

April 8, 2010

Mr. Jim A. Kay, Licensing Manager
AREVA Enrichment Services LLC
Solomon Pond Park
400 Donald Lynch Boulevard
Marlborough, MA 01752

SUBJECT: AREVA ENRICHMENT SERVICES QUALITY ASSURANCE PROGRAM
DESCRIPTION FOR THE EAGLE ROCK ENRICHMENT FACILITY (TAC L32738)

Dear Mr. Kay:

We have completed the technical review of the AREVA Enrichment Services LLC (AES) Quality Assurance Program Description (QAPD), Revision 2, for the Eagle Rock Enrichment Facility (EREF), submitted by letter dated October 30, 2009. The QAPD was initially included as an appendix to Chapter 11 of the AES Safety Analysis Report for the EREF, submitted to the U.S. Nuclear Regulatory Commission (NRC) on December 30, 2008, and subsequently revised on April 23, 2009. The QAPD describes the AES quality assurance (QA) program for application of management measures for QA elements for items relied on for safety (IROFS) for the design, construction, operation, including maintenance and modification, and decommissioning of the proposed EREF. The staff review addressed only the QA elements of management measures. Other management measures commitments in the license application will be reviewed separately.

NRC staff notes that, on January 7, 2010, AES submitted a letter to the NRC proposing an approach in which the safe-by-design components listed in Appendices B and C of the Integrated Safety Analysis Summary will be recategorized and designated as IROFS that are safe by their respective attribute (diameter, volume, or thickness) or as IROFS that are safe by criticality analysis. The current QAPD refers to the safe-by-design components as "credited attributes of safe-by-design." Under either the former approach or the proposed approach, the QA Level 1 requirements will apply to the safe-by-design components. In addition, for SSC's that could interact with safe-by-design components, QA Level 2 requirements will apply. Once the proposed approach is formally adopted, AES will update the terminology in the QAPD to reflect the re-categorization and designation of the safe-by-design components as IROFS.

The staff has determined that the AES QAPD, Revision 2, is acceptable for application to the design, construction, operation, including maintenance and modification, and decommissioning of the proposed EREF. The enclosed Staff Evaluation Report discusses the staff review of the QAPD which was based on NUREG-1520, "Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility," dated March 2002. The NRC staff concludes that the AES's QAPD adequately describes the application of other QA elements and has adequately established other QA elements as part of Management Measures as required by 10 CFR Part 70.62(d).

The staff review of the QAPD included the definitions for QA Levels and the application of QA elements to IROFS; credited attributes of safe-by-design components; and structures, systems and components (SSCs) that could interact with IROFS or credited attributes of safe-by-design components, due to a seismic event. The staff will evaluate the adequacy of the QA Level categorization of EREF IROFS, credited attributes of safe-by-design components, and SSCs and the application of management measures for them during the ongoing license application review. The implementation of the QA elements as well as other management measures and license application commitments will be verified during staff reviews, inspections, and assessments of the EREF design and construction activities to ensure that the facility is constructed in accordance with the license application and can be operated safely and securely.

TAC No. L32738 is closed upon issuance of this letter.

Should you have any questions regarding this letter or the enclosed Staff Evaluation Report, please contact Breeda Reilly at (301) 492-3110 or via email to breeda.reilly@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of the Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,

/RA/

Thomas G. Hiltz, Chief
Advanced Fuel Cycle, Enrichment, and
Uranium Conversion Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No.: 70-7015

Enclosure: Staff Evaluation Report

cc: Mr. James Curtiss
Curtiss Law
P.O. Box 153
Brookville, MD 20833

Mr. George Harper
Vice-President of Engineering
AREVA Enrichment Services
400 Donald Lynch Blvd
Marlborough, MA 01752

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Closes TAC L32738

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STAFF EVALUATION REPORT

DOCKET NUMBER: 70-7015

APPLICANT: AREVA ENRICHMENT SERVICES LLC

SUBJECT: Staff Evaluation Report: AREVA Enrichment Services Eagle Rock
Enrichment Facility: Quality Assurance Program Description, Revision 2

1.0 Introduction

In a letter dated October 30, 2009, AREVA Enrichment Services, LLC (AES or Applicant) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) for the expedited review and approval of the Quality Assurance Program Description (QAPD) for the Eagle Rock Enrichment Facility (EREF). Revision 2 to the QAPD was submitted as an enclosure with the request. The Applicant is requesting the expedited approval in order to be able to apply the QAPD language during the procurement of services and material.

2.0 Background

AES initially submitted the QAPD, as an appendix to Chapter 11 of the Safety Analysis Report, by letter dated December 30, 2008 (ADAMS Accession Number ML090300658). Subsequently, the license application was revised, by letter dated April 23, 2009, to reflect the Applicant's plan to expand the EREF (ADAMS Accession Number ML091210558). Revision 1 to the QAPD was submitted as part of the revised license application. In addition, by letter dated June 15, 2009, AES submitted notification of an organization change that affects the quality assurance (QA) program (ADAMS Accession Number ML091740265).

Staff reviewed the license application, including the QAPD, and issued a request for additional information (RAI) to AES on August 26, 2009 (ADAMS Accession Number ML092190320). AES submitted a response to the RAI in a letter dated September 9, 2009 (ADAMS Accession Number ML092530636). The RAI response included proposed changes to the QAPD. In a letter dated October 30, 2009, AES submitted a request for the expedited review and approval of Revision 2 of the QAPD (ADAMS Accession Number ML093080196). Revision 2 of the QAPD incorporates the change to the EREF organization and the proposed changes provided by AES in its response to the RAI.

