

DOCKET NUMBER: 70-3103

LICENSE NUMBER: SNM-2010

LICENSEE: Louisiana Energy Services, LLC
National Enrichment Facility
Lea County, New Mexico

SUBJECT: LICENSE AMENDMENT REQUEST 12-01 QUALITY
ASSURANCE AUDIT FREQUENCY CHANGE

1.0 BACKGROUND

By letter dated February 10, 2012, Louisiana Energy Services (LES), LLC, submitted License Amendment Request (LAR) 12-01, which requested approval of an amendment to Special Material License (SNM)-2010 to authorize a periodicity change of Quality Assurance Audits for Operational Phase activities from annual to biennial in the Safety Analysis Report (SAR) and the Quality Assurance Program Description (QAPD) (Ref. 1). In addition, LES provided further information related to this amendment in letter dated April 13, 2012, "Response to Request for Additional Information on License Amendment Request (LAR) 12-01, Quality Assurance (QA) Audit Frequency Change."

2.0 REGULATORY REQUIREMENTS

Under Title 10 of the *Code of Federal Regulations* (10 CFR) 70.62, a licensee is required to establish and maintain a safety program, including management measures, that demonstrates compliance with the performance requirements of 10 CFR 70.61. The licensee's management measures are required to ensure that engineered and administrative controls and control systems that are identified as items relied on for safety (IROFS) are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function when needed to comply with the performance requirements of 10 CFR 70.61.

In its application, LES committed to comply with the requirements of Appendix B to 10 CFR Part 50; and, as such, is required to establish a QA program to be applied to the design, fabrication, construction, and testing of structures, systems, and components of a facility.

Title 10 CFR Part 70, Section 70.72(c), identifies changes that may be made to license basis documents without prior U.S. Nuclear Regulatory Commission (NRC) review and approval. Changes that do not meet the criteria established in Section 70.72(c) require a license amendment request in accordance with Section 70.34.

3.0 PROPOSED CHANGES

LAR 12-01 requested NRC's approval of an amendment to the Materials License SNM-2010 to authorize a QA audit frequency change for operational phase activities. Specifically, LAR 12-01 proposed to revise the SAR and the QAPD to change the QA audit frequency from annual to biennial basis for operational phase activities. Changes made to the SAR include modifications to Section 3.1, "Safety Program;" Section 6.4.7, "Chemical Safety Audits;" and Section 11.5, "Audits and Assessments." Section 3.1 of the SAR was revised to indicate that, as a minimum, all activities associated with maintaining IROFS will generally be assessed on an annual basis and audited on a biennial basis with exceptions credited within the Independent Safety Analysis

(Ref. 2). In addition, Section 3.1 of the SAR was also revised to include a statement indicating that: (1) Section 11.5 of the facility's SAR describes the Management Measures, Audits and Assessments; and (2) additional requirements and allowances for the conduct of Audits are contained in Section 18 of the SAR, Appendix A, QAPD (Ref. 2). Furthermore, Section 6.4.7 was modified to include that audits will be conducted on a biennial basis on select functions and areas for Operations Phase activities, as applicable. Section 11.5.2 was modified to include audit frequency commitment for Construction Phase activities and Operational Phase activities (Ref. 2). Specifically, LES will continue to commit to perform QA audits for Construction Phase activities on an annual basis; but for Operations Phase activities, LES committed to perform QA audits on a biennial basis as described in its QAPD (Ref. 2). The NRC staff evaluated these changes to the LES SAR and found it to be consistent with the requirements of Appendix B to 10 CFR Part 50.

LES also proposed to modify its QAPD to include commitments and clarification related to QA audits as a result of the modifications made to its SAR (Ref. 2). Section 2 of the LES QAPD was modified to include a statement indicating that audits conducted in accordance with QAPD, Section 18, may be used to fulfill the annual assessment requirement. In addition, Section 18, "Audits," was modified to clarify that for Construction Phase activities, internal audits of LES's QA Level 1; QA Level 1 Graded; QA Level 1F; and QA Level 2AC activities will continue to be performed on an annual basis (Ref. 2). Furthermore, LES included a commitment to perform internal audits for Operational Phase activities on a biennial basis, and the schedules will be based on the month in which the audit starts with a maximum extension period not to exceed 90 days (Ref. 2). