page. Removed Section 3.2, Control of Unqualified Data. Replaced with Section 1.20, Guidance on Qualification of Existing Data. Added a row to Appendix A, INL Implementing Matrix, describing data qualification. Added code reference to ASME NQA-1-2008/1a-2009.
6	09/21/2010	3, 13, 20, and 28	See eCR No. 583239. Replaced NQA-1-2008/1a-2009, Part 1, reference with NQA-1-2008/1a-2009, Part III, reference. Replaced the title for LWP-13840. Replaced references to PLN-1485 with PLN-3319.
7	06/28/2011	1, 4, 5, 7, 17, 18, Appendix A, and Appendix C	See eCR No. 593256. Added a background section to explain the change from NQA-1-2000 to NQA-1-2008/1a-2009 and the associated procedures. Modified Figure 1.3-1 to show new regulatory drivers. Added Figure 1.3-2 for clarification. Updated the organization chart. Cleaned up R2A2 statements. Updated deviation and clarification statements in Section 3.1. Modified Appendix A to show implementing procedures for either the INL program or the NGNP program. Updated Appendix C.
8	07/28/2011	4, 5, 7, and 8	See eCR No. 595070. Added statement in Section 1.3 to clarify Figure 1.3-1 purpose. Revised Figure 1.3-1, Requirements and implementation flowdown diagram. Added statement in Section 1.3 to clarify Appendix A purpose. Updated organization chart and added reference to expanded organization chart in EDMS.
9	07/18/2012	All	Organizational change and annual review. Changed the procedure implementation matrix. Clarified VHTR research and development direction.
10	01/09/2013	2, 7, 9, 14, 21, and 22	Clarified deviation statements for Requirements 5.0, Instructions, Procedures, and Drawings, and 14.0, Inspection, Test, and Operating Status. Added Requirement C for NCRs. Updated organization chart. Removed reference to Engineering and the Engineering staff position. Added scope to include high temperature materials work under the Small Modular Reactor Program.
11	01/15/2014	All	Routine update.

Rev.	Date	Affected Pages	Revision Description
12	02/04/2014	All	See eCR No. 620171. Replaced reference to NQA-1 with NQA-1-2008, where necessary, and included reference to NQA-1a-2009, where missing. Revised to reflect current references; added/corrected reference titles, where necessary, Corrected document number for the Next Generation Nuclear Plan from PLN-172 to PDD-172. Deleted Appendix C and associated procedure text regarding the independent document review process, as there is sufficient information available in LWP-1201 for the review process and having the information in this document adds no value. Made minor editorial changes that do not affect the intent of this procedure.
13	03/13/2015	All	See eCR No. 629675. Renamed the procedure to "Idaho National Laboratory Advanced Reactor Technologies Technology Development Office Quality Assurance Program Plan." Replaced all program level MCPs with INL Site procedures. Removed Appendix B. Added requirements source as PDD-13000 and Requirements Roll-Down Report.
14	09/24/2015	13	Clarified Section 3.1.18 to differentiate between triennial audit and verification audit of deficiencies.
15	10/13/2015	1	Minor typo per DOE QA auditor need to add dashes to NQA 1a 2009 to be NQA-1a-2009.
16	08/23/2017	All	Update includes recent organization chart, addition of NTRD QRLs, changes in INL QLD process and other editorial changes.
17	06/12/2018	All	Update includes removal of Technology Development Office, update requirement 7 in Section 3.17, removal of clarification in Section 3.1.18, update of references and other editorial changes. Removal of reference to 10 CFR 50, Appendix B and 10 CFR 21.
18	08/16/2018	Appendix A	Updated Appendix A to include research life cycles and QRL 1 peer review requirements.
19	03/18/2020	All	Update includes removal of NTRD requirements and Appendix A, changes in organization chart and associated technology areas.

