

Quality Assurance Program Plan

For

AGR Fuel Development and Qualification Program

W. K. Sowder

October 2003



*Idaho National Engineering and Environmental Laboratory
Bechtel BWXT Idaho, LLC*

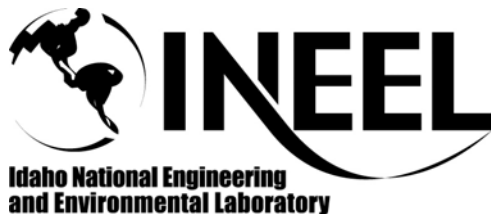
Quality Assurance Program Plan

For

AGR Fuel Development and Qualification Program

Project Number 23841

Prepared for:
U.S. Department of Energy
Idaho Operations Office
Idaho Falls, Idaho



Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier: Revision: Page:	INEEL/EXT-04-01825 0 1 of 24
AGR Fuel Development and Qualification Program Plan		For Additional Info: http://EDMS	Effective Date: 10/30/03

Document Type: PLN		Document INEEL/EXT-04-01825	
Title: Quality Assurance Program Plan for the AGR Fuel Development and Qualification Program		Identifier:	
Author: W.K. Sowder		Project No. (if applicable):	
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AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	2 of 24

CONTENTS

ACRONYMS/ABBREVIATIONS.....	4
BACKGROUND	6
1. PURPOSE AND SCOPE.....	6
1.1 Purpose.....	7
1.2 Scope.....	7
1.3 Codes, Standards, and Regulations.....	7
1.4 Implementation.....	8
1.5 QPP Change Control.....	10
1.6 Organizational Responsibilities.....	10
2. ASSOCIATED PROGRAM DOCUMENTS	13
3. QUALITY PROGRAM ELEMENTS	13
3.1 Organization	14
3.2 Quality Assurance Program	14
3.3 Design Control.....	14
3.4 Procurement Document Control.....	15
3.5 Instructions, Procedures, and Drawings.....	15
3.6 Document Control	15
3.7 Control Of Purchased Items And Services.....	16
3.8 Identification And Control Of Items.....	16
3.9 Control Of Special Processes	16
3.10 Inspection	17
3.11 Test Control.....	17
3.12 Control Of Measuring And Test Equipment.....	17
3.13 Handling, Storage And Shipping.....	17

<i>Idaho National Engineering and Environmental Laboratory</i>			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	3 of 24

3.14	Inspection, Test And Operating Status	18
3.15	Nonconformances	18
3.16	Corrective Action	18
3.17	Quality Assurance Records	18
3.18	Audits	19
3.19	Software	19
3.20	Scientific Investigation	19

FIGURES

1.	Requirements and Implementation Flow Diagram.....	9
2.	Generation IV Organizational Structure	12

TABLES

1.	Selected Source Documents	8
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APPENDICES

Appendix A—Implementing Document Matrix.....	21
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<i>Idaho National Engineering and Environmental Laboratory</i>			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	4 of 24

ACRONYMS/ABBREVIATIONS

BBWI	Bechtel BWXT Idaho, LLC
CFR	Code of Federal Regulations
DOE	Department of Energy
DOE-ID	Department of Energy Idaho Operations Office
ESH&QA	Environment, Safety, Health, and Quality Assurance
GDE	Guide
INEEL	Idaho National Engineering and Environmental Laboratory
M&O	Management and Operating
M&TE	Measuring and Test Equipment
MCP	Management Control Procedure
MOA	Memorandum of Agreement
NQA-1	American Society of Mechanical Engineers Quality Assurance Requirements for Nuclear Facility Applications
NRC	Nuclear Regulatory Commission
NUREG	Nuclear Regulation
PBS	Project Baseline Structure
PDD	Program Description Document
PLN	Plan
POL	Policy
PRD	Program Requirements Document
QA	Quality Assurance
QPP	Quality Assurance Program
Q-List	Quality Level List
QPP	Quality Assurance Program Plan
ROD	Record of Decision

<i>Idaho National Engineering and Environmental Laboratory</i>			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	5 of 24

ACRONYMS/ABBREVIATIONS (Continued)

SSCs	Systems, Structures, and Components
STD	Standard
TBD	To Be Determined
TOC	Table of Contents
WBS	Work Breakdown Structure

<i>Idaho National Engineering and Environmental Laboratory</i>			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	6 of 24

BACKGROUND

Bechtel BWXT Idaho, LLC (BBWI) is required to comply with Contract number DE-AC07-99ID13727 between the Department of Energy Idaho Operations Office (DOE-ID) and BBWI which specifies the use of applicable portions of ASME NQA-1 1997, as the baseline standard for developing and implementing a quality assurance program for INEEL activities. Quality objectives will be achieved through the development and implementation of individual Quality Assurance Plans (QPPs) for NGNP Fuel Development and Qualification Program/Project.

