April 9, 2004

Mr. Rod Krich, Vice President
Licensing, Safety and Nuclear Engineering
Louisiana Energy Services
1133 Connecticut Avenue, NW Suite 200
Washington, DC 20036

SUBJECT: LOUISIANA ENERGY SERVICES QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE NATIONAL ENRICHMENT FACILITY

Dear Mr. Krich:

We have completed the technical review of the Louisiana Energy Services (LES) Quality Assurance Program Description (QAPD), Revision 0, for the National Enrichment Facility (NEF), submitted by letter dated November 21, 2003. The QAPD was included as Appendix A of the LES license application (LA) for the NEF, which was sent to the U.S. Nuclear Regulatory Commission (NRC) on December 12, 2003. The QAPD describes the LES 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 NEF. The staff review addressed only the QA elements of management measures. Other management measures commitments in the LA will be reviewed separately.

The staff has determined that the LES QAPD, Revision 0, is acceptable for application to the design, construction, operation, including maintenance and modification, and decommissioning of the proposed NEF. The enclosed Safety Evaluation Report (SER) 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 LES has, in its QAPD, adequately described its management measures for QA elements, and that the QAPD commitments meet the requirements of 10 CFR Part 70 and provide reasonable assurance of protection of public and worker health and safety and the environment.

The staff review of the QAPD included the definitions for QA Levels, the methods, process, and criteria for assigning QA Levels to structures, systems, and components (SSCs), and identification of QA controls for SSCs and IROFS. The staff will evaluate the adequacy of the QA Level categorization of NEF IROFS 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 LA commitments will be verified during staff reviews, inspections, and assessments of the NEF design and construction activities to ensure that the facility is constructed in accordance with the LA and can be operated safely and securely.

Should you have any questions regarding this letter or the enclosed SER, please contact Timothy Johnson at (301) 415-7299, or Wilkins Smith at (301) 415-5788, of my staff.

Sincerely,

/RA/

Joseph G. Giitter ,Chief
Special Projects Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-3103

Enclosure: Safety Evaluation Report

cc: William Szymanski/DOE
James Curtiss/W&S
Peter Miner/USEC
James Ferland/LES
Dennis Holmberg/Lea County
James Brown/Eunice
Michael Marriotte/NIRS
Terry Sweeton/CSC
Carol O'Clair/EMA
Lee Chaney/CNIC
Claydean Claiborne/Jal
Troy Harris/Lovington
Betty Richman/Tatum
Glen Hackler/Andrews
William Floyd/New Mexico
Richard Ratliff/Texas
Jerry Clift/Hartsville
Monty Newman/Hobbs
Derrith Watchman-Moore/New Mexico

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SAFETY EVALUATION REPORT

DOCKET NUMBER: 70-3103

APPLICANT: Louisiana Energy Services, L. P.

SUBJECT: Safety Evaluation Report: Louisiana Energy Services Quality Assurance Program Description For The National Enrichment Facility

1.0 Background

Louisiana Energy Services (LES) initially submitted the Quality Assurance Program Description (QAPD) by letter dated November 26, 2002, as the required description of its management measures for the application of QA elements for items relied on for safety (IROFS) for the design, construction, operation, including maintenance and modification, and decommissioning in support of the planned License Application (LA) for a 10 CFR 70 license for the National Enrichment Facility (NEF). LES requested that the U.S. Nuclear Regulatory Commission (NRC) conduct an early review of the QAPD. NRC conducted a preliminary review and issued a request for additional information (RAI) on March 25, 2003. LES responded to the RAI and submitted a revised QAPD, identified as Revision 0, by letter dated November 21, 2003. The QAPD, Revision 0, was also submitted with the NEF LA as Appendix A on December 15, 2003. The staff review addressed only the QA elements of management measures. Other LA management measures commitments for configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, and records management will be reviewed separately.

2.0 Regulatory Requirements

The requirements for fuel cycle facility management measures are specified in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

1. 10 CFR 70.4 states that management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other QA elements.

2. 10 CFR 70.62(d) requires an applicant to establish management measures, for application to engineered and administrative controls and control systems that are identified as IROFS, pursuant to 10 CFR 70.61(e), so they are available and reliable to perform their functions when needed.

3. 10 CFR 70.64 requires that baseline design criteria (BDC) and defense-in-depth practices be incorporated into the design of new facilities. Section 10 CFR 70.64(a)(1) states, in pertinent part, that for quality standards and records, the facility design must be developed and implemented in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

3.0 Regulatory Acceptance Criteria

The staff reviewed the LES QAPD in accordance with the regulatory requirements identified in Section 2.0 above, and utilized the acceptance criteria in Section 11.4.3.8 of NUREG-1520, "Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility," dated March 2002. (Ref. 6.2).

4.0 Staff Review and Analysis

The purpose of this review was to verify whether the applicant's QAPD provided a complete and sufficient description of the applicant's application of QA elements. The description must be sufficient to determine that the QA elements to be applied to IROFS are based on accepted QA principles and that they provide reasonable assurance that the IROFS will be available and able to perform their functions, when needed, consistent with the performance requirements of 10 CFR 70.61.

The staff reviewed the initial QAPD submitted in 2002 and the revised QAPD, Revision 0, which was submitted by letter dated November 21, 2003, and with the LA dated December 12, 2003. The staff also reviewed the LES commitments and clarifications in response to the staff RAI which were submitted with Revision 0. LES, in the LA and QAPD, committed to implement a QA program that meets the QA criteria of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," referred to hereafter as Appendix B. To meet these criteria, LES committed to compliance with the provisions of American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," as revised by the ASME NQA-1a-1995 Addenda, hereafter referred to as NQA-1.

The staff review compared and evaluated the QAPD against the guidance of the SRP. The staff also reviewed the QAPD to verify that the LES commitments to Appendix B criteria and NQA-1 requirements were described and that they adequately addressed the 10 CFR Part 70 requirements. The staff review verified that the QAPD is consistent with the requirements of NQA-1. The staff notes that the applicant's commitments to Appendix B and NQA-1 are not regulatory requirements for a 10 CFR Part 70 license. Based on its review of the QAPD, and the LES commitment to the provisions of NQA-1, the staff concluded that the applicant has provided sufficient information to demonstrate that adequate QA elements have been provided for the NEF.

The following discussion of the QA elements review is consistent with the QAPD sections, which are organized, in general, with the Appendix B and NQA-1 QA criteria.

i) Introduction

The applicant states that it maintains full responsibility for ensuring that the NEF is designed, constructed, operated, and decommissioned in conformance with regulatory and design requirements, applicable industry standards, and good engineering practices in a manner to protect the health and safety of the employees and the public. The LES QA Program,

described in the QAPD, is committed to conform to Appendix B and the consensus QA programmatic standard NQA-1. The staff review verified that the QAPD addressed the criteria of Appendix B and is consistent with the requirements of NQA-1. The staff reviewed the applicant's QAPD for adequate application of QA elements to IROFS in accordance with the guidance and criteria in NUREG-1520. All of the QAPD sections are to apply to IROFS, and a formal graded approach to application of graded QA controls on IROFS is not to be applied. The staff notes that Criteria II of Appendix B states that, "The QA program shall provide control over activities affecting the quality of the identified structures, systems, and components (SSCs), to an extent consistent with their importance to safety." The QAPD states that all of its requirements are to be applied exclusively to QA Level 1 items which are defined as IROFS and any items which are determined to affect the function of the IROFS. The requirements for QA Level 1 SSCs, the QA Level 2 SSCs "owner-defined" QA controls, and QA Level 3 SSCs for application of standard commercial practices are also addressed in the QAPD Introduction. The staff review of the QA Level requirements is discussed in Section iii), "QA Program", below.

ii) Organization

Section 1 of the QAPD describes: (a) the organizational structure, (b) functional responsibilities, and (c) interfaces of responsibility and authority for all organizations performing QAPD activities. These are provided as organization charts and functional and organizational responsibility descriptions for the design, construction, and operations phases. As the owner and operator of the NEF, LES maintains overall responsibility for design, construction, operation, and decommissioning in accordance with the QA Program. The LES President has the responsibility for establishing the basic policies of the QA Program, as described in the QAPD. The LES QA Director has overall responsibility for development, management, and implementation of the LES QA Program during all phases of the NEF, for QA oversight of all activities and conduct of audits, surveillances, inspections, and assessments. The QA Director is also responsible for ensuring that contractor QA programs meet all applicable requirements of the LES QA program. The LES QA Director reports to the LES President and has independent oversight responsibility for implementation of the QAPD. Positions and organizations responsible for ensuring that appropriate QA has been established and for verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities. Organizational responsibilities for engineering, design, procurement, maintenance, operations, audits, and assessments are identified. Delegation of work between LES and contractors is controlled by plans, contracts, and implementing procedures. Methods for resolution of disputes and responsibilities of each employee to identify concerns using the corrective action process are addressed.

iii) QA Program

The applicant described its application of QA elements for the NEF in Section 2, "QA Program," of the QAPD. The applicant has committed to implement a QA program that meets the QA criteria of Appendix B through compliance with the provisions of NQA-1. The application of QA elements is documented, planned, implemented, and maintained to provide reasonable assurance that, together with the other management measures, IROFS will be available and

reliable when needed. The QA program is applied to the facility, structures, processes, systems, equipment, components, computer programs, and activities of personnel, in accordance with their QA Level designation. Identification and application of QA controls is in accordance with three QA Levels which are categorized in the QAPD Section 2 as follows:

QA Level 1 Requirements

QA Level 1 controls will be applied to all SSCs and activities identified by the integrated safety analysis (ISA) process as IROFS and any items, SSCs, or administrative controls which are determined to affect the function of the IROFS. All applicable sections and requirements of the QAPD are applied to items requiring the QA Level 1 controls.

QA Level 2 Requirements

QA Level 2 designation for selected SSCs will require application of owner-defined QA controls using NQA-1 as guidance. Selected QA controls will be applied to items requiring Level 2 controls in accordance with Section 20 of the QAPD. QA Level 2 controls are applied to items that provide support of normal operations of the facility, but are not IROFS and do not affect the functions of IROFS.

QA Level 3 Requirements

Any item, SSC, or activity not designated as QA Level 1 or 2 will have QA Level 3 controls applied. QA Level 3 controls are defined as standard commercial practice, and a documented QA program is not required for these controls or activities.

Implementation of the QA Level designations and controls is a part of the ISA process, which is controlled under procedures in accordance with the QAPD as a QA Level 1 activity. The staff, during this review, has not made any evaluation or conclusion as to the adequacy of the QA Level categorization or the application of management measures or QA controls for any IROFS or SSC. The adequacy of these will be determined as part of the ongoing LA technical review. The implementation of the QA elements, as well as other management measures and LA commitments, will also be verified during staff reviews, inspections, and assessments of NEF design and construction activities to ensure that the facility is constructed in accordance with the LA and can be operated safely and securely.

Requirements that invoke QA controls and requirements applicable to contractors in procurement documents are identified in Sections 2, 4, and 7 of the QAPD. Appropriate requirements are addressed for QA training, management assessments, and reporting of QA program status, including adverse trends and lessons.

The QA program commitments include the personnel training, testing, experience or qualification requirements of American Society for Nondestructive Testing Recommended Practice No. SNT-TC-1A, “Personnel Qualification and Certification in Nondestructive Testing,” December 1988 Edition, and Supplements 2S-1, “Supplementary Requirements for the Qualification of Inspection and Test Personnel,” 2S-2, “Supplementary Requirements for the

Qualification of Nondestructive Examination Personnel," and 2S-3, "Supplemental Requirements for the Qualification of QA Program Audit Personnel," of Part I of NQA-1.

iv) Design Control

Section 3 of the QAPD describes the applicant's design control process and procedures that include controls for design inputs, process, analyses, verification, interfaces, changes, and design documentation and records. Procedures provide for performing the design in a planned, controlled, and documented manner. Design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, are identified and documented as design requirements. Design methods, materials, parts, equipment, and processes that are essential to the function of the IROFS are selected and reviewed for suitability of application. Final design output documents, including changes, can be related to the design input to permit verification. Software that is used directly in the design, analysis, and operation of IROFS will be developed, validated, and managed in accordance with NQA-1, Part I, Supplement 11S-2, "Supplementary Requirements for Computer Program Testing," and Part II, Subpart 2.7, "QA Requirements of Computer Software for Nuclear Facility Applications." The applicant states that design interfaces are identified and controlled and design efforts are coordinated among interfacing design organizations. Design information transmitted across interfaces is reviewed, approved, documented, and procedurally controlled. Final design documentation and records that provide evidence that the design and design verification processes were performed in accordance with the QAPD are collected, stored, and maintained.

v) Instructions, Procedures, and Drawings

In Section 5 of the QAPD, the applicant states that activities affecting quality are prescribed by and conducted in accordance with approved instructions, procedures, and drawings of a type appropriate for the circumstances. These documents include or reference appropriate acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The QAPD identifies the major types of documents and their content, and establishes the programmatic requirements for these documents. The applicant's QA organization reviews and/or approves procedures that implement the QA program requirements for compliance and consistency with the QAPD and conducts oversight reviews of other procedures to assure adequacy and that the QAPD provisions are effectively incorporated.

vi) Document Control

The applicant's commitments and provisions for the application of the document control QA element are addressed in QAPD Section 6, "Document Control." The preparation, issuance, and modification of documents that specify quality requirements or prescribe activities affecting quality are controlled to provide assurance that the appropriate documents are in use. Documents are reviewed for adequacy and approved for implementation by authorized personnel. Procedures and instructions assure that documents are prepared; reviewed for adequacy, correctness, and completeness by a qualified individual; approved for release by authorized personnel; and distributed to the location where the activity is performed. The applicant's description addresses the types of documents, the requirements for a document control system for preparation, review and control of documents, and the maintenance of a document control database and master list to track and control approved documents including

verification of correct revisions. Changes to documents are reviewed and approved in the same manner as the original unless other organizations are specifically designated.

vii) Procurement Control

The applicant's commitments and provisions for control of the procurement process, procurement documents, and procured material, components, and services are described in QAPD Section 4, "Procurement Document Control," and Section 7, "Control of Purchased Material, Equipment, and Services." The applicant states that applicable design bases and other requirements necessary to provide reasonable assurance of quality are included or referenced in documents for procurement of items or services relied on for safety. Requirements are identified for content, review, approval, and change of procurement documents. Responsibilities for source inspection, surveillances, evaluation of objective evidence of quality, approved supplier list maintenance, and examination of received items and services are specified. Commitments are addressed for procurement planning, source evaluation and selection, proposal and supplier performance evaluations, and acceptance of items and services. Suppliers are required to have acceptable QA programs or systems consistent with the applicable QAPD sections and the quality level of the item or service to be procured. Nonconformances on purchased items and services are controlled, reviewed, and dispositioned by LES to provide reasonable assurance of conformance with specified requirements.

viii) Identification and Control of Items

In QAPD Section 8, "Identification and Control [of] Materials, Parts, and Components," the applicant states that QA procedure controls will be required to ensure that only correct and accepted items are used or installed. Identification requirements for materials, parts, and components are to be stated in design specifications, drawings, and procurement documents. Specific requirements are identified for item markings, traceability, degradation due to marking, nonconforming or rejected items, and receipt inspection.

ix) Control of Special Processes

In QAPD Section 9, "Control of Special Processes," the applicant describes its commitments for control of processes affecting the quality of items and services. The applicant states that written procedures will ensure that process parameters are controlled to maintain the acceptability of special processes, such as those used in welding, heat treating, and nondestructive examination, and to assure that they are performed by qualified personnel using qualified procedures in accordance with specified requirements. Certification of individuals, qualification of processes, and control of process parameters, equipment, calibration or acceptance criteria will be prescribed when necessary. Records will be maintained of currently qualified personnel, processes, and equipment for each special process.

x) Inspection

The applicant's commitments for the QA inspection element are described in QAPD Section 10, "Inspection." The applicant commits to planned inspections to verify conformance of items to specified requirements. Inspection methods and requirements are specified in procedures. Commitments are identified for inspection planning, personnel independence and selection, hold points, statistical sampling, in-process, final, and in-service inspections, and acceptance of items, with provisions included for documenting and evaluating inspection results. Personnel qualification programs are established for inspection personnel. Inspection records are to contain information related to the item, inspector, type of observation or inspection plan, results of the inspection or acceptability of the item, and reference to actions taken with regard to any non-conformances.

xi) Test Control

The applicant stated in QAPD Section 11, "Test Control," that tests are required, planned, and executed to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service. These tests are to include prototype qualification, production, proof, construction, pre-operational, and operational tests. Test requirements are specified in written procedures with provisions included for test objectives, methods, prerequisites, hold points, equipment, and personnel qualifications. Requirements are identified for performance of tests, oversight of supplier tests, and documentation and evaluation of test results. Test records are to contain the item tested, test date, tester, type of observation, test procedure, results and acceptability, actions taken on any deviations, and person evaluating the results.

xii) Control of Measuring and Test Equipment

Section 12 of the QAPD, "Control of Measuring and Test Equipment," describes the applicant's controls to provide reasonable assurance that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals to maintain performance within required limits. This section appropriately specifies requirements for calibration procedures, control of items requiring calibration, application and actual item use documentation, out-of-calibration actions, including validity and acceptability of previously collected data, processes monitored or items previously inspected or tested, and records.

xiii) Handling, Storage, and Shipping

QAPD Section 13, "Handling, Storage, and Shipping," describes the applicant's measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items, in accordance with design and procurement requirements and work and inspection procedures and shipping or specific activity instructions to prevent loss, damage, or deterioration. Special equipment, and protective environments are required, verified, and monitored where necessary for the protection of particular items. Special handling tools and equipment are provided, controlled, and maintained, and operators are trained or appropriately experienced. Special

handling, preservation, storage, cleaning, packaging, or shipping instructions are established and used when essential to maintain acceptable quality.