CONTENTS

FIGURES

POLICY STATEMENT

The Idaho National Laboratory (INL) Advanced Reactor Technologies (ART) Program was established to coordinate the research and development activities required to design and license the first high temperature reactor (HTR) and perform other research and development projects to support DOE advanced reactor technologies. It is the policy of INL ART to provide high quality, technically-defensible scientific/engineering information and services, while complying with applicable requirements using a graded approach appropriate for the task. It is the responsibility of personnel involved in ART activities to comply with the mandatory requirements of this Quality Assurance Program Plan, which will be executed in accordance with a combination of INL and INL ART approved directives, procedures, and internal policies.

ACRONYMS

AMP	annual mission plan
ART	Advanced Reactor Technologies
ATR	Advanced Test Reactor
BEA	Battelle Energy Alliance, LLC
DOE	Department of Energy
DOE-ID	Idaho Operations Office
EDMS	Electronic Document Management System
HTR	high temperature reactor
INL	Idaho National Laboratory
ISOP	integrated strategic operations plan
MFC	Materials and Fuels Complex
NEUP	Nuclear Energy University Program
NGNP	Next Generation Nuclear Plant
NRC	Nuclear Regulatory Commission
PIE	post-irradiation examination
QA	quality assurance
QAP	Quality Assurance Program
QAPP	Quality Assurance Program Plan
QE	quality engineer
QL	quality level
QLD	quality level determination
R&D	research and development
R2A2	roles, responsibilities, accountabilities, and authorities
S/CI	suspect/counterfeit item
SOW	statement of work
SQA	software quality assurance
SSC	structure, system, and component
TRAIN	Training Records and Information Network
VHTR	very high temperature reactor

1. INTRODUCTION

1.1 Background

The Idaho National Laboratory (INL) Advanced Reactor Technologies (ART) Program manages and integrates program elements across multiple technology areas including fuel development and qualification, high temperature materials, graphite research and development (R&D), design methods and validation, licensing, international collaborations and support activities. INL ART manages R&D for high temperature reactors (HTRs) and other advanced reactor technologies and ensures that Nuclear Regulatory Commission (NRC) requirements and stakeholder needs are factored into the R&D activities performed.

The management and operating contract (DE-AC07-051D14517) between Battelle Energy Alliance, LLC (BEA), and the Department of Energy (DOE) Idaho Operations Office (ID), authorizing BEA to operate the INL, requires BEA to comply with 10 CFR 830, Subpart A, "Quality Assurance Requirements," and DOE Order 414.1D, "Quality Assurance." The INL Quality Assurance Program (QAP) described in PDD-13000, "Quality Assurance Program Description," complies with those requirements and is based on the American Society of Mechanical Engineers Nuclear Quality Assurance (QA) consensus standard, NQA-1-2008/1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications" (NQA-1-2008/1a-2009).

All INL ART work shall be performed and documented in accordance with these standards to ensure that the applicable QA requirements are satisfied to support the R&D activities for future NRC licensing and design of an HTR.

1.2 Purpose

This Quality Assurance Program Plan (QAPP) describes the planning, structure, documentation, implementation, and maintenance of the INL ART QAPP, which flows from PDD-13000. This QAPP explains how the INL ART complies with the INL QAP.

1.3 Scope

This QAPP covers INL ART R&D, licensing, and program support activities. QA implementing procedures will be identified for all activities to ensure work is documented and the results are capable of successfully completing a technical review by DOE. For work performed by other organizations under contract or other agreements with INL, applicable requirements will be flowed down through the contract or other agreements, but the organizations will be responsible to implement the flowed down requirements through their own specific implementing procedures.

This QAPP also covers implementation of software QA (SQA) requirements for software used exclusively by INL ART. Software that is used to support multiple INL programs/projects is not covered by this QAPP; the responsibility for implementing SQA requirements for that software resides with the owners and respective managers of the software.

This QAPP does not cover activities for installing and operating experiments in the Advanced Test Reactor (ATR) at INL, nor does it cover ATR facility modifications designed to meet INL ART testing needs (such as temperature, pressure, gas flow, and control systems). Those activities are controlled by the INL QAP and specific ATR

implementing procedures. ATR facility management and INL ART management jointly approve experiment designs and functional system requirements. This QAPP does apply to INL ART R&D experiments that will be inserted into ATR and any support activities associated with those R&D activities.