<i>Idaho National Engineering and Environmental Laboratory</i>			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	7 of 24

1.1 Purpose

The purpose of this Quality Assurance Plan (QPP) is to document the Idaho National Engineering and Environmental Laboratory (INEEL) Management and Operating (M&O) Contractor's quality assurance program for AGR Fuel Development and Qualification activities, which is under the control of the INEEL. The QPP is an integral part of the Gen IV Program Execution Plan (PEP) and establishes the set of management controls for those systems, structures and components (SSCs) and related quality affecting activities, necessary to provide adequate confidence that items will perform satisfactorily in service.

This QPP establishes the ASME NQA-1 requirements matrix by identifying: where the NQA requirements are directly addressed; where the NQA requirements are not applicable based on scope of work; and, where exceptions to NQA requirements have been taken, including justification.

1.2 Scope

The scope of this QPP spans items and activities by or for the INEEL M&O contractor. This encompasses not only INEEL facilities supported by various internal organizations in addition to the INEEL DOE Program Office but also support contractors and other DOE Laboratories.

The QPP applies to items and quality-related activities in the performance of, but not limited to, the following functions:

1. Preparation for acceptance by NRC of fuel development activities by various DOE contracted facilities either at the INEEL or INEEL subcontractors.
2. Development and maintenance of data and records required for fuel development activities in item 1 above.

1.3 Codes, Standards, and Regulations

The Department of Energy Rule, 10 CFR 830, is the primary source of requirements for the INEEL Quality Assurance Program. The source documents that contain requirements applicable to the defined scope of work are listed in Table 1. Judicious application of the appropriate requirements will provide effective compliance with the following additional codes, standards, and regulations:

- 10 CFR 50 Appendix A & B
- 10 CFR 830
- ASME NQA-1-1997
- ASME NQA-1 2000
- DOE Order O 414.1A
- DOE-ID Order ID O 414.A.