In preparing this Staff Evaluation Report, the staff review addressed only the QA elements of management measures. Other management measures commitments described in the license application, for configuration management, maintenance, training and qualification, procedures, audits and assessments, incident investigations, and records management will be reviewed separately.

3.0 Regulatory Evaluation

The Applicant's QA program for design and construction of the AES EREF is described in the QAPD. The QAPD identifies the regulatory guides and standards to which the Applicant has committed. The acceptance criteria for the NRC's review of EREF QAPD are contained in Section 11.4.3 of NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," dated March 2002 (NRC, 2002).

Enclosure

4.0 Technical Evaluation

4.1 Introduction and Organization

In Section 1.0 of the QAPD, the Applicant states that the QAPD applies to the design, fabrication, testing, operation, and decommissioning of the EREF to be located in Bonneville County, Idaho. The QAPD will be applied as described in Section 2 of the QAPD.

4.1.1 Organization

The overall responsibility for design, refurbishment, construction, start-up, operations, and decommissioning of the EREF will be maintained by AES. The Applicant provides the site management operating organization and the engineering, procurement, construction and initial start-up organization in two organizational charts in their QAPD.

4.1.2 Design, Construction, Start-up, and Operations Organization

The AES President, as described in the application, has the overall responsibility for the design, construction, startup, and operation of the EREF. In addition, he/she will have the overall responsibility for the QA Program and for determining the status, adequacy, and effectiveness of the QAPD. The AES President's responsibilities for design, construction, procurement and initial start-up are delegated to the Vice President Engineering and Engineering, Procurement and Construction Project Manager. Also, the responsibility for operation, maintenance, and associated support activities is delegated to the Plant Manager.

The Applicant provides the functional responsibilities, line of management and authorities for the following functions:

- QA Manager
- QA Auditors
- QA Inspectors
- QA Technical Support personnel
- Operations Manager
- Production Manager
- Production Supervisor
- Maintenance Manager
- Uranium Management Manager
- Training Manager
- Project Manager
- Engineering Manager
- Procurement Manager
- Construction Manager
- Start-Up Manager
- Environmental, Health, Safety and Licensing Manager
- Nuclear Criticality Safety Manager
- Radiation Protection/Chemistry Manager
- Safety, Security and Emergency Preparedness Manager
- Licensing and Compliance Manager

- Safeguards Manager
- Information Technology (IT) Manager

The Applicant will establish a Safety Review Committee (SRC) to assist with the safe operation of the facility. The SRC will report to the President and will provide technical and administrative review and evaluation of operations that could impact plant worker safety, public safety, or the environment.

4.1.3 QA Responsibilities

In Section 1.3 of the QAPD, the Applicant states that the QA Manager is responsible for independent oversight of EREF activities covered by this QAPD including maintenance of the QAPD and assessing its effective implementation. Among his/her responsibilities, the Applicant lists the following:

- Maintaining the QAPD for the EREF;
- Reviewing and approving implementing procedures;
- Reviewing and approving supplier QA programs;
- Providing oversight of supplier QA program implementation;
- Performing QA technical reviews of procurement documents;
- Maintaining the Approved Suppliers List (ASL);
- Administering the corrective action and nonconformance process;
- Administering the Auditor and Lead Auditor certification process;
- Monitoring the implementation of the QAPD and assessing the effectiveness of the QAPD through audit and surveillance;
- Investigating any aspect of the QAPD to identify problems with execution and to verify that corrective action is taken in a timely manner;
- Stopping unsatisfactory work or controlling further processing when warranted for safety considerations;
- Attending status meetings, and staying abreast of day-to-day activities to ensure adequate oversight;
- Providing quality control activities for purchased and in-house manufactured items.

4.1.4 QA Philosophy

In Section 1.4 of the QAPD, the Applicant describes the principles regarding QA and basis for the philosophy presented in the QAPD. These principles include identification of quality problems, correction of quality problems by those performing the work; independent verifications and controls; and delegation of work and responsibilities. The details on each of the principles are presented within Section 1.4 of the QAPD.

4.2 Quality Assurance Program

In Section 2.0 of the QAPD, the Applicant states that QA elements will be applied to items relied on for safety (IROFS); credited attributes of safe-by-design components; and structures, systems and components (SSCs) that could interact with IROFS or credited attributes of safe-by-design components, due to a seismic event, to assure that they will be available and reliable in performing their safety functions when needed. The Applicant will classify items as QA Level 1, QA Level 2, and QA Level 3 based on their critical attributes.

The Applicant describes QA Level 1 items as those items whose failure or malfunction could directly result in a condition that adversely affects the public, worker and the environment as described in the performance requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61. QA Level 2 items are defined by the Applicant as those items whose failure or malfunction could indirectly result in a condition that adversely affects the public, worker and the environment, as described in the performance requirements in 10 CFR 70.61. The Applicant includes all building and structure IROFS as QA Level 2. In addition, the Applicant includes in QA Level 2 the attributes of items that could interact with IROFS or credited attributes of safe-by-design components, due to seismic events, and result in high or intermediate consequences as described in 10 CFR 70.61. The Applicant describes QA Level 3 as those items that are not QA Level 1 or QA Level 2. QA Level 3 items will be controlled in accordance with standard commercial practices.

