March 21, 2012

Mr. Zachary Rad
Licensing Manager
Louisiana Energy Services, LLC
P.O. Box 1789
Eunice, NM 88231

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR LICENSE AMENDMENT REQUEST 12-01 QUALITY AUDIT FREQUENCY CHANGE AND THE QUALITY ASSURANCE PROGRAM DESCRIPTION UPDATE

Dear Mr. Rad:

We reviewed your License Amendment Request 12-01, Quality Audit Frequency Change, submitted on February 10, 2012 and your Quality Assurance Program Description update, submitted on February 16, 2012. We find that additional information is needed before final action can be taken on your submittal. We are enclosing a request for additional information and ask that you provide a response within 30 days of the date of this letter.

If you have any questions, please contact Mr. Michael Raddatz at 301-492-3108, or via e-mail to Michael.Raddatz@nrc.gov.

Sincerely,

/RA/ J. Downs for

Brian W. Smith, Chief
Uranium Enrichment Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As stated

Docket No. 70-3103
License No. SNM-2010

Mr. Zachary Rad
Licensing Manager
Louisiana Energy Services, LLC
P.O. Box 1789
Eunice, NM 88231

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR LICENSE AMENDMENT REQUEST 12-01 QUALITY AUDIT FREQUENCY CHANGE AND THE QUALITY ASSURANCE PROGRAM DESCRIPTION UPDATE

Dear Mr. Rad:

We reviewed your License Amendment Request 12-01, Quality Audit Frequency Change, submitted on February 10, 2012 and your Quality Assurance Program Description update, submitted on February 16, 2012. We find that additional information is needed before final action can be taken on your submittal. We are enclosing a request for additional information and ask that you provide a response within 30 days of the date of this letter.

If you have any questions, please contact Mr. Michael Raddatz at 301-492-3108, or via e-mail to Michael.Raddatz@nrc.gov.

Sincerely,

/RA/ J. Downs for

Brian W. Smith, Chief
Uranium Enrichment Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As stated

Docket No. 70-3103
License No. SNM-2010

DISTRIBUTION:

RidsNmssOd r/f	UEB r/f	JWeil/OCA	AGody/Reg II
DSeymour/Reg II	DMcIntyre/OPA	RHannah/Reg II	WMaier/Reg IV
CTaylor/Reg II	KEverly/NSIR	BStapleton/NSIR	SSoto/FCSS

ML120680407

OFFICE	FCSS/UEB	FCSS/UEB	FCSS/UEB
NAME	MRaddatz	TRichmond	BSmith J. Downs for
DATE	3/8/2012	3/15/2012	3/21/2012

OFFICIAL RECORD COPY

REQUEST FOR ADDITIONAL INFORMATION
LOUISIANA ENERGY SERVICES, LLC

Request for Additional Information (RAIs)

The U.S. Nuclear Regulatory (NRC) staff has reviewed the License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change (Ref. 1), submitted on February 10, 2012 and the Quality Assurance Program Description (QAPD) Update, submitted on February 16, 2012 (Ref. 2). The NRC staff has identified areas in which further information is required to demonstrate compliance with regulations, license conditions, and guidelines provided by the American Society of Mechanical Engineer (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," including supplements as revised by the ASME NQA-1a-1995 Addenda (Ref. 3), which Louisiana Energy Services (LES) has committed to follow.

LAR 12-01 QA Audit Frequency Change

1. The LES LAR 12-01 states, "A biennial audit frequency for Operational Phase activities is a standard feature in most 10 CFR 50 Appendix B licensee's programs. Additionally, a general provision is being added to the SAR and QAPD to allow the application of a 25% grace period to the required audit frequency." It further states, "A 25% grace period for conduct of audits is a standard feature in most 10CFR50 Appendix B licensee's programs."

   Section 18 of the QAPD, Audits, states in part, "For example, for audits on a 24-month frequency, the maximum time between specific audits shall not exceed 30 months. Likewise, audits on an annual (12 months) frequency shall not be extended beyond 15 months."

   In addition, further revision to NQA-1-1994 (e.g. ASME NQA-1-2008, Part III, Non-mandatory Appendix 18A-1), limits the industry to a grace period of 90 days from the scheduled audit interval regardless of the original audit schedule frequency.

   The 25% grace period is consistent with the 90 days grace period provided in industry guidance for audit scheduled on an annual basis. However, for audits scheduled on a biennial basis, a 25% grace period would be 180 days and would exceed accepted industry practice. Therefore, please provide justification as to why a 25% grace period is appropriate for audit frequency in the Safety Analysis Report (SAR) and Section 11 of the QAPD for audits scheduled to be performed biennially.

2. Section 11.5.2 of the SAR states, "For Operations Phase activities, audits shall be conducted on a biennial basis as described in the QAPD."

   Furthermore, Section 18 of the LES QAPD states, "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 25% of the audit interval shall be allowed." In addition, Section 18 of the QAPD further states, "When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the original anniversary month rather than from the month of the extended audit.

The provision for audit start date extension shall also apply to supplier audits and the evaluations except that a total combined time interval for any three consecutive inspection or audit intervals should not exceed 3.25 times the specified inspection or audit interval."

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).

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.

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.

QAPD Update

1. Section 17, QA Records, of the LES QAPD states, "Electronic records may be generated using several different methods, which may include electronic data, electronic mail and records resulting from the conversion from one media type to another. A process shall be provided within approved procedures which provide the requirements for electronic records authorization by electronic signatures, electronic approvals, or any other mean that ensures traceability to a specific individual or organization of authorization with an associated date. The authentication information must be identified on the media or contained within or linked to the document itself."

   NQA-1-1994, Section 17, "Quality Assurance Records," addresses the following criteria: distribution, classification, receipt, storage, preservation and safekeeping, retrieval, and disposition."

   Describe how the process used to control electronic QA records will not present a reduction in commitment to the current controls provided in Section 17, QA Records, of the LES QAPD. In your description, include the specific requirements for distribution, classification, receipt, storage, preservation and safekeeping, retrieval, and disposition applicable to electronically generated QA records.

   Section 17, QA Records, of the LES QAPD states, "In addition, the storage process for electronic QA records shall be provided within approved procedures requiring both media and compatible processing systems which ensure a retrievable and legible format for the entire retention period of the record."

In addition, further revision to NQA-1-1994 (e.g. ASME NQA-1-2008); included electronic records guidance in Non-mandatory Appendix 17A-2, "Guidance for Electronic Records." It states in part, "Organizations that generate and maintain QA records in an electronic format should develop controls and associated procedures that address the unique capabilities and requirements of this technology. Electronic record controls should address how electronic records are identified, generated, authenticated, stored, and maintained per the required retention schedule."

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. In your description, describe how the specific guidance used to develop and maintain procedures to control electronic QA records, if any, will not present a reduction in commitment to the current controls provided in Section 17, QA Records, of the LES QAPD. In addition, describe the controls to develop and implement procedures to identify, generate, authenticate, store, maintain, and control electronically generated QA records, or describe these processes.

REFERENCES

1. LAR 12-01 QA Audit Frequency Change. February 10, 2012. Agencywide Documents Access and Management Systems (ADAMS) Accession Number ML12045A290.

2. QAPD Update. February 16, 2012. ADAMS Accession Number ML12053A135.

3. The ASME, "Quality Assurance Requirement for Nuclear Facility Applications," ASME NQA-1-1994. July 29, 1994.