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	8 of 24

Table 1. Selected Source Documents

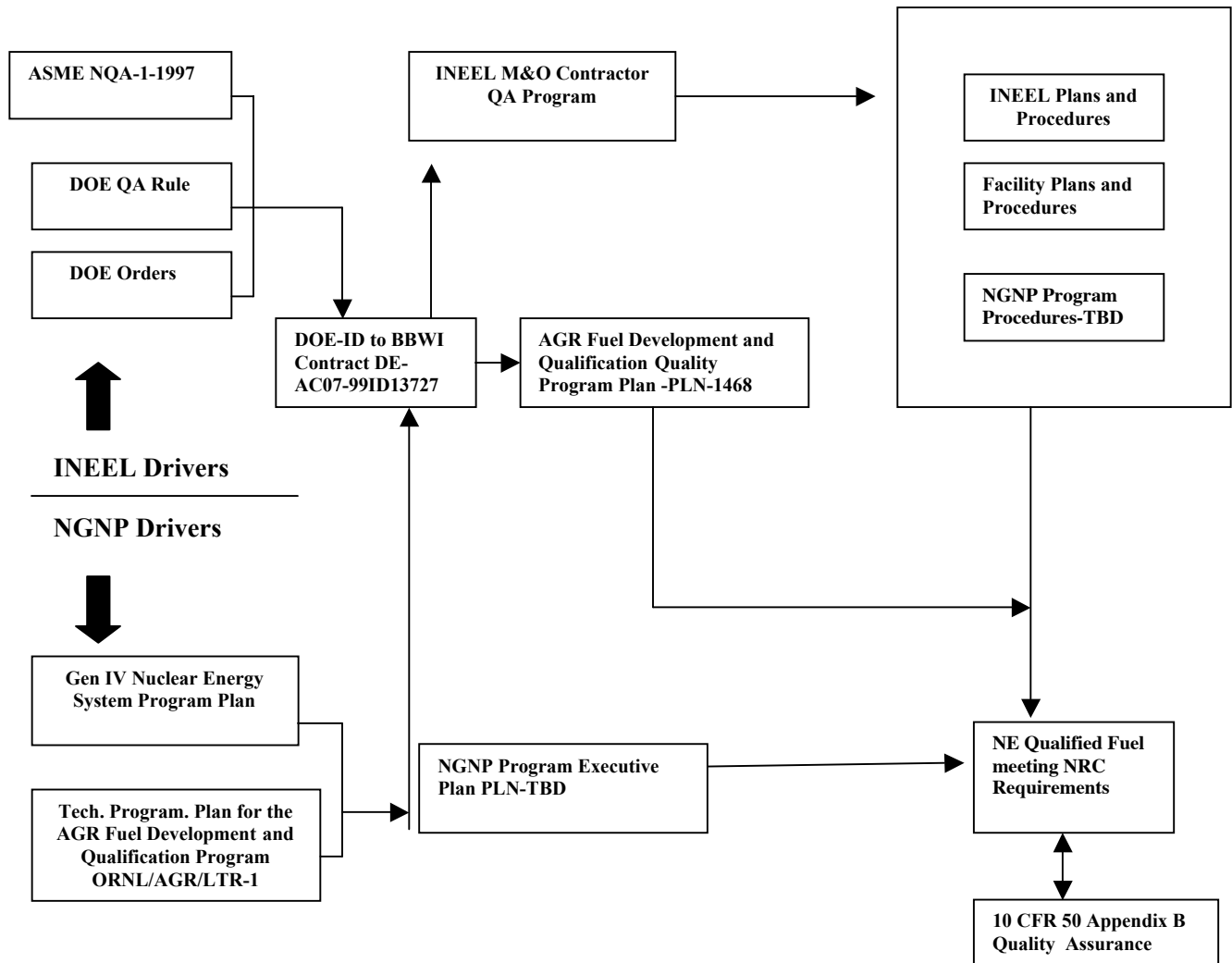
<u>Regulatory Documents</u>	
10 CFR 830	Nuclear Safety Management
<u>Commitment Documents</u>	
NQA-1-1997	Quality Assurance Requirements for Nuclear Facility Applications
<u>Guidance Documents</u>	
ASME NQA-1 1997,1999 addenda	Part 2.7 “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications”
ASME NQA-1 2000	SUBPART 4.2 “Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development
ASME NQA-1 2003	SUBPART 4.4-Application Guide for Managing Electronic Information
ASME NQA-1 2003	Appendix 3.1-Nonmandatory Guidance on Qualification of Existing Data
ASME NQA-1 2003	Appendix 3.2-Nonmandatory Guidance on the Control of Scientific Investigations
10 CFR 50, Appendix B (Current)	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

1.4 Implementation

The relationship of quality assurance drivers and INEEL Program drivers for accomplishment of the Program mission is shown in Figure 1. Appendix A provides a listing of implementing documents based on the functions performed and the applicable requirements. Implementing documents will be incorporated or deleted as the needs arise.

Figure 1

Requirements and Implementation Flow Diagram



Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	10 of 24

1.5 QPP Change Control

This QPP is a controlled document issued by the BBWI Document Management Control System (DMCS). The QPP is assigned a unique identification number obtained from the DMCS. Revisions require, as a minimum, approval of the INEEL AGR Fuel Development and Qualification Project Manager and the INEEL Generation IV Program QA Lead.

1.6 Organizational Responsibilities

Authority for implementing Quality Assurance Program (QPP) elements applicable to AGR Fuel Development and Qualification Program items and activities is delegated by DOE-ID to BBWI through Contract Number DE-AC07-99ID13727. In all cases, quality achievement will be verified by persons or organizations not directly responsible for performing the work. Positions or organizations responsible for establishing and executing the QA Program described in this QPP may delegate work to other organizations. However, the positions or organizations making the delegation retain overall responsibility for the delegated work.

The President and General Manager of BBWI is responsible for overall management of M&O contractor activities including establishing and executing the site-wide quality assurance program. The site-wide Quality Assurance Program delegates through the General Manager of ESH&QA, the responsibility for establishing, maintaining, and monitoring the implementation of the overall INEEL Quality Assurance Program. The Quality Assurance Director has the delegated responsibility for Quality Assurance program administration and has delegated the day-to-day implementation of the AGR Fuel Development and Qualification Program QA Plan to the INEEL Generation IV Program QA Lead.

Specific responsibilities related to the AGR Fuel Development and Qualification Project QA activities are:

NGNP Program Lead

Directs the AGR Fuel Development and Qualification program at the INEEL and assists DOE-HQ and DOE-ID in fulfilling responsibilities and commitments to the Gen IV Program. Directs the strategic planning associated with work required to identify and comply with applicable codes, standards, regulations, and DOE Orders.

AGR Fuel Development and Qualification Project Manager

Responsible for the day-to-day management and direction for AGR Fuel Development and Qualification program. In addition, this position is responsible for:

- Implementation of the quality assurance requirements described in this QPP.
- Planning and integration of schedules, programs and cost profiles;
- Complex-wide AGR Fuel Development and Qualification integration;

Responsible for the management and direction for processes to achieve compliance with administrative and technical codes, standards and regulations applicable to the AGR Fuel Program. This includes:

- Identification and interpretation of contractual and regulatory requirements;
- Resolution of requirement inconsistencies and conflicts;

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	11 of 24

- Preparation and maintenance of INEEL plans and procedures for effective implementation of requirements;
- Interface with INEEL Program and support personnel to ensure consistent implementation of requirements;
- Monitoring and reporting of INEEL Program compliance status; and
- Timely development and implementation of corrective action planning, validation and closure.

INEEL Quality Assurance Director

Responsible for the company-level QA program and for independent assessment of the QA program and its implementation. This position is separate from any other duties not related to QA that would compromise the required independence from cost and schedule and is filled by an individual with appropriate experience in management and QA.

INEEL Generation IV Program QA Lead

The Gen IV QA Lead establishes and maintains the INEEL Gen. IV Quality Program, provides quality assurance guidance to the INEEL Gen. IV and the AGR Fuel Development and Qualification Program, and interprets QA program requirements as they apply to the INEEL Gen. IV Quality Programs. The Gen IV QA Lead is required to approve this QPP and all subsequent revisions. The Gen IV QA Lead has access to senior INEEL Gen IV Program management and the INEEL Quality Assurance Director of which the Gen IV QA Lead has an existing direct reporting line for resolution of quality issues. The Gen IV QA Lead is responsible for the administration and implementation of the INEEL Gen IV QA Program and the AGR Fuel Qualification QA Program.

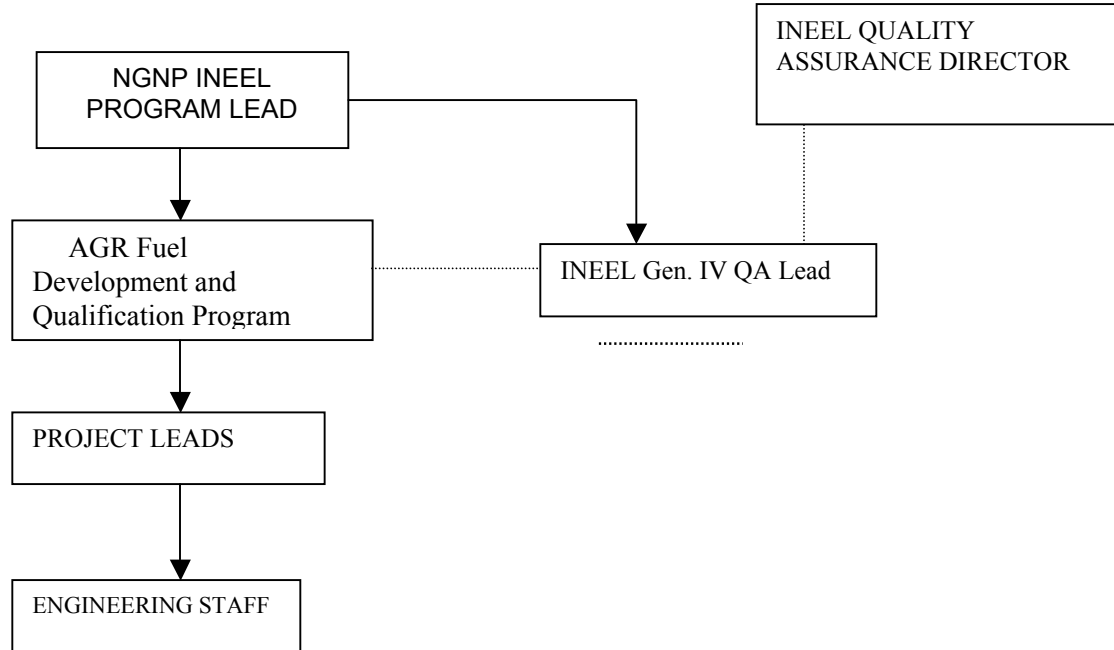
- Annually reviews status, effectiveness and suitability of the INEEL implementation of quality requirements described in this QPP and reports the level of compliance to appropriate senior management.
- Effective implementation of the Gen IV QA Program;

NGNP Program Personnel

Personnel assigned to the INEEL AGR Fuel Development and Qualification Program are empowered and responsible for implementing the QA Program described in this QPP for their scope of work.