This QAPP does not cover activities for installing and operating general post-irradiation examination (PIE) test equipment in Materials and Fuels Complex (MFC) facilities. Those activities are controlled by the INL QAP and MFC implementing procedures. However, this QAPP does apply to MFC facility modifications designed to meet specific INL ART testing needs. It also applies to INL ART experiments that will have PIE performed on them and any support activities associated with the PIE activities.

1.3.1 INL ART Interfaces with Associated Work Groups

INL ART is a national organization with international participants. The intent of the organization is to staff the program with the right people to accomplish the work, regardless of location or affiliation. As appropriate, the technology development and execution activities will use facilities and staff from national laboratories, universities, commercial industry, industrial alliance partners, consulting organizations, and research groups from cooperating foreign countries.

INL ART is responsible for:

- Defining the technical work scope, deliverables, reporting, schedules, earned value tracking, and QA requirements for those efforts
- Putting the necessary memorandum purchase orders, inter-entity work orders, and subcontracts in place to document work requirements
- Concurrence with work schedules and deliverables, and transferring funds
- Providing oversight of work activities and associated deliverables for INL ART program.

Section 1.6 of this QAPP further clarifies INL ART interfaces through defined personnel roles and responsibilities.

1.3.2 Advanced Test Reactor (ATR)/INL ART Interface

ATR/INL ART interface is established and maintained through ATR participation in INL ART experiment design reviews, INL ART participation in experimenters' meetings, interoffice memoranda, and periodic meetings where INL ART program support, needs, and priorities are discussed. INL ART coordinates the planning and scheduling of its experiments into the ATR Integrated Strategic Operations Plan (ISOP) with ATR experiment management for use of reactor positions, power requirements, schedules, and resources.

1.3.3 Materials and Fuels Complex (MFC)/INL ART Interface

MFC/INL ART interface is established and maintained through MFC participation in INL ART PIE plan reviews, experiment design reviews, INL ART participation in routine users working group meetings, interoffice memoranda, and periodic meetings where INL ART program support, needs,

and priorities are discussed. INL ART coordinates with MFC management in the development of the Annual Mission Plan (AMP) for use of facilities, equipment, and resources at MFC.

1.4 Codes, Standards, and Regulations

The INL ART QAPP regulatory documents include 10 CFR 830, and Subpart A, "Quality Assurance Requirements" and DOE O 414.1D, "Quality Assurance." The QAPP requirements documents include NQA-1-2008/1a-2009 and PDD-13000, "Quality Assurance Program Description," which includes reference to PDD-171, "Contractor Assurance System". Additional documents and their hierarchy used to accomplish INL ART mission are referenced in this plan.

1.4.1 Implementation of PDD-13000

The INL QAP describes how the NQA-1-2008/1a-2009 requirements are met. The INL ART implements the requirements of the INL QAP, along with the additional clarifications in Section 3 of this QAPP.

1.5 Quality Assurance Program Plan Change Control

This QAPP is controlled within the Electronic Document Management System (EDMS). This QAPP will be reviewed at least annually and revised as necessary. Revisions will be authored by an INL Quality Engineer (or require review and concurrence by an INL Quality Engineer) and approval by the INL ART director, ART Program Manager or designated alternates, and INL QA Program Manager or designated alternate.

1.6 Organizational Roles, Responsibilities, Accountabilities, and Authorities

The INL ART organizational structure is shown in Figure 1. A current detailed organization chart is maintained in EDMS.