The Applicant states that QA Level 1 requirements include: (1) design documentation to verify, review and approval of new designs and modifications to existing designs; (2) results of reviews and monitoring of work performance; (3) documentation to verify review and approval of qualified vendors; (4) procurement documents and material certifications from qualified vendors to verify traceability; (5) qualifications of personnel with responsibilities such as welder, nondestructive examination inspector, lead QA auditor, and quality control inspector; (6) activities such as welding, inspection, auditing, and procurement are done in accordance with approved procedures; (7) list of equipment used and documentation to verify calibration; (8) inspection and test results for qualification and facility operation activities, identification of inspectors, type of observation, acceptance criteria, and action taken in connection with any noted deficiencies; and (9) supporting documentation with regards to the commercial grade dedication program needs to be maintained.

QA Level 2 requirements as described by the Applicant are the same as those for QA Level 1, except that for QA Level 2 there are no requirements for (1) documentation to verify review and approval of vendors and (2) procurement documentation and material certifications from qualified vendors to verify traceability. QA Level 3 will be controlled by the Applicant as standard commercial practice. The QAPD will apply to QA Level 1 and QA Level 2 items, as applicable.

The Applicant states that compliance with the QAPD requirements and associated procedures is mandatory. The Applicant will impose the requirements for QA Level 1 and Level 2 items on contractors and suppliers through the respective procurement documents. The QA Manager has the final authority over the QAPD requirements. Senior managers in each of the organizations implementing the QAPD, or portions thereof, will regularly assess the adequacy and effective implementation of the QA elements.

The Applicant establishes indoctrination and training of personnel performing or managing activities affecting quality such as quality control, nondestructive examination, and audits. Each manager will be responsible for the applicable indoctrination, training, and qualification of their personnel.

4.3 Design Control

Section 3.0 of the QAPD provides the design control function description including design inputs, process, analyses, verification, interfaces, changes, and design documentation and records. The Applicant will identify and document design inputs as design requirements. The design requirement document review and approval process will provide a consistent basis for

making design decisions, accomplishing design verification measures, and evaluating design changes. The Applicant will identify, approve, document and control all changes, including the rationale and whether or not the changes need NRC approval before implementation.

The Applicant commits to plan the design process activities in a timely manner, to the level of detail necessary to permit the design process to be carried out correctly, to permit verification of the design input translation to design documents and to support the operations of interfacing design, procurement, fabrication and operation. The appropriate quality standards and any deviations from these standards will be identified, approved, documented and controlled. The design methods, materials, equipment and processes that are essential to the function of IROFS, credited attributes of safe-by-design components, or applicable SSCs will be selected for suitability by the Applicant.

Sufficient detail will be provided by the Applicant in the design output documents to permit design verification between design output and design input documents. The Applicant commits to develop, validate and manage computer programs that produced design outputs in accordance with American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1, 1994 edition, Basic Requirement 11 and NQA-1, Part II, Subpart 2.7, QA Requirements for Computer Software for Nuclear Power Plant Applications.

The design analyses documents will contain enough information that a person that is qualified in the subject, other than the originator, can understand and verify the analyses results. Computer systems design analyses will include the information regarding the software and version, hardware, inputs and outputs, and the verification/validation results for the program.

The design verification as described by the Applicant will be performed and documented in accordance with written procedures and by individuals knowledgeable about design verification, other than the originators. The design verification will be graded commensurate with the importance to safety, the complexity of the design, the degree of standardization, the state of the art, past performance and similarity with previous proven designs. Design changes will be verified by the Applicant including the impact of the changes on the overall design. The Applicant will perform the following methods for design verification, or a combination of them: design reviews, alternate calculations or performance of qualification tests. The Applicant commits to perform verifications prior to relying on the associated IROFS, credited attributes of safe-by-design components, applicable SSCs, or computer program to perform the item's functions. The Applicant states that verifiers will be knowledgeable in the subject area that they are verifying. Supervisors can be verifiers provided that they were not involved or directly responsible for the design or that they are the only individuals with the required knowledge to perform the verification.

The Applicant states that changes, modifications, or nonconforming items that are dispositioned as "use-as-is" or "repair" will be in accordance with the Control on Nonconforming Items process as described in Section 15 of the QAPD. The Applicant will identify the internal and external design interfaces and coordinate the efforts among the applicable organizations. Design documentation records will be collected and stored in accordance with the Quality Assurance Record processes described in Section 17 of the QAPD.

The corrective action process described in Section 16 of the QAPD will be applied to any design deficiencies discovered during the design process affecting IROFS, credited attributes of safe-by-design components or applicable SSCs. The Applicant will maintain configuration management in accordance with applicable procedures.

4.4 Procurement Document Control

The Applicant will include in the procurement documents the requirements necessary to ensure that IROFS, credited attributes of safe-by-design components and applicable SSCs are of the desired quality. The procurement documents will reference any applicable design bases or requirements to ensure that IROFS, credited attributes of safe-by-design components and applicable SSCs are of the desired quality. Moreover, the procurement documents will include, as applicable, (1) scope of work, (2) basic technical requirements, (3) QA requirements, (4) requirements for control of nonconforming items, (5) requirements on subtier suppliers and (6) documentation requirements.

The Applicant will apply the requirements of 10 CFR Part 21 "Reporting of Defects and Noncompliance" for procurement of QA Level 1 and QA Level 2 items. The Applicant will assume the reporting requirements responsibilities for commercially procured items. The Applicant will review procurement documents and changes thereto to ensure that the appropriate requirements are included.

4.5 Instructions Procedures and Drawings

The Applicant states that any activities affecting the availability and reliability of IROFS, credited attributes of safe-by-design components or applicable SSCs will be prescribed by and performed in accordance with appropriate documented procedures, instructions, and drawings. The Applicant will establish standard guidelines for the format, content, review and approval processes for these documents.

The Applicant describes the documentation hierarchy in this section. The QAPD establishes the Applicant's policy that the QAPD is the first tier of documentation; procedures are the second tier; and instructions providing step-by-step directions are the third tier. The applicable manager will be responsible for the preparation, review and approval of procedures and instructions. The QA organization will be responsible for reviewing the procedures and instructions to ensure compliance, consistency and effective implementation of the provisions provided in the QAPD.

The adherence to policy, procedures and instructions, as stated by the Applicant, is mandatory. The policies, procedures, instructions and drawings will be controlled, including changes, in accordance with Section 6 of the QAPD, Document Control.

4.6 Document Control

The Applicant will control documents and changes thereto, prescribing or specifying quality requirements or activities affecting the availability and reliability of IROFS, credited attributes of safe-by-design components or applicable SSCs to ensure that only correct documents will be used. Authorized personnel will review and approve the documents for release. The document control provides, as described by the Applicant, a process to ensure that documents will be prepared, reviewed for adequacy and correctness, completed by qualified individuals, distributed prior to commencing work, and used in performing the activities. The Applicant will identify or remove deleted or obsolete documents, as appropriate. Controlled documents will be identified and the responsibilities for preparing, reviewing, approving and issuing them will be prescribed in procedures. The Applicant will have procedures to require the establishment of a distributions list that must be kept current and updated. In addition, the Applicant will have a controlled document index, including the appropriate revisions.

The Applicant provides a process for review and approval of changes that are considered more than minor. The process includes a review for adequacy, correctness and completeness prior to issuance. Major changes, whenever appropriate, will be reviewed and approved by the same organization that performed the original. Temporary changes are controlled by applicable procedures and must be approved by two members of the facility staff, at least one of whom must be a Production Manager. The Applicant defines the organizational positions and acceptable criteria for making minor changes in procedures. Minor changes will not require the same level of review and approval requirements as those for major changes.

4.7 Control of Purchased Items and Services

The Applicant will control the procurement of QA Level 1 and QA Level 2 items and services through procedures to assure conformance with specified requirements providing as appropriate: source evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; source inspection; audit; and examination of items or services upon delivery or completion. The Applicant will use a systematic approach through planning and implementation of procurement activities. Procurement Document Control is described by the Applicant in Section 4 of the QAPD.

The QA Manager will be responsible of providing the QA functions to support procurement including: review of supplier quality documentation; evaluation of supplier's capability, supplier audits and evaluations; and for the development and maintenance of an approved supplier's list (ASL). The Engineering Manager will be responsible for determining specific methods of acceptance to be applied to purchased items; reviewing the specific acceptance methods to be applied to services; and approving dispositions and technical evaluations of supplier generated nonconformances for items and services dispositioned as "repair" or "use-as-is". In addition, the Engineering Manager will assist the QA Manager by performing the evaluations of the supplier's technical capabilities. The Procurement Manager will be responsible for the planning, bid evaluation and procurement of the items and services from suppliers on the ASL, when required.

The ASL is the responsibility of the AES QA Manager and is maintained by the QA organization. As described by the Applicant, the ASL contains suppliers with acceptable QA Programs evaluated and accepted by AES. As described by the Applicant, each ASL listing defines the product or service scope of supply that the supplier is approved to provide and defines any approval restrictions and conditions. The AES QA organization evaluates and documents the evaluation of suppliers in the ASL once every 12 months, or in the case of initial approval by audit or survey, the audits are performed at least triennially. Unacceptable evaluations or failure to have any procurement orders in three years will result in removal of those suppliers from the ASL.

The Applicant describes two procurement methods: Procurement of QA Level 1 and QA Level 2 Components and Services and Procurement of QA Level 1 and QA Level 2 by Commercial Grade Dedication. The Applicant states that a combination of the methods can also be utilized.

As described by the Applicant, the supplier selection for procurement of QA Level 1 and QA Level 2 items, components and services will be based on a pre-award evaluation that includes, as applicable, an evaluation of the potential supplier's history of providing identical or similar products that performs satisfactorily in actual use; a supplier QA program meeting the applicable requirements of accepted industry regulation and standards, as appropriate for the

part or service being procured; a valid Certificate of Accreditation issued by the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology for calibration services; if the supplier maintains and implements an NRC-approved QA program; and if the supplier maintains a valid ASME Code certification for the item or service being provided. For QA Level 1, when supplier selection is based on the potential supplier's history, the Applicant specifies that at least one other method of supplier evaluation will be used. The Applicant will establish measures, as necessary, to interface with the supplier and to verify the supplier's performance without relieving the supplier's responsibility for verification of quality achievement. The Applicant requires that the supplier-generated documents, such as engineering documents, involve AES technical approval, and that verification documents and information documents are submitted in accordance with procurement documents and review for acceptability. The Applicant describes methods for acceptance of items including:

- Certificates of Conformance will include minimum requirements such as identification of the purchased material or equipment or purchase order; identification of specific procurement requirements met, not met, or waived; and authentication by a responsible person within the QA function, among others.
- Source verification will be performed at intervals consistent with the quality level and complexity of the item or service. This method provides for inspection, examinations or tests at pre-determined points.
- Receiving inspection will verify conformance of purchased items in accordance with procurement documents. This methods objective is to verify features such as proper configuration, identification; dimensional, physical or other characteristics; freedom of damage from shipping, cleanliness, and review of supplier documentation when procurement documents require the documentation to be furnished.
- Post-Installation testing will be used to establish the test requirements and acceptance criteria in conjunction with the supplier, if necessary.

The Applicant establishes that for QA Level 1 items, the Certificate of Conformance will be used in combination with one or more of the other methods for acceptance of items. For QA Level 2, any one or more of the methods will be used to establish acceptance of items. The documentation of acceptance will be in place prior to placing the item in service. The Applicant will have controls in place when conditional release is necessary.

The acceptance of services as described by the Applicant will be based in the technical verification of data produced; surveillances and/or audits of the activity; and review of objective evidence for conformance to procurement document requirements. It will also include a review of contractor deliverables, determination of acceptability for use, completion of acceptance testing, completion of start-up testing, turnover, etc.

The Applicant establishes that supplier nonconformances will be process in accordance with Section 15 of the QAPD, Control of Nonconforming Items. Supplier nonconformances will be identified by the supplier or the Applicant and are defined as violations to the technical or material requirements of supplied documents, or violations to the requirements of purchaser-approved supplier documents. The Applicant states that supplier-identified nonconformances will include a recommended disposition and technical justification for the condition. The Applicant will not release nonconforming conditions until the appropriate review and acceptance from Engineering is performed and the disposition implementation is verified.

The Applicant will procure commercially available items and services in accordance with approved procedures. The Applicant defines commercial grade items in accordance with 10 CFR 21 definitions. The Applicant criteria and methods for the identification of the critical characteristics that will be utilized for acceptance will be established and will be subject to design control measure in accordance to Section 3 of the QAPD, Design Control. The critical characteristics selected by the Applicant to be verified will provide reasonable assurance that the item or service procured meets the specifications. The Applicant will identify the commercial grade items by the manufacturer's published product descriptions and commercial grade services will be identified by the service provider's description.

The Applicant states that it will perform, at a minimum, receipt inspections for the acceptance of commercial grade items to ensure that the item received is the item ordered and that it will perform its intended safety function. The Applicant will perform acceptance reviews for commercial grade services to ensure that the service performed was the service that was ordered. The Applicant states that methods such as: (1) special tests or inspections or both, (2) commercial grade survey of the supplier, (3) source verification, and (4) acceptable supplier history of performance will be used to provide reasonable assurance that the item or service meets the acceptance criteria. When using the supplier history of performance the Applicant will use at least one more method for acceptance. The Applicant will base its decision on the method or combination of methods to be utilized on the selected critical characteristics, available supplier information, quality history, degree of standardization of the service, and the importance to safety and complexity of the service.

The Applicant commits to assume all reporting responsibilities for all dedicated QA Level 1 and QA Level 2 items.

4.8 Identification and Control of Items

The Applicant will establish controls to assure that only correct and accepted items will be used and installed. The Applicant will identify and control items from initial receipt and fabrication up to and including installation and use. The Applicant will use physical identification to the maximum extent. If physical identification is impractical, the Applicant will employ other means such as physical separation and procedural control, among others. The Applicant will establish measures to ensure that markings are clear, legible, and do not have a detrimental effect on the item function or service life. Any markings will be transferrable to each part of the item when subdividing and are not to be obliterated by surface treatments or coating unless other means of identification are provided.

The Applicant will provide traceability for QA Level 1 items to specific records when required by codes, standards or specifications. Items having a limited operating or shelf life will be identified by the Applicant to preclude the use of those items after the operating or shelf life has expired. The Applicant will provide item identification procedures consistent with the planned duration and conditions of storage.

4.9 Control of Special Processes

The Applicant commits to control special processes affecting the quality of items and services by procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means to ensure that parameters are controlled and special environmental conditions are maintained. The special processes that control or verify quality such as heat treating; non destructive examination; and those used on welding will be performed by qualified or certified

personnel in accordance with specified requirements, codes or standards. The Applicant will pre-qualify any process or equipment that will be used on special processes that are highly dependent on the control of process parameters. The Applicant's procedures for special processes will provide the necessary equipment, process parameters, calibration, and acceptance criteria. The records for special processes personnel, processes and equipment will be maintained in accordance with Section 17 of the QAPD, Quality Assurance Records.

4.10 Inspection

Inspections will be performed by the Applicant to verify conformance of items or activities to specified requirements. The Applicant specifies inspections requirements and provisions for documenting and evaluating inspection results in written procedures. Personnel who perform inspections are qualified in accordance with Section 2 of the QAPD, Quality Assurance Program. The Applicant states that inspectors for acceptance will be personnel other than those who performed or directly supervised the work being inspected.

The Applicant will plan inspection activities, methods, and attributes commensurate with the importance of the item or activity to be inspected; mandatory inspections required by codes, standards, regulatory requirements and commitments; the complexity of the item or activity; and the quality history of the process. The inspection planning, as described by the Applicant will include (1) characteristics to be inspected, (2) responsibilities, (3) methods, (4) measuring and test equipment, (5) acceptance criteria and (6) referenced instructions and design documents. In addition, inspection planning will provide for hold points, as established in the work controlling documents, to ensure that work does not bypass required inspections.

The Applicant states that if sampling is used to verify acceptability of the items, the sampling bases must be clearly identified in documented procedures. If the inspection of completed work is impractical the Applicant commits to indirect verification by process monitoring to ensure quality. The Applicant describes final inspections as those including review of results and resolutions of any nonconformances identified by prior inspections. Re-inspection will be required by the Applicant if there is any modification, repair or replacement of items after the final inspection is performed. Inspection records will include, at a minimum: (1) item inspected; (2) date of inspections; (3) inspector; (4) data recorder, as applicable; (5) type of observation and inspection plan; (6) acceptance criteria; (7) results of acceptability of characteristics inspected; and (8) action taken in connection with nonconformances, as applicable.

4.11 Test Control

The Applicant will perform tests as required to verify conformance with specified requirements, to demonstrate satisfactory performance, or to collect data. The Applicant will specify test requirements in written procedures or, in lieu of written procedures, appropriate sections of related documents (such as American Society for Testing and Materials methods, external manuals, maintenance instructions, or approved drawings or traveler¹ with acceptance criteria) may be used and incorporated by reference to the test or procedure. Tests as described by the Applicant include design verification tests, acceptance tests, pre-operational tests, post-maintenance tests, and operational tests. Tests will be performed by qualified personnel in accordance with Section 2 of the QAPD, Quality Assurance Program. The Applicant will carry out the Computer Program Testing in accordance with ASME NQA-1-1994, Basic

¹ The term "traveler" refers to the paperwork that accompanies a piece of equipment or other item and documents the history of quality assurance activities for that piece of equipment or item.

Requirement 11, Test Control and Supplement 11S-2, Supplementary Requirements for Computer Program Testing.

The Applicant describes the information contained in test procedures as follows:

- Test objectives, responsibilities, characteristics to be tested, hold points, test methods to be employed, and acceptance criteria;
- References and related documents;
- Provisions for ensuring that prerequisites for a given test have been met. These include, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, and provisions for data acquisition;
- Adequate instrumentation is available and suitable environmental conditions are maintained;
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria; and
- Qualifications for test personnel.

Test records will be maintained by the Applicant and will include item tested, test date, tester, data recorder as applicable, type of observation, test procedure, acceptance criteria, results and acceptability of characteristics tested, actions taken in connection with any nonconformances or deviations noted as applicable, person evaluating the results, and identification of the measuring and test equipment (M&TE) used during the test.

4.12 Control of Measuring and Test Equipment

In Section 12 of the QAPD, the Applicant states that M&TE used in activities affecting the availability and/or reliability of IROFS or credited attributes of safe-by-design components will be controlled, calibrated, and adjusted at specified intervals to maintain equipment performance within required limits. The Applicant will use procedures to ensure that devices and standards used for measurement, tests, and calibration are appropriate. The Applicant will establish a list of M&TE that are within the calibration control system including the date for the next calibration and any use limitations. Calibrations will be performed at specified intervals or prior to use. The Applicant will perform the calibrations against equipment having a valid known relationship to a nationally recognized standard and if no recognized standard exists, the Applicant will document the basis for the calibration.

The Applicant will mark the M&TE equipment in such a way that the due date or interval of the next calibration are documented and uniquely identified to provide traceability of its calibration date. If the Applicant finds an M&TE out of calibration, the M&TE will be tagged or segregated, the Applicant will record the as-found data and evaluate the validity of previous inspections and test results and the acceptability of items previously inspected. The Applicant will repair or replace any M&TE that is found out of calibration consistently. If M&TE is lost, the Applicant will evaluate the validity of the results obtained with the equipment since the last calibration.

Records will be maintained by the Applicant.

4.13 Handling, Storage and Shipping

As described in Section 13 of the QAPD, the Applicant will handle, store, and ship materials and equipment in accordance with design and procurement requirements to protect against damage, deterioration, or loss. The Applicant will specify and provide any special handling coverings, equipment, and protective environments for the protection of particular items from damage or deterioration.

Any special handling tools and equipment will be provided, controlled and maintained where necessary to ensure that items can be handled safely and without damage. Special controls as described by the Applicant will include periodic inspection and testing to verify that special handling tools and equipment have been properly maintained. The operators of special equipment will be experienced or trained in the use of the equipment.

The Applicant will pay special attention to marking and labeling items during packaging, shipment, and storage. Moreover, the Applicant will provide any additional marking or labeling as necessary to ensure that items can be properly maintained and preserved. The Applicant establishes and uses instructions, when appropriate for special handling, preservation, storage, cleaning, packaging, or shipping to maintain acceptable quality.

4.14 Inspection, Test and Operating Status

The Applicant will establish procedures to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item. When necessary, the Applicant will require status indication to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. The status indicators will include the operating status of systems and components to prevent inadvertent operation. The Applicant will specify in procedures the authority for the application and removal of tags, markings, labels, and stamps.

4.15 Control of Nonconforming Items

As described in Section 15 of the QAPD, the Applicant will control items and related activities that do not conform to specified requirements to prevent inadvertent installation or use. Nonconforming items will be identified by markings, tagging, and other appropriate methods that do not adversely affect the end use of the items. When practical, the Applicant will segregate the nonconforming items by placing them in a clearly identified and designated area until properly disposition. When segregation is impractical or impossible due to physical conditions, the Applicant will employ other measures to preclude inadvertent use of the item.

The Applicant will review nonconforming items and will disposition as "reject," "rework," "repair," or "use-as-is." The Applicant controls any further processing such as delivery, installation, or use of the nonconforming item until the appropriate evaluation of the item and approved disposition has been determined by engineering personnel, and any affected organizations are notified. The disposition of nonconforming items as described by the Applicant is identified and documented as required to carry out the disposition. The Applicant requires that technical justification for the acceptability of nonconforming items dispositioned as "repair" or "use-as-is" is documented and subject to design control measures as described in Section 3.0 of the QAPD, Design Control.

The Applicant defines the responsibilities and authorities for the evaluation and disposition of nonconforming items. As stated by the Applicant, the personnel performing evaluations to determine the dispositions will have to demonstrate competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

Any repaired or reworked items will be re-examined by the Applicant in accordance with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria. The nonconformance documentation will identify the nonconforming item; describe the nonconformance; include the disposition and any re-inspection requirements; and includes the signature(s) approving the disposition.

4.16 Corrective Action

In Section 16 of the QAOD, the Applicant commits to promptly identify and correct conditions adverse to quality. The Applicant classifies the types of conditions adverse to quality into two categories, depending on their significance and the corrective actions to be taken: conditions adverse to quality (CAQ) and significant conditions adverse to quality (SCAQ). The Applicant describes CAQ as an all inclusive term including activities and services referring to failures, malfunctions, deficiencies, deviations, defective items and nonconformances. The Applicant will document and report any CAQ to the appropriate management levels.

The SCAQ are described by the Applicant as those including:

- A deficiency that would seriously impact an item, activity or service from meeting or performing its intended function or output of assuring public health and safety;
- A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;
- A deficiency in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, redesign or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;
- A deviation from performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;
- A significant error in a computer program used to support activities affecting quality after it has been released for use;
- A deficiency, repetitive in nature, related to an activity or item subject to the AES QA Program; and
- A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the AES QA Program controls.

If the Applicant identifies a significant condition adverse to quality, the cause of the condition will be determined, and corrective action will be taken to preclude recurrence. In addition, SCAQ will be evaluated for stop work conditions to determine if work stoppage is warranted. If appropriate, stop work orders will be issued in accordance with applicable procedures. The Applicant will lift and close, in total or in part, the stop work order upon resolution of the related significant condition adverse to quality. The Applicant will document significant conditions, their causes, and corrective actions and report them to appropriate levels of management.

Moreover, the Applicant will provide follow-up actions to verify implementation of corrective actions through procedures implementing the Corrective Action Program.

The Applicant states that procedures establishing the Corrective Action Program assign organizational responsibilities for trending significant conditions adverse to quality and the criteria for determining trends. The Applicant will evaluate the reports of significant conditions adverse to quality to identify adverse quality trends and help identify root causes. The trend evaluation will be performed by the Applicant in a manner and at a frequency that provides for prompt identification of adverse quality trends. Any adverse trends identified by the Applicant will be handled in accordance with the Corrective Action Program and reported to the appropriate management.

The Applicant states that if a supplier or subtier supplier discovers a defect or noncompliance which the supplier evaluates as a substantial safety hazard, then the supplier shall be required to report the item under 10 CFR 21, Reporting of Defects and Noncompliance, and notify the Applicant in writing. If the supplier or subtier supplier is unable to determine if the defect/non compliance is a substantial safety hazard then the supplier or subtier supplier is required to report the item to the Applicant for determination of reportability in accordance with 10 CFR 21.

4.17 Quality Assurance Records

As described in Section 17 of the QAPD, the Applicant's QA record system will ensure that records are specified, prepared, and maintained in a manner to provide retrievability and to provide protection against damage, deterioration, and loss. The Applicant states that design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records to be generated, supplied, or maintained. Records will be considered valid by the Applicant when the records are complete, identified, authenticated and legible. The Applicant will index the records in such a way to provide sufficient information to permit identification between the record and the item or activity to which it applies and to ensure retrievability. The Applicant classifies records as lifetime or nonpermanent records for retention purposes.

The Applicant defines lifetime records in accordance with ASME NQA-1-1994, Supplement 17S-1, Section 2.7.1, Supplementary Requirements for Quality Assurance Records. The Applicant will enter lifetime records into record storage after receipt or validation. Lifetime records will be specified in applicable documents and retained for the life of the item to which they apply or as required by regulatory agencies. The Applicant provides temporary storage for lifetime records in approved containers until the records are entered into lifetime storage. The storage of lifetime records will be in a central location unless otherwise specified in applicable procedures. In addition, for lifetime records storage, the Applicant will assign custodianship responsibilities including receipt and status control; storage; preservation; and safekeeping using hard copy, microfilm, or electronic document management system. As specified by the Applicant, records may be originals, copies, or electronic format.

Nonpermanent records, as defined by the Applicant are those required to show evidence that an activity was performed in accordance with applicable requirements. The Applicant will not retain nonpermanent records for the life of a particular item. Nonpermanent records will be retained by the responsible organization until they are no longer useful. The responsible organization establishes in writing the retention periods for those nonpermanent records.

Any corrections will include the date and the identification of the individual authorized to issue the correction and will be reviewed and approved by the originating organization. The Applicant will perform replacement, restoration, or substitution of lost or damaged records in accordance with implementing procedures.