The organizational structure for work covered under this QPP is depicted in Figure 2.

Figure 2. Gen IV Organizational Structure



NOTE: DASHED LINES INDICATE LINES OF COMMUNICATION

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	13 of 24

2. ASSOCIATED PROGRAM DOCUMENTS

The following requirements apply to the development and implementation of QPPs, and the associated implementing procedures:

1. QA Plans and implementation plans (e.g., facility implementation plans, test plans, etc.), and implementing procedures provide controls over internal and external interfaces. An interface exists when one participant prescribes an activity or requirement to, or shares an activity or requirement with, another participant. Interfaces are defined, documented and controlled by these plans and procedures.
2. Implementing procedures will provide for top-down implementation of the QPPs and implementing plans as applicable.
3. QPPs will identify or list the implementing procedures and interfaces associated with the performance of their respective processes or responsibilities.

In addition to this QPP, the following specific documents implement INEEL AGR Fuel Development and Qualification Program requirements.

Technical Program Plan for the Advanced Gas Reactor Fuel Development and Qualification Program (ORNL/TM-2002/262)

The Technical Program Plan for the Advanced Gas Reactor Fuel Development and Qualification Program provides the management controls to achieve mission success. The TPP specifically addresses:

- Mission, strategy, goals and objectives;
- Program participants;
- External and internal interfaces;
- Organizational structure;
- Roles and responsibilities;
- Deliverables and end products;
- Program baselines for scope, cost and schedule;
- Program requirements;
- Risk management; and
- Performance reporting.

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	14 of 24

3. QUALITY PROGRAM ELEMENTS

Implement the Technical Program Plan for the Advanced Gas Reactor Fuel Development and Qualification Program in accordance with the DOE quality assurance (QA) requirements specified in 10 CFR 830 "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements" and in DOE Order 414.1A, "Quality Assurance." All activities that have direct input to the irradiation test specimen fabrication and irradiation campaigns will be conducted in accordance with the national consensus standard ASME NQA-1-1997, "Quality Assurance Requirements for Nuclear Facility Applications," published by the American Society of Mechanical Engineers (ASME). Each participating organization shall prepare specific Quality Assurance Plans (QPPs) for its assigned scope of work and may prepare additional project-specific plans for individual work-breakdown-structure (WBS) elements as appropriate.

The following sections describe the quality elements implemented by the INEEL AGR Fuel Development and Qualification Program for the performance of non-licensed quality related activities. These elements are arranged to coincide with the elements contained in ASME NQA-1-1997.

3.1 Organization

The requirements of ASME NQA-1-1997 Requirement 1.0 *ORGANIZATION*, will be implemented and applied to the following areas: •

- Roles, responsibilities and authorities for development and support shall be defined and shall address who is doing the work and those performing independent verification that work objectives have been met.
- Interfaces with scientific and engineering functions shall be defined to ensure that developmental results are usable.

3.2 Quality Assurance Program

The requirements of ASME NQA-1 1997 Requirement 2.0 *QUALITY ASSURANCE PROGRAM*, will be implemented and applied to the following areas: The AGR program participant's Quality Assurance Programs (QPP) will ensure a structured but flexible management approach to development and fabrication activities.

- Experimental plans and statistical experiment designs shall be controlled to ensure tests are performed and measured against known, specific criteria.
- Experimental data and reports shall be peer reviewed as required by technical program plan.
- Indoctrination and Training
- Qualification and Certification Requirements of Personnel
- Records

3.3 Design Control

The requirements of ASME NQA-1 1997 Requirement 3.0 *Design Control* will be implemented and applied to the following areas: Design controls shall be applied to support the input needs of the design

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	15 of 24

process. Considerable importance will be placed on R&D results for acceptability of scientific data to be used as design inputs thus design controls will be applied to experiments or experimental plans or statistical design of experiments as required to support these design input needs.

- Design inputs
- Design Process
- Design Analysis
- Design Verification
- Change Control
- Interface Control
- Software Design Control
- Documentation and Records

3.4 Procurement Document Control

The requirements of ASME NQA-1 1997 Requirement 4.0 *Procurement Document Control* will be implemented and applied to the following areas: Procurement actions required for development equipment shall be controlled as required to generate a solid design basis for potential future procurements related to pilot or production facilities.

- Content of the Procurement Documents
- Procurement Document Review
- Procurement Document Changes

3.5 Instructions, Procedures, and Drawings

The requirements of ASME NQA-1 1997 Requirement 5.0, *Implementing Documents* will be implemented and applied to the following areas: Activities shall be performed in accordance with documented instructions, procedures, or drawings, as directed by the researcher/developer. Experiments, tests, and material processing should be performed to a written instruction outlining the required steps/actions and documented in lab notebooks, travelers, or run sheets to ensure that the process is documented and a permanent record of this information is available to the purchaser.

3.6 Document Control

The requirements of ASME NQA-1 1997 Requirement 6.0, *Document Control* will be implemented and applied to the following areas: As a minimum, laboratory notebooks and intellectual property documentation should be subject to document control. Any laboratory procedures or written instructions, process travelers, run sheets, calibration data and other records generated for control of the technical activities shall be controlled and may become part of the AGR Program QA Record. When laboratory notebooks are used to document the researcher/developer's activities and or data, these

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	16 of 24

notebooks shall be issued under control conditions and periodically copies made to be placed in project files.

- Document Control

Review and Approvals defined

Control issuance defined

- Document Changes

Major changes

Minor changes

3.7 Control Of Purchased Items And Services

The requirements of ASME NQA-1 1997 Requirement 7.0, *Control of Purchased Items and Services*, will be implemented and applied to the following areas: Where the quality of work results is dependant on the pedigree of materials, items or services and assurance of conformance to specified requirements within the objectives of the work and performance boundaries is required the suppliers of these materials, items or services shall be reviewed and accepted for use. The specific name, manufacturer, chemical information, and model or serial number should be documented for all materials and chemicals used in development processes that affect the quality of the product.

- Supplier Evaluation and Selection
- Bid Evaluation
- Control of Supplier-Generated Documents
- Acceptance of Item or Services
- Control of Supplier NonConformances

3.8 Identification And Control Of Items

The requirements of ASME NQA-1 1997 Requirement 8.0, *Identification and Control of Items*, will be implemented and applied to the following areas:

- Identification Methods
- Specific Requirements

3.9 Control Of Special Processes

The requirements of ASME NQA-1 1997 Requirement 9.0, *Control of Special Processes*, will be implemented and applied to the following areas:

- Process control instructions may be defined in laboratory notebooks, instructions or procedures. Initial process controls shall be documented in laboratory notebooks or operating logs for

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	17 of 24

experimental processes and then specific procedures developed once the process has been defined and shall address specific process methodology, quality, safety, and training needs.

- Responsibility of organizations and personnel performing special processes.

3.10 Inspection

The requirements of ASME NQA-1 1997 Requirement 10.0, *Inspection*, will be implemented and applied to the following areas:

- Inspection Requirements
- Inspection Hold Points
- Inspection Planning
- In-Process Inspection
- Final Inspections

3.11 Test Control

The requirements of ASME NQA-1 1997 Requirement 11.0, *Test Control*, will be implemented and applied to the following areas: Test shall be planned, documented and evaluated. Characteristics to be tested and test methods shall be specified and results documented and evaluated. The test controls shall be formalized into specific procedures once the test process has been defined.

- Test Requirements
- Test Procedures (Other Than for Computer Programs)
- Computer Program Test Procedures
- Test Results

3.12 Control Of Measuring And Test Equipment

The requirements of ASME NQA-1 1997 Requirement 12.0, *Control of Measuring and Test Equipment*, will be implemented and applied to the following areas: All measuring and test equipment used directly for setup/management of essential processes and quality determination shall be calibrated and controlled using an approved calibration program.

- Selection of measuring and test equipment
- Calibration and Control

3.13 Handling, Storage And Shipping

The requirements of ASME NQA-1 1997 Requirement 13.0, *Handling, Storage and Shipping*, will be implemented and applied to the following areas:

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	18 of 24

- Special Requirements
- Procedures
- Tools and Equipment
- Operators
- Marking or Labeling

3.14 Inspection, Test And Operating Status

The requirements of ASME NQA-1 1997 Requirement 14.0, *Inspection, Test and Operating Status*, will be implemented.

3.15 Control of Nonconforming Items

The requirements of ASME NQA-1 1997 Requirement 15.0, *Nonconformances*, will be implemented and applied to the following areas: Items that do not conform to specified requirements shall be controlled to prevent inadvertent use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

- Identification
- Segregation
- Disposition

3.16 Corrective Action

The requirements of ASME NQA-1 1997 Requirement 16.0, *Corrective Action*, will be implemented.

