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LES-12-00056-NRC

ATTN: Document Control Desk
Director, Division of Security Operations
Office of Nuclear Security and Incident Response
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Louisiana Energy Services, LLC
NRC Docket Number: 70-3103

Subject: Response to Request for Additional Information on License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change

Reference:
1. Letter from B. Smith (NRC) to Z. Rad (LES), Request for Additional Information for License Amendment Request 12-01 Quality Audit Frequency Change and the Quality Assurance Program Description Update, March 21, 2012

2. LES-12-00025 License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change, February 10, 2012

Pursuant to the Ref. 1 Request for Additional Information (RAI) on the Ref. 2 License Amendment Request (LAR), Louisiana Energy Services, LLC (dba "UUSA") herewith provides the Enclosure 1 response. Enclosure 2 provides the proposed revision to the SAR and QAPD based on our Enclosure 1 response.

UUSA appreciates the efforts of the NRC staff in supporting the review and approval of this License Amendment Request in a timely manner. Should there be any questions, please contact Zackary Rad, UUSA Licensing Manager, at 575.394.6689.

Respectfully,

Russell L Williams J.

Russell Williams for
Jay Laughlin
Chief Nuclear Officer and Head of Technical Services

Enclosures:
1) Response to Request for Additional Information
2) Marked up version of SAR and QAPD.

NMSSDI

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Enclosure 1
Response to Request for Additional Information

LAR 12-01 QA Audit Frequency Change

Request 2.1

Clarify if the provision of a 25% grace period of audit interval will be applicable to both internal and external audits (e.g. supplier audits).

Response to 2.1

After further consideration, UUSA has determined that a 90 day maximum grace period for internal and external audits frequency will provide the flexibility needed for scheduling and staffing audits. This is in agreement with NRC endorsed NQA-1 2008 through Reg. Guide 1.28. The 90 day grace period will apply to both external and internal audits. The Enclosure 2 revised SAR and QAPD pages reflect this change.

Request 2.2

Clarify if the exception of a total combined time interval for any three consecutive inspection or audit intervals not exceeding 3.25 times the specified audit interval will only be applicable to supplier audits.

Response to 2.2

Based upon the response to 2.1, the 3.25 factor will not apply.

Request 2.3

Please clarify how audit extensions will be processed. Specifically, guidance provided in NQA-1-2008 allows the application of a 90 days grace period to scheduled audit intervals but requires that the periodicity of these audits should be based on the original schedule. Where the provision is included in the QAPD for audits to be scheduled from the original anniversary month, please provide justification as to why the audit is not scheduled from the original audit date, rather than the month.

Response to 2.3

When preparing this license amendment request UUSA reviewed the 2005 Farley SER (letter dated June 17, 2005, from Robert E. Martin (NRC) to Jeffrey T. Gasser Southern Nuclear Operating Company, INC, Accession Number, ML051570349) that allowed a 25% grace period for internal audits up to a two-year frequency and allowed the use of the month in which the audit starts versus a specific date (Section 3.4). Tracking by the original month versus exact day simplifies tracking and scheduling and is consistent with the previously mentioned SER approved by the NRC.

Procedures QA-3-2000-01, Quality Assurance Audit and QA-3-2000-08, Approved Supplier List will be revised to incorporate this LAR.

QAPD Update

Request

Describe how the process used to control electronic QA records will not present a reduction in commitment. Include the specific requirements for distribution, classification, receipt, storage, preservation and safekeeping, retrieval, and disposition applicable to electronically generated QA records. Describe how the controls needed for electronically generated QA records will be impacted by the current guidance used in the facility to develop and control procedures for QA records. Describe how the specific guidance used to develop and maintain procedures to control electronic QA records will not present a reduction in commitment to the current controls. Describe the controls to develop and implement procedures to identify, generate, authenticate, store, maintain, and control electronically generated QA records.

Response

The process for the creation and management of electronic quality assurance records is in development. The process cannot be currently described as it has not been developed or tested. URENCO USA has contracted with a vendor to develop a system that will meet the requirements of electronic quality records, as defined in the regulatory requirements and technical guidance, described below. The processes will require compliance with NRC guidance in Regulatory Issue Summary RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media", dated October 23, 2000 which endorses the Nuclear Information and Records Management Association (NIRMA) guidelines 1-4 below:

1. NIRMA Technical Guide (TG) 11-1998, "Authentication of Records and Media", Revision 3
2. NIRMA TG 15-1998, "Management of Electronic Records", Revision 3.
3. NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance", Revision 1.
4. NIRMA TG 21-1998, "Electronic Records Protection and Restoration", Revision 4 (In Revision 4 of NIRMA TG 21-2011, the title was changed to "Required Records Protection, Disaster Recovery and Business Continuation").

The controls needed for electronically generated QA records will only be impacted by the current guidance to the extent the processes are changed to create electronic QA records. Those controls will be developed independently of the current controls and the controls for both electronic and hard copy will be aligned to ensure the guidance is clear for the processing of QA records in either format. There are currently in place administrative system controls that restrict the access to creating and editing official procedures that are located in the electronic system as reference copies.

The current process of drafting or editing a procedure is implemented electronically within a current workflow process by authorized individuals. However, due to the lack of approved electronic signature technology, electronic authentication processes and retention requirements within the current system, the electronic workflow process cannot be used to complete the procedure. The procedure process is currently a hybrid of electronic and hard copy processing to meet the QA records requirements, originating as electronic but finalized as hard copy. Once electronic technologies and processes are developed which meet the commitments required for QA records, then the procedure will be revised to incorporate the change of processing methodology.

The use of electronic quality records and storage does not produce a reduction in commitment of the requirements under NQA-1-1994, Section 17, but requires different processes to be established in order to meet those commitments. As noted above, the development of these processes is currently being undertaken as a proof of concept to determine what processes can or cannot be automated while maintaining the specific attributes of a quality record. If the electronic process that is proposed does not support these commitments, then the process will not be implemented and the quality records would continue to be processed in the current manner under the current procedural requirements by producing an authenticated hard copy.

QA records originally created in hard-copy form will be retained in hard-copy until such time as electronic versions of the QA records are created, copied, and verified as legible on two independent copies of an appropriate electronic storage medium. QA records will be stored on electronic storage media in accordance with the NIRMA guidelines, mentioned above. These media may include optical disk, magnetic tape, network drive array, etc. Determination of appropriate electronic media will be made by the UUSA Information Technology Department based upon data format and level of access required.

File legibility verifications will be completed on all QA records stored on electronic storage media by either visually verifying the file's legibility or by electronically verifying the exact binary file transfer. Periodic media inspections to monitor image degradation will be conducted in accordance with the NIRMA guidelines or the media manufacturer's recommendations, with these inspections being documented. QA records stored on electronic media will be refreshed or copied onto new media and subsequently verified if the projected lifetime of the media does not exceed the retention period of the records stored on the media.

QA records originally created in electronic form will be retained in electronic form. Backup copies of associated electronic QA records will be maintained in multiple physically-independent electronic locations until such time as these QA records are copied and verified to an appropriate electronic storage medium. A copy of the electronic storage media will then be stored in two separate physical locations.

Enclosure 2

License Amendment Request (LAR) 12-01 Revised Pages
Marked up version of the Safety Analysis Report and Quality Assurance Program Description. (Revision bars, underlines, and strikethroughs were utilized)

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SAFETY ANALYSIS REPORT

Revision 31a

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Procedures

All activities involving IROFS, and any items that are essential to the function of IROFS, are conducted in accordance with approved procedures. Each of the other IROFS management measures (e.g., configuration management, maintenance, training) is implemented via approved procedures. These procedures are intended to provide a pre-planned method of conducting the activity in order to eliminate errors due to on-the-spot analysis and judgments.

All procedures are sufficiently detailed that qualified individuals can perform the required functions without direct supervision. However, written procedures cannot address all contingencies and operating conditions. Therefore, they contain a degree of flexibility appropriate to the activities being performed. Procedural guidance exists to identify the manner in which procedures are to be implemented. For example, routine procedural actions may not require the procedure to be present during implementation of the actions, while complex jobs, or checking with numerous sequences may require valve alignment checks, approved operator aids, or in-hand procedures that are referenced directly when the job is conducted.

To support the requirement to minimize challenges to IROFS, and any items that are essential to the function of IROFS, specific procedures for abnormal events are also provided. These procedures are based on a sequence of observations and actions to prevent or mitigate the consequences of an abnormal situation.

Audits and Assessments

Audits are focused on verifying compliance with regulatory and procedural requirements and licensing commitments. Assessments are focused on effectiveness of activities and ensuring that IROFS are reliable and are available to perform their intended safety functions as documented in the ISA. The frequency of audits and assessments is based upon the status and safety importance of the activities being performed and upon work history. However, at a minimum, all activities associated with maintaining IROFS will generally be ~~audited or~~ assessed on an annual basis and audited on a biennial basis (any exceptions credited within the ISA are discussed in the National Enrichment Facility Integrated Safety Analysis Summary).). Section 11.5 of the facility SAR describes the Management Measures, Audits and Assessments. Additional requirements and allowances for the conduct of Audits are contained in Section 18 of the Safety Analysis Report, Appendix A, Quality Assurance Program Description.

Incident Investigations

Incident investigations are conducted within the Corrective Action Program (CAP). Incidents associated with IROFS, and any items that are essential to the function of IROFS, encompass a range of items, including (a) processes that behave in unexpected ways, (b) procedural activities not performed in accordance with the approved procedure, (c) discovered deficiency, degradation, or non-conformance with an IROFS, or any items that are essential to the function of IROFS. Additionally, audit and assessment results are tracked in the Corrective Action Program.

Feedback from the results of incident investigations and identified root causes are used, as appropriate, to modify management measures to provided continued assurance that the reliability and availability of IROFS remain consistent with the performance requirements assumed in the ISA documentation.

- Nuclear criticality, radiation, chemical, and fire safety
- Quality assurance
- Design control
- Plant personnel training and qualification
- Audits and assessments
- Incident investigations
- Record keeping and document control
- Reporting.

Administrative procedures are also used for:

- Implementing the Fundamental Nuclear Material Control (FNMC) Plan
- Implementing the Emergency Plan
- Implementing the Physical Security Plan
- Implementing the Standard Practice Procedures Plan for the Protection of Classified Matter.

Maintenance procedures address:

- Preventive and corrective maintenance of IROFS
- Surveillance (includes calibration, inspection, and other surveillance testing)
- Functional testing of IROFS
- Requirements for pre maintenance activity involving reviews of the work to be performed and reviews of procedures.

Emergency procedures address the preplanned actions of operators and other plant personnel in the event of an emergency.

A more detailed description of the procedural development and management program can be found in Section 11.4, Procedures Development and Implementation.

6.4.7 Chemical Safety Audits

Audits are conducted to determine that plant operations are performed in compliance with regulatory requirements, license conditions, and written procedures. As a minimum, they assess activities related to radiation protection, criticality safety control, hazardous chemical safety, fire protection, and environmental protection.

Audits are performed in accordance with a written plan, which identifies and schedules audits to be performed. Audit team members shall not have direct responsibility for the function and area being audited. Team members have technical expertise or experience in the area being audited and are indoctrinated in audit techniques. Audits are conducted on an ~~annual~~biennial basis on select functions and areas as defined above as applicable to Operations Phase activities. The chemical process safety functions and areas will be audited at least triennially.

Qualified staff personnel that are not directly responsible for production activities are utilized to perform routine surveillances/assessments. Deficiencies noted during the inspection requiring

11.5 Audits and Assessments

LES will have a tiered approach to verifying compliance to procedures and performance to regulatory requirements.

11.5.1 ASSESSMENTS

Assessments are focused on effectiveness of activities and ensuring that IROFS, and any items that are essential to the function of IROFS, are reliable and are available to perform their intended safety functions. This approach includes performing Assessments on critical work activities associated with facility safety, environmental protection and other areas as identified via trends.

Assessments are divided into two categories that will be owned and managed by the line organizations as follows:

- Management Assessments conducted by the line organizations responsible for the work activity
- Independent Assessments conducted by individuals not involved in the area being assessed.

Assessments are performed to assure that facility activities are conducted in accordance with the written procedures and that the processes reviewed are effective. As a minimum, these assessments shall assess activities related to radiation protection, criticality safety control, hazardous chemical safety, industrial safety, ~~including~~ fire protection, and environmental protection.

Personnel performing assessments do not require certification, but they are required to complete QA orientation training, as well as training on the assessment process. The nuclear criticality safety assessments are performed under the direction of the criticality safety staff. Personnel performing these assessments do not report to the production organization and have no direct responsibility for the function or area being assessed. Assessments are conducted using approved procedures that meet the QAPD requirements. A schedule is established and maintained that identifies assessments to be performed and the responsible organization assigned to conduct the activity.

Assessments shall be performed routinely by qualified staff personnel that are not directly responsible for production activities. Deficiencies identified during the assessments requiring corrective action shall be forwarded to the responsible manager of the applicable area or function for action in accordance with the CAP procedure.

The Operations Group is assessed periodically to ensure that nuclear critical safety procedures are being followed and the process conditions have not been altered to adversely affect nuclear criticality safety. The frequency of these assessments is based on the controls identified in the NCS analyses and NCS evaluations. Assessments are conducted at least semi-annually. In addition, weekly nuclear criticality safety walkthroughs of UF_6 process areas are conducted and documented.

Assessment results are tracked and the data is periodically analyzed for potential trends. Needed program improvements are identified to prevent recurrence and/or for continuous

program improvements. The resulting trend is evaluated and reported to applicable management. This report documents the effectiveness of management measures in controlling activities, as well as deficiencies. Deficiencies identified in the trend report require corrective action in accordance with the applicable CAP procedure.

Assessments of nuclear criticality safety, performed in accordance with ANSI/ANS-8.19, will ensure that operations conform to criticality requirements.

11.5.2 AUDITS

Audits of the QA Level 1, QA Level 1 Graded, and QA Level 1-Fire Protection (Ql-1F) work activities are performed in accordance with the QAPD. The audit scope will include those activities associated with IROFS and any items that are essential to the function of the IROFS and items required to satisfy regulatory requirements for which QA Level 1, QA Level 1 Graded, and QL-1F requirements are applied will be the responsibility of the QA Department. Audits are focused on verifying compliance with regulatory and procedural requirements and licensing commitments.

Audits are performed to assure that facility activities are conducted in accordance with the written procedures and that the processes reviewed are effective. As a minimum, they shall assess activities related to radiation protection, criticality safety control, hazardous chemical safety, industrial safety including fire protection, and environmental protection.

Audits shall be performed routinely by qualified staff personnel that are not directly responsible for production activities. Deficiencies identified during the audits requiring corrective action shall be forwarded to the responsible manager of the applicable area or function for action in accordance with the CAP procedure. Future audits shall include a review to evaluate if corrective actions have been effective.

The Quality Assurance Department shall be responsible for performing the audits. Audits shall be performed in accordance QAPD requirements. The Audit Team members shall not have direct responsibility for the function and area being audited. Team members shall have technical expertise or experience in the area being audited and shall be indoctrinated in audit techniques. For Construction Phase activities, Aaudits shall be conducted on an annual basis ~~periodically~~ as described in the QAPD. For Operations Phase activities, audits shall be conducted on a biennial basis as described in the QAPD. The frequency of audits is based upon the status and safety importance of the activities being performed and upon work history. All major activities will be audited on an annual basis. The audit schedule is reviewed periodically and revised as necessary to ensure coverage commensurate with current and planned activities. All aspects of the Nuclear Criticality Safety Program will be audited at least every two years.

Corrective actions following issuance of the audit report require compliance with the applicable CAP procedures. Audit reports are required to contain an effectiveness evaluation and statement for each of the applicable QA program elements reviewed during the audit. The audit is closed with the proper documentation as required by the applicable audit procedure. The QA organization will conduct follow-up audits to verify that corrective actions were taken in a timely manner. In addition, future audits will include a review to evaluate if corrective actions have been effective.

11.8 Other QA Elements

The QA Program and its supporting manuals, procedures and instructions are applicable to items and activities designated as QA Level 1, 1 Graded, QA Level 1-Fire Protection (QL-1F), 2AC, and 2.

The Head of Compliance is responsible for developing and revising the QA Program and assuring it is in compliance with applicable regulations, codes and standards.

The QA Program specifies mandatory requirements for performing activities affecting quality and is set forth in procedures which are distributed on a controlled basis to organizations and individuals responsible for quality. Revisions to these procedures are also distributed on a controlled basis. Applicable portions of the QA Program are documented, approved and implemented prior to undertaking an activity.

A management assessment of the QA program is performed at least six months prior to scheduled receipt of licensed material on the site. Items identified as needing completion or modification are entered into the CAP and corrective action completed before scheduled receipt of licensed material. LES Management monitors the QA program prior to this initial management assessment through project review meetings and annual assessments. This management assessment along with integrated schedules and program review meetings ensure that the QA program is in place and effective prior to receiving licensed material.

The LES QA program for design, construction, and preoperational testing continues simultaneously with the QA program for the ~~operational~~ operations phase while construction activities are in progress.

Anyone may propose changes to the QA Program supporting manuals and procedures. When reviewed by the Head of Compliance and found acceptable and compatible with applicable requirements, guidelines and LES policy, the changes may be implemented. The QA Program and supporting manuals and procedures are reviewed periodically to ensure they are in compliance with applicable regulations, codes, and standards. New or revised regulations, codes, and standards are reviewed for incorporation into the QA Program and supporting manuals and procedures as necessary.

Personnel performing activities covered by the QA program shall perform work in accordance with approved procedures, and must demonstrate suitable proficiency in their assigned tasks. Formal training programs are established for quality assurance policies, requirements, procedures, and methods. Ongoing training is provided to ensure continuing proficiency as procedural requirements change. New employees are required to attend a QA indoctrination class on authority, organization, policies, manuals, and procedures.

Additional formal training is conducted in specific topics such as NRC regulations and guidance, procedures, auditing, and applicable codes and standards. Supplemental training is performed as required. On-the-job training is performed by the employee's supervisor in QA area-specific procedures and requirements. Training records are maintained for each person performing quality-related job functions.

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SAFETY ANALYSIS REPORT
APPENDIX A

QUALITY ASSURANCE PROGRAM DESCRIPTION

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contractor's QAPD is reviewed and accepted by the LES QA Manager. The QA Level 2 SSCs which support normal operations shall be identified in applicable QA procedures and implementing documents and documents specifying quality requirements or prescribing activities affecting quality.

QA LEVEL 3 REQUIREMENTS

The QA Level 3 program is defined as standard commercial practice. A documented QA Level 3 program is not required. QA Level 3 governs all activities not designated as QA Level 1, QA Level 1 Graded, QA Level 1F, QA Level 2AC, or QA Level 2.

Any removal of the management measures designed to provide assurance of other equipment attributes, identified in Table 3.4-1 of the SAR, that are used by the worker would be considered a reduction in commitment and require regulatory approval prior to implementation.

QUALITY ASSURANCE TRAINING

Personnel who are assigned to perform QA Level 1 activities receive LES QA Indoctrination Training. This training includes general criteria, such as an introduction to applicable codes, standards, QA Procedures, QAPD elements and job responsibilities and authorities. Personnel assigned to perform QA Level 1, QA Level 1 Graded, or QA Level 1F activities are also required to complete training in the specific LES QA procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the LES QAPD and job specific QA procedures prior to an employee beginning QA Level 1, QA Level 1 Graded, or QA Level 1F work. Supervision is responsible for ensuring that personnel performing work under their supervision are appropriately trained. LES will also include a version of QA Indoctrination Training as part of the general employee training for those individuals required to take the training.

The Training Manager provides the support function for coordinating this QA training. Plant Support provides centralized training support for supervision in coordinating training and maintaining QA training records. This responsibility is carried out as support for line management. LES supervisory personnel are responsible for determining the type and extent of the training to be provided to an individual, and ensuring that the training is properly documented for personnel performing QA Level 1, QA Level 1 Graded, and QA Level 1F activities. Retraining is performed and documented, when applicable, shall occur in order to maintain proficiency or when changes to work methods, technology, or job responsibilities occur.

MANAGEMENT ASSESSMENTS

The Head of Compliance is responsible for ensuring that management assessments are conducted annually to determine if the LES QA Program is effective. Audits conducted in accordance with QAPD Section 18 may be used to fulfill this annual Assessment requirement. Recommendations are provided to the Chief Nuclear Officer and President for action. Functional Managers and the QA Manger conduct assessments annually of QA activities under their control. The managers report the results to the Head of Operations, Head of Technical Services or Head of Compliance for review and assignments as appropriate, and to the Chief Nuclear Officer or President for review. The results of these assessments are reviewed by senior management to determine the adequacy of implementation of the LES QA Program and to direct any needed changes for program improvements.

SECTION 18 AUDITS

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 18, Audits, of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 18 and Supplement 18S-1 of NQA-1-1994 Part 1.

In accordance with the description of the QA organization during the various phases of design, construction, and operation provided in Section 1, Organization, the LES QA Manager shall verify LES compliance with all aspects of the LES QA Program and determine QA Program effectiveness by ensuring that planned and scheduled audits are conducted. Elements that have been selected for audit shall be evaluated against specified requirements. An auditing function reports to the LES QA Manager and has the organizational independence and authority to execute an effective audit process to meet all requirements of the QAPD. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. LES audits are performed in accordance with written procedures or checklists by appropriately trained and qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and provided to the appropriate management for review and corrective action as applicable. Follow-up actions are taken where indicated.

AUDIT SCHEDULES

Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. Internal or external audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. For Construction Phase activities~~As a minimum~~, internal audits of LES QA Level 1, QA Level 1 Graded, QA Level 1F, and QA Level 2AC activities shall be ~~at least once per year~~conducted on an annual basis or at least once during the life of the activity, whichever is shorter. For Operational Phase activities, internal audits shall be conducted on a biennial basis. Exceptions to these audit frequencies are those audit intervals defined by codes or regulations as committed to by the facility license and applicable to specific functional areas. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate determination of the effectiveness of the QAPD. Internal audits to determine QAPD effectiveness shall be performed on selected work products. The audit schedule shall be developed annually and revised as necessary to ensure that coverage is maintained current. Frequency of audits should be based upon evaluation of all applicable and active elements of the QAPD applicable to LES workscope. These evaluations should include an assessment of the effectiveness of the applicable and active elements of the QAPD based upon previous audit results and corrective actions, nonconformance reports, identified trends, and significant organizational changes. Audits maybe supplemented by QA Surveillances conducted in accordance with approved procedures to ensure that QA is providing sufficient oversight of important QAPD activities. These surveillances are performed by the QA organization.

Audits shall be performed at the intervals designated herein for each audit area. Schedules shall be based on the month in which the audit starts. A maximum extension not to exceed 90 days for internal and external audits shall be allowed. When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the month the original audit started. The provision for audit start date extension shall also apply to supplier audits, surveys and evaluations.