The storage facilities as described by the Applicant will protect against the risk of loss or deterioration of lifetime records. The hard copy or microfilm storage facilities meet the requirements of ASME NQA-1-1994, Supplement 17S-1, Section 4.4, Supplementary Requirements for Quality Assurance Records. The records storage facility access will be controlled. For electronic storage, the Applicant will generate backups or duplicate files. The Applicant will replace lost or damaged records with the concurrence of the QA organization, unless deemed impractical by the Applicant.

The Applicant will have access to records maintained by suppliers at their facilities either directly or through the procuring organization. The records maintained by suppliers will not be disposed until the contractual requirements are satisfied.

The Applicant states that for computer codes and computerized data used for activities relied on for safety, procedures are provided for maintaining readability and usability of older codes and data as computing technology changes. The procedures as described by the Applicant will include transfer of older forms of information and codes associated with older computing equipment to contemporary computing media and equipment.

4.18 Audits

As described in Section 18 of the QAPD, the Applicant will plan and schedule audits to verify compliance with the aspects of the QA program and to determine its effectiveness. The audits will be performed by the QA organization and will also verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application.

4.18.1 Internal Audits

The Applicant will perform internal audits of organizational units performing quality program activities at a frequency commensurate with the status and importance of the activity. The Applicant will supplement regular scheduled audits with additional audits/assessments of specific subjects. The system of audits and assessments will ensure comprehensive program oversight at least once every three years for flexibility and to maximize effectiveness of QA resources.

Audits as specified by the Applicant will be conducted in accordance with documented procedures. Each audit will have a plan prepared that identifies the audit scope, requirements, audit personnel, activities to be audited, applicable documents, organizations to be audited, schedule and written procedures or checklists. Internal audits will be performed in accordance with checklists or equivalent. During the audits, the objective evidence will be examined to determine if the QAPD elements are being implemented effectively. If the Applicant finds any conditions requiring prompt corrective action, those will be documented as audit findings and will be reported immediately to the management of the audited organization. The results of the audit will also be discussed with the appropriate management and they will investigate adverse audit findings, scheduled corrective actions, including measures to prevent recurrence, and will

notify the QA organization in writing of the action taken. The QA organization will evaluate the audit responses and verify that the corrective actions are implemented, effective, documented and determine any further corrective actions as appropriate.

The internal audit report as specified by the Applicant will include, as appropriate:

- Description of the audit scope;
- Identification of the auditors;
- Identification of persons contacted during audit activities;
- Summary of audit results, including a statement on the effectiveness of the QA program elements audited; and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

The audit team as described by the Applicant will contain one or more auditors, one being designated lead auditor who prepares, organizes, and directs the audit; coordinates the preparation and issuance of the audit report; and evaluates responses. The auditors will (1) have experience commensurate with the scope, complexity, or special nature of the audit, (2) have no direct responsibility for the function or area being audited, and (3) have sufficient authority and organizational freedom to make the audit process meaningful and effective. The lead auditors will be qualified in accordance with Section 2 of the QAPD, Quality Assurance Program. The Applicant describes audit records as those such as audit plans, audit reports, written replies, and the record of completion of corrective action.

4.18.2 External Audits

The Applicant will perform external audits to verify the acceptability of suppliers. External audits are performed in accordance with checklists or equivalent. During the audits, the objective evidence will be examined to determine if the QAPD elements are being implemented effectively. If the Applicant finds any conditions requiring prompt corrective action, those will be documented as audit findings and will be reported immediately to the management of the audited organization. The QA organization will evaluate follow-up actions and verify that the corrective actions are implemented, effective, documented and determine any further corrective actions as appropriate.

The Applicant will perform follow-up audits of suppliers on the approved supplier list commensurate with the status and importance of the activity, based on annual evaluations of the supplier's performance. Third-party audits may be used by the Applicant to satisfy the supplier audit requirement, after review and acceptance of the audit records by QA.

The audit reports for external audits will include the same information as the audit reports for internal audits.

4.19 Provisions for Changes

In Section 19 of the QAPD, the Applicant states that QAPD changes may be initiated by events such as reorganizations or revised activities, lessons learned, changes to applicable regulations, process changes, or other reasons. QAPD changes will be governed by approved procedures.

Prior to NRC issuance of the license, the Applicant will incorporate any changes to the QA Program in the QAPD and it will be submitted to the NRC with the next revision of the license application, or no later than annually, whichever occurs first.

After the license is issued, the Applicant will submit annually any changes to the QAPD that do not involve a reduction of commitments. The Applicant will submit to the NRC any changes that reduce commitments in the QAPD for review and approval prior to implementation.

5.0 Conclusions

The NRC staff has reviewed the quality assurance program as documented in the QAPD, Revision 2 and concluded that the Applicant has adequately described the application of other QA elements. Based on that description, the staff concludes that the Applicant has established and documented a commitment to an organization responsible for developing, implementing, and assessing other QA elements in the design, construction, operation, maintenance, and modification phases of the life of the facility. The organizations and persons performing QA element functions have the required qualifications, independence and authority to effectively carry out their QA element functions without undue influence from those directly responsible for process operations.

Based on the above, the staff concludes that the Applicant's QAPD adequately describes the application of other QA elements and has adequately established other QA elements as part of Management Measures as required by 10 CFR Part 70.62(d).

6.0 References

(NRC, 2002) U.S. Nuclear Regulatory Commission (NRC). NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," 2002.