3.17 Quality Assurance Records

The requirements of ASME NQA-1 1997 Requirement 17.0, *Quality Assurance Records*, will be implemented and applied to the following areas:

- Technical documentation generated to support the AGR Fuel Development and Qualification Program shall be specified to be controlled as Records. Technical documentation may include laboratory notebooks, calculation sheets, processing procedures, operating logs, travelers, run sheets, chemical or physical analysis results, and equipment calibration records.
- Electronic media may be used to record data and should be subject to appropriate administrative controls for handling and storage of data. Computer-generated records shall also list the specific program, manufacturer, version, and date that was used to collect the information.
- Records shall be stored in a central AGR Project location with administrative controls for handling and storage.

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier: Revision: Page:	INEEL/EXT-04-01825 0 19 of 24

- Authentication of Records
- Classification
- Receipt Control and retention of Records
- Storage
- Disposition

3.18 Audits

The requirements of ASME NQA-1 1997 Requirement 18.0, *Audits*, will be implemented and applied to the following areas: The objectives of the audit process may be achieved as a part of the peer review activities during the initial stages of the AGR Program and as the AGR Program matures program management assessments of the adequacy of methods used to ensure the quality of the AGR technical program.

- Scheduling
- Preparation
- Performance
- Reporting
- Response
- Follow-up Action

3.19 Software

The requirements of ASME NQA-1 1997, 1999 addenda, Part 2.7 “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications”, will be implemented and applied to the following areas:

- Software Engineering Documentation
- Software Configuration Management
- Problem Reporting and Corrective Action
- Software Acquisition
- Software Engineering Methods
- Support Software

3.20 Scientific Investigation

Scientific investigations will be planned and performed to ensure that investigation results can be verified and used as the investigation intends. The following areas are particularly important:

<i>Idaho National Engineering and Environmental Laboratory</i>			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	20 of 24

1. Planning scientific investigations;
2. Performing scientific investigations;
3. Data identification;
4. Data review, adequacy, and usage;
5. Technical report review.

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	21 of 24

APPENDIX A

IMPLEMENTING DOCUMENT MATRIX	
ASME NQA-1 1997	IMPLEMENTING DOCUMENT
1. ORGANIZATION	PRD-5070, Organization
2. QA PROGRAM	PRD-5071, Quality Assurance Program PRD-5072, Personnel Training and Qualification INT-17, Introduction (QA Policy Statement) MCP-33, Personnel Qualification and Certification MCP-589, Quality Assurance Surveillance MCP-2783, Startup and Restart of Nuclear Facilities MCP-2971, Data Package Assembly and Qualification MCP-9082, Trend Identification and Analysis MCP-9106, Management of INEEL Projects
3. DESIGN CONTROL	PRD-5074, Design Control MCP-2374, Analysis and Calculations MCP-2377, Development, Assessment and Maintenance of Drawings MCP-2387, Quality Engineering Review MCP-2811, Design Control MCP-3039, Analysis Software Control MCP-3056, Test Control MCP-3630, Computer System Change Control MCP-9185, Technical and Functional Requirements MCP-9217, Design Verification
4. PROCUREMENT DOCUMENT CONTROL	PRD-5075, Procurement Document Control MCP-590, Flow-down of Standard Procurement Quality Requirements MCP-2387, Quality Engineering Review MCP-3513, Procurement Document Preparation and Control MCP-3514, Bid/Proposal Evaluation MCP-3515, Control of Subcontract Changes
5. INSTRUCTION, PROCEDURES , AND DRAWINGS	PRD-5076, Instruction, Procedures, and Drawings MCP-135, Creating, Modifying, and Canceling Procedures and Other DMCS-Controlled Documents
6. DOCUMENT CONTROL	PRD-5077, Document Control MCP-135, Creating, Modifying, and Canceling Procedures and Other DMCS-Controlled Documents MCP-3570, INTEC Document Development and Review Process