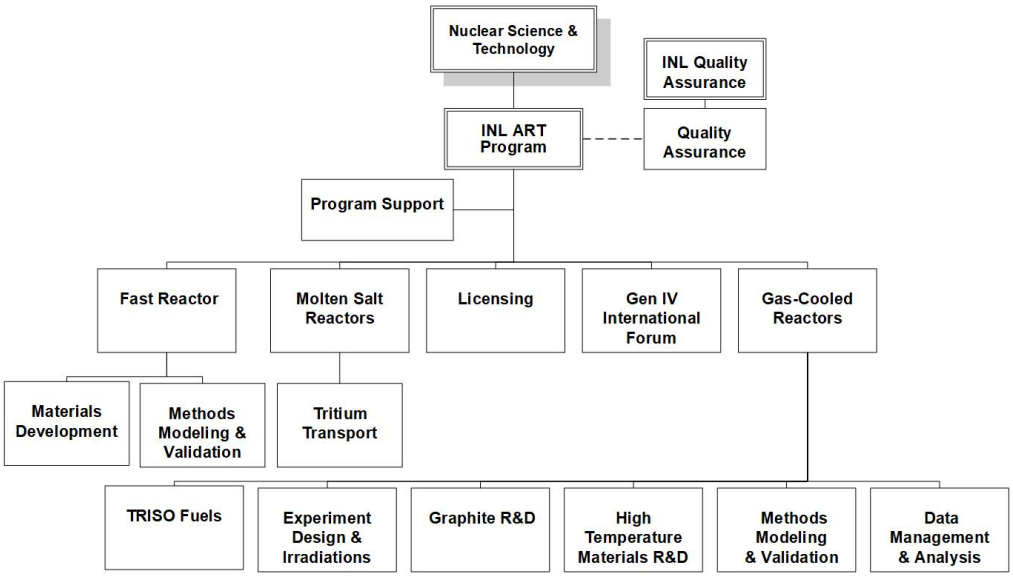

Figure 1. INL ART Organization

Because it is comprised of many different contributors, it is important to maintain the "single point of control" concept focused through the INL ART director and program team. The DOE federal project director receives the mission, goals, and objectives from the DOE Office of Nuclear Energy and passes them to the INL ART director by way of formal guidance letters. The INL ART director directs the program team to implement the program through requirements, plans, organizations, and the delegation of responsibilities, scopes, budgets, and controls.

The detailed roles, responsibilities, accountabilities, and authorities (R2A2s) for the following positions can be found in PLN-2494, "Advanced Reactor Technologies Program Management Plan," and are summarized below for convenience:

- **INL ART Director:** Provides overall expectations for and leadership and management of the INL ART Program and is ultimately responsible for employing INL ART processes to achieve the desired results.
- **INL ART Program Manager:** Assists the INL ART director in accomplishing his/her R2A2s, and acts for the director in his/her absence.
- **INL ART Project Managers:** Develop and maintain baseline work scope, schedules, and budgets, and oversee the execution of work to ensure it is performed within the baselines.
- **INL ART Technical Leads:** Oversee all the technical aspects within their assigned work scope, and develop, maintain, and execute work packages using INL ART processes.
- **INL ART Licensing Lead:** Coordinates with the NRC, environmental and state regulators, and INL ART personnel to ensure all work performed supports licensing and regulatory needs.
- **INL QA Engineer:** Provides QA support for INL ART activities, ensures quality requirements are satisfied, performs oversight and audits, and resolves quality issues.
- **INL ART Program Support Staff:** Provides support to other INL ART personnel in the routine activities of the INL ART Program.

2. ASSOCIATED QUALITY ASSURANCE PROGRAM DOCUMENTS

The following documents support the implementation of this QAPP.

- PLN-2494, "Advanced Reactor Technologies Program Management Plan"
- PLN-2497, "Graphite Technology Development Plan"
- PLN-2498, "Advanced Reactor Technologies High Temperature Reactor Methods Technical Program Plan"
- PLN-2709, "Nuclear Data Management and Analysis Plan"
- PLN-2803, "Next Generation Nuclear Plant Reactor Pressure Vessel Materials Research and Development Plan"

- PLN-2804, "Next Generation Nuclear Plant Steam Generator and Intermediate Heat Exchanger Materials Research and Development Plan"
- PLN-3247, "Risk Management Plan for the Next Generation Nuclear Plant Project"
- PLN-3636, 'Technical Program Plan for INL Advanced Reactor Technologies/Advanced Gas Reactor Fuel Development and Qualification Program"

3. QUALITY ASSURANCE PROGRAM ELEMENTS

3.1 Quality Assurance Program Elements

All requirements met by this QAPP are documented in LST-1118, "Quality Assurance Program Requirements Mapping" which identifies implementing documents.

This QAPP implements requirements per PDD-13000. The following sections address the implementation of each INL ART QAPP element and any clarifications, including additions necessary for INL ART QAPP implementation, and/or deviations (currently there are no deviations). The words "shall," "must," or "will" denote a requirement that must be met. The words "should" or "may" denote guidance.

3.1.1 Requirement 1.0: Organization

Implementation Clarifications:
PLN-2494, identifies the INL ART organization structure. The INL ART Organization Chart is provided in Figure 1. PLN-2494 also defines roles and responsibilities from the highest program management level, INL ART Director, through support staff. INL implementing procedures also identify roles and responsibilities for personnel conducting specific work scope.

3.1.2 Requirement 2.0: Quality Assurance Program

Implementation Clarifications:

- INL quality level determinations (QLDs), following the process described in LWP-13014, "Determining Quality Levels," are required for all INL ART work.
- A research program may involve multiple research types (basic and applied R&D work). As the research matures, requirement changes are identified and documented through the QLD process described in LWP-13014.
- NQA-1-2008/1a-2009, Part IV, Subpart 4.2 allows the graded application of requirements to QA activities for R&D activities.
- LWP-13012, "Addressing Program/Project Specific Quality Assurance Requirements:" The INL ART will use LWP-13012 Appendix A, "QAPP Format and Content Guidelines," as a guide only. The INL Quality Engineer will define the QAPP format and content to meet requirements of the INL ART QAPP and NQA-1-2008/1a-2009.

3.1.3 Requirement 3.0: Design Control

Implementation Clarifications:

- Once an HTR design is documented, a list of structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public will be developed. Safety-related SSCs will be identified in design documents. The technical aspects of the safety-related SSCs will be considered when determining QAP requirement applicability, including designed safety functions.
- The responsibility for implementing software design control requirements resides with the owners and respective managers of the software.

3.1.4 Requirement 4.0: Procurement Document Control

***Implementation Clarifications*:** In addition to use of TEM-10400-4, "Template for Statement of Work," all INL ART statements of work (SOWs) will include a signature page identifying the Quality Level, preparer, approver, and staff who concur on the document.

- An INL quality engineer (QE) will review and concur with INL ART Quality Levels assigned on SOWs and procurement specifications to assist with specifying the QA requirements to be flowed down prior to the requisition being provided to INL Procurement. The review and concurrence will be documented.

3.1.5 Requirement 5.0: Instructions, Procedures, and Drawings

Implementation Clarifications:

- The instructions, operations, and drawings for INL ART program R&D monitoring/test/equipment/systems (such as the fission product monitoring system) shall be documented and authorized in documents (such as test plans, laboratory notebooks, or instructions). Affected facility managers and/or laboratory custodians will have the opportunity to provide input. Test plans, laboratory notebooks, or instructions shall specify the need to document the successful training of personnel operating the system. Documentation of training shall be maintained.
- This graded approach does not apply to activities that: (1) have direct impact to the ATR safety operation envelope; (2) are support activities/operations; or (3) are beyond R&D (i.e., design, operations, and engineering activities).

3.1.6 Requirement 6.0: Document Control

***Implementation Clarifications*:**

- ART documents will use the current ART templates including applicable signature pages.

3.1.7 Requirement 7.0: Control of Purchased Items and Services

Implementation Clarifications:

- If items (such as test specimens) are to be modified or machined under a service requisition, receipt inspections for such items will be completed by an INL quality inspector. Receipt inspection documentation shall be maintained in program files as a quality record.
- Quality Level 3 (QL-3) items purchased for applied or developmental research experiments require receipt inspection. The need for receipt inspection must be identified in iBuy or Asset Suite prior to the purchase.
- Service procurement quality levels for activities are Quality Level 1 (QL-1) if the service is credited in the safety basis, and QL-3 if the service is not credited in the safety basis. Quality requirements will be documented in a SOW and approved by a project QE.

  Service supplier evaluation requirements will be determined and documented by the ART responsible person (such as the principal investigator [PI]) or work package manager (WPM) and the project QE on Form 415.60 “Supplier Evaluation Report”. The PI/WPM and project QE will determine the need for and extent of QL-3 supplier evaluation and oversight. QL-3 service suppliers will not be added to the INL qualified suppliers list but may be audited.

3.1.8 Requirement 8.0: Identification and Control of Items

Implementation Clarifications: None.

3.1.9 Requirement 9.0: Control of Special Processes

Implementation Clarifications:

- Process control instructions associated with basic or applied research may be defined in laboratory notebooks, instructions, or procedures.
- Initial process controls shall be documented in laboratory notebooks or operating logs for scoping studies, basic, or applied research. Procedures that address specific process methodology, quality, safety, and training will be developed once the experimental process has been defined.

3.1.10 Requirement 10.0: Inspection

***Implementation Clarifications*:** PDD-13000 inspection requirements shall also be applied to:

- All test apparatus used for research that impacts safety of operation
- All experiments being inserted into ATR
- All circumstances where inspection is critical to the outcome of the research and/or experiment.

3.1.11 Requirement 11.0: Test Control

Implementation Clarifications: None.

3.1.12 Requirement 12.0: Control of Measuring and Test Equipment

Implementation Clarifications:

- Measuring and test equipment requiring calibration shall be calibrated by the INL Standards and Calibration Laboratory, a facility on BEA's Qualified Supplier List, or INL ART with documented training on specific equipment.
- Equipment calibrations performed by INL ART personnel will be in accordance with an approved procedure. Vendor procedures and American Society for Testing and Materials International instructions are acceptable for calibrations. All other procedures shall be formally controlled through EDMS. Calibration procedures may be a part of other approved documents.
- Calibration records generated by a qualified supplier will be retained by the supplier per the supplier's procedures. The procurement subcontract may also require record copies be provided to INL. INL ART will retain those records. Records for calibration of gas and other standards will be retained as INL ART records. INL ART calibration records for equipment sent to a qualified vendor by the INL Standards and Calibration Laboratory will be maintained by that laboratory.
- Selection of measuring and test equipment and its calibration status will be documented in the respective test plan, laboratory notebooks, work support records, INL Calibration Database, or a combination of those records.
- Calibration training will be documented in the INL Training Records and Information Network (TRAIN) System or laboratory notebooks.

3.1.13 Requirement 13.0: Handling, Storage, and Shipping

Implementation Clarifications:

- Special requirements that include, but are not limited to, shipping approvals for new fuel compacts, verifications that storage limits are not exceeded, and shipping containers for post-irradiated fuel/material for examination, shall be documented in SOWs, specifications, procurement documentation, or other supporting calculation and analysis program records.

3.1.14 Requirement 14.0: Inspection, Test, and Operating Status

Implementation Clarifications:

- INL ART program systems used specifically for R&D (such as benchtop tests and the fission product monitoring system) are not required to have rigorous nuclear-facility-type operating status indicators applied. A system to communicate off-normal conditions (such as automatic notifications) between facility operators and INL

ART personnel shall be established and documented (such as for fission product monitors, fuel accident condition simulator furnace, and others). Facility managers and/or laboratory custodians shall be made aware of the tests or systems in operation. A R&D Technical Authority shall define and document any required inspection, test and operating status criteria, or performance for INL ART program systems in test plans, laboratory notebooks, or instructions.

3.1.15 Requirement 15.0: Control of Nonconforming Items

***Implementation Clarifications*:** Nonconformance requirements apply to all research activities with defined acceptance criteria.

- Technical leads of the applicable organization (such as the fuel development technical lead or graphite technical lead) and the INL QE will be informed when a nonconforming item is identified.
- All supplier nonconformance dispositions must obtain the approval of the appropriate technical lead or authority.

3.1.16 Requirement 16.0: Corrective Action

Implementation Clarifications: None.

3.1.17 Requirement 17.0: Quality Assurance Records

***Implementation Clarifications*:**

- Laboratory notebooks used to document R&D work activities shall be registered in EDMS.
- The experiment irradiation technical lead will copy quality records related to fuel receipt and fabrication of test assemblies that are covered under the ATR work control processes and submit them to the INL ART records coordinator. This will normally be accomplished within one month after work package closure. Laboratory procedures, written instructions, process travelers, run sheets, calibration data, and any other records generated for control of technical activities shall be maintained as INL ART program records.
- Completed notebooks documenting researcher or developer activities or data shall be maintained as INL ART project records. These notebooks will be submitted to records management when no longer needed in the laboratory.
- All INL ART SOWs, including changes, will be placed in EDMS as records.

3.1.18 Requirement 18.0: Audits

Implementation Clarifications:

- All INL ART surveillance and inspection-type assessment reports will be reviewed by an INL QE to ensure a clear written scope or extent of review, sample size, accuracy of language and absence of typos, and approval of assessments by management.

3.2 NQA-1-2008/1a-2009, Part II, Subpart 2.7

LWP-13620, "Management Information Technology Assets" implements NQA-1-2008/1a-2009, Part II, Subpart 2.7, requirements for starting work on any safety software.

Implementation Clarifications:

- Work includes code development (when required) and scoping activities to determine the software applicability to the INL ART mission. Software modification and development along with code verification and validation will occur after establishing the software baseline. The technical lead for Gas-Cooled Reactors, Methods Modeling and Validation group will decide when to baseline the code, based on code development results and customer approval.

3.3 NQA-1-2008/1a-2009, Part III, Subpart 3.3, Nonmandatory Appendix 3.1

Implementation Clarifications:

- NQA-1-2008/1a-2009, Part III, Subpart 3.3, Nonmandatory Appendix 3.1, will be implemented per MCP-2691, "Data Qualification." MCP-2691 provides a means to evaluate data of an indeterminate quality.

3.4 Clarification of Laboratory Notebook Signature Requirements

Laboratory notebook signature requirements are implemented by MCP-2875, "Proper Use and Maintenance of Laboratory Notebooks."

Implementation Clarifications: Laboratory notebooks will have the following signature requirements:

- The owner of the laboratory notebook will sign the first page identifying ownership
- The owner will sign and date each entry that identifies instrument calibration
- The owner will sign and date each entry that verifies a piece of equipment passed an operations test (such as leak test, software operation test, or check of a relief valve set point)
- When a person other than the laboratory notebook owner makes an entry into a laboratory notebook, that person will sign and date the data entry
- The final entry made in a laboratory notebook will be signed and dated
- Additional signatures may be added at the researcher's or manager's direction.

3.5 Suspect/Counterfeit Items Prevention

Implementation Clarifications: None.

4. QUALITY ASSURANCE REQUIREMENTS FOR WORK PERFORMED BY UNIVERSITIES

Universities conduct work for the INL ART program through contracts direct to universities from the INL ART Program and via contracts through the Nuclear Energy University Program (NEUP), as administered through co-operative agreements with DOE. Universities performing

INL ART Program work as a direct subcontractor to INL shall comply with the requirements of the contractual documents. Those contractual documents shall include the flowdown of the applicable requirements of this QAPP, either with a University QA Requirements Worksheet or through inclusion of the specific QA requirements into the QA section of the SOW or subcontract. The INL ART responsible person (such as the PI or WPM) shall ensure that QA requirements and acceptance criteria are identified, flowed down, and implemented by the university. The INL ART responsible person shall obtain an INL QE review of all quality affecting SOWs and procurement documents to assist with specifying the QA requirements. Universities performing work under NEUPs shall follow the requirements specified in the NEUP agreement.

5. REFERENCES

10 CFR 830, Subpart A, “Quality Assurance Requirements”

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Form 415.60 “Supplier Evaluation Report”

LST-1118, “Quality Assurance Program Requirements Mapping”

LWP-13012, “Addressing Program/Project Specific Quality Assurance Requirements”

LWP-13014, “Determining Quality Levels”

LWP-13620, “Managing Information Technology Assets”

MCP-2691, “Data Qualification”

MCP-2875, “Proper Use and Maintenance of Laboratory Notebooks”

NQA-1-2008/1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications”

PDD-171, “Contractor Assurance System”

PDD-13000, “Quality Assurance Program Description”

PLN-2494, “Advanced Reactor Technologies Program Management Plan”

TEM-10400-4, “Template for Statement of Work”