xiv) Inspection, Test, and Operating Status

The applicant's provisions for inspection, test, and operating status are described in QAPD Section 14, "Inspection, Test, and Operating Status." These commitments are for control of inspection and test activities for items to prevent inadvertent use of nonconforming items or bypassing of inspections and tests. The applicant states that procedures are established to control these activities to ensure that required inspections and tests are performed, and to ensure that items that have not passed the required inspections or tests are not installed, used, or operated. During operation, status indicators are utilized when required, and issuance and removal of status indicators is documented. Procedures require that the operability of an item removed for maintenance or testing be verified prior to use.

xv) Nonconforming Items

QAPD Section 15, "Nonconforming Items," specifies the applicant's provisions to control the identification, segregation, disposition, and prevention of installation or use of nonconforming items. Nonconforming items are identified and segregated or measures are employed to prevent use of the item. Nonconforming items are reviewed and appropriately dispositioned and documented. The responsibility and authority for the evaluation and disposition of nonconforming items is defined and technical justification for the disposition is documented and subject to design control measures when applicable. The applicant's QA organization is responsible for administering the nonconformance process. Repaired or reworked items are re-examined in accordance with the original acceptance criteria or alternate disposition/acceptance criteria. Documentation of the nonconformance includes its description, disposition, and disposition signatures.

xvi) Corrective Action

QAPD Section 16, "Corrective Action," states that conditions adverse to quality are identified and corrected as soon as practical. For significant conditions adverse to quality, the cause of the condition is determined and corrective action is taken to preclude recurrence. These actions are documented and reported to appropriate levels of management. Requirements are specified for identification and classification of conditions adverse to quality, trending of significant conditions adverse to quality, criteria for determining trends, and follow-up action to be taken to verify implementation of the corrective action.

xvii) QA Records

QAPD Section 17, "QA Records," describes the applicant's QA records system for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for IROFS. Requirements for lifetime and nonpermanent records are identified. The applicant's QA program for QA records will implement the requirements of

NQA-1, Basic Requirement 17 and Supplement 17S-1, "Supplementary Requirements for QA Records." The applicant commits to a records management system and records center as early as practicable that is consistent with the work activities and in compliance with the QAPD requirements. Specific requirements and responsibilities for generation, classification, retention, receiving, storage, and preserving of QA records are identified.

xviii) Audits

QAPD Section 18, "Audits," identifies the applicant's commitments for planning, performing, and reporting internal and external audits to verify compliance with QA commitments and to determine the effectiveness of the LES QA program. Responsibilities and requirements for audit plans, schedules, teams, audit performance, and reporting of audit results are addressed. Requirements and responsibilities are identified for responding to and evaluating audit results and for follow-up action and records.

xix) Provisions for Change

QAPD Section 19, "Provisions for Change," describes the applicant's provisions for continuing QA reviews and revision of the QAPD based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes. Changes to the LES QA Program will be incorporated in the QAPD and submitted to the NRC within 30 days of implementation. Any changes that reduce the applicant's commitments in the approved QAPD will be submitted to the NRC for review and approval prior to implementation.

xx) QA Program for QA Level 2 Activities

LES QAPD Section 20, "QA Program for QA Level 2 Activities," describes the requirements for the owner-defined QA program for QA Level 2 activities. The QA Level requirements and controls are discussed in Section iii above.

5.0 Evaluation Findings

Based on its review of the QA elements described in the submitted license application and QAPD, the NRC staff has concluded that the applicant has adequately described the application of QA elements. The QA elements address the criteria of Appendix B and are consistent with the requirements of NQA-1. 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 the QA elements in the design, construction, operation, maintenance, and modification phases of the life of the facility. Accordingly, the staff has reasonable assurance of safe facility operations in accordance with the criteria guidance in NUREG-1520. The organizations and persons performing QA element functions have the required independence and authority to effectively carry out their QA element functions without undue influence from those directly responsible for process operations.

Accordingly, the staff concludes that the applicant's application of QA elements as described in the QAPD meets the requirements of 10 CFR Part 70 and provides reasonable assurance of

protection of public and worker health and safety and the environment.

6.0 References

1. American Society of Mechanical Engineering. Quality Assurance Requirements for Nuclear Facility Applications. ASME NQA-1-1994, as revised by the ASME NQA-1a-1995 Addenda, New York, NY: American Society of Mechanical Engineers. 1994/1995.

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