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	22 of 24

IMPLEMENTING DOCUMENT MATRIX	
ASME NQA-1 1997	IMPLEMENTING DOCUMENT
7. CONTROL OF PURCHASED ITEMS AND SERVICES	PRD-5078, Control of Purchased Items and Services MCP-590, Flow-down of Standard Procurement Requirements MCP-591, Supplier Evaluation and Qualification MCP-1185, Acquisition of Materials and Services MCP-2387, Quality Engineering Review MCP-2482, Inspection for Conformance MCP-2489, Supplier Surveillance MCP-3491, Acceptance of Procured Items and Services MCP-3513, Procurement Document Preparation and Control MCP-3514, Bid/Proposal Evaluation MCP-3515, Procurement Document Change Control MCP-3517, Supplier Performance Evaluation MCP-3573, Vendor Data MCP-3772, D&E Evaluation of Commercial Grade Items MCP-3810, Requesting Offsite Affiliate Services MCP-3862, Supplier Qualification Records Control MCP-3863, Qualification Suppliers List Change Control MCP-9108, External Supplier Audits MCP-9151, Develop and Control Inspection Instructions MCP-9155, Product Verification Records Control
8. IDENTIFICATION AND CONTROL OF ITEMS	PRD-5079, Identification and Control of Items MCP-590, Flow-down of Standard Procurement Quality Requirements MCP-2464, Storing Government Property MCP-3491, Acceptance of Procured Materials and Services MCP-9436, Identification, Control and Transfer of Item Traceability
9. CONTROL OF SPECIAL PROCESSES	PRD-5080, Control of Special Processes MCP-37, Control of Special Processes MCP-195, NDE Equipment and Procedure Qualifications MCP-535, Inspection and NDE Personnel Certification
10. INSPECTION	PRD-5081, Inspection MCP-535, Inspection and NDE Personnel Certification MCP-2482, Inspection for Conformance MCP-3056, Test Control
11. TEST CONTROL	PRD-5082, Test Control MCP-3056, Test Control MCP-3630, Computer System Change Control
12. CONTROL OF MEASURING AND TEST EQUIPMENT	PRD-5083, Control of Measuring and Test Equipment MCP-1155, INTEC/TAN/PBF Calibration Program (Supplement to MCP-2391) MCP-2391, Control of Measuring and Test Equipment MCP-2492, S&CL Operations

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	23 of 24

IMPLEMENTING DOCUMENT MATRIX	
ASME NQA-1 1997	IMPLEMENTING DOCUMENT
13. HANDLING STORAGE AND SHIPPING	PRD-5084, Handling, Shipping and Storage MCP-2464, Storing Government Property MCP-6503, Inspection and Testing of Hoisting and Rigging Equipment MCP-9436, Identification, Control and Transfer of Item Traceability
14. INSPECTION TEST AND OPERATING STATUS	PRD-5085, Inspection, Test and Operating Status MCP-538, Control of Nonconforming Items MCP-2482, Inspection for Conformance MCP-2978, Chapter VIII - Control of Equipment and System Status MCP-3056, Test Control MCP-3491, Acceptance of Procured Materials and Services
15. CONTROL OF NONCONFORMING ITEMS	PRD-5086, Control of Nonconforming Items MCP-538, Control of Nonconforming Items MCP-553, Stop Work Authority MCP-9082, Trend Identification and Analysis
16. CORRECTIVE ACTION	PRD-5087, Corrective Action MCP-553, Stop Work Authority MCP-598, Corrective Action System MCP-9082, Trend Identification and Analysis
17. QUALITY ASSURANCE RECORDS	PRD-111, Records and Forms Management PRD-5088, Quality Assurance Records MCP-557, Managing Records
18. AUDITS	PRD-5073, Auditor/Lead Auditor Qualifications/Certifications PRD-5089, Quality Assurance Internal and External Audits MCP-196, Selection, Indoctrination, Training, and Qualification of Personnel Performing Audits MCP-591, Supplier Evaluation and Qualification MCP-598, Corrective Action System MCP-9108, External Supplier Audits MCP-9278, Independent Oversight Assessment Process
SOFTWARE	PRD-5092, Software Quality Assurance MCP-550, Software Management MCP-2374, Analysis and Calculations MCP-3039, Analysis Software Control MCP-3630, Computer System Change Control

Idaho National Engineering and Environmental Laboratory			
AGR FUEL DEVELOPMENT AND QUALIFICATION QUALITY ASSURANCE PROGRAM PLAN		Identifier:	INEEL/EXT-04-01825
		Revision:	0
		Page:	24 of 24

IMPLEMENTING DOCUMENT MATRIX	
ASME NQA-1 1997	IMPLEMENTING DOCUMENT
Scientific Investigation	MCP-135, Creating, Modifying, and Canceling Procedures and Other DMCS-Controlled Documents MCP-2875, Maintaining Lab Notebooks MCP-3042, Scientific Investigation
Control of the Electronic Management of Data	MCP-3041, Electronic Data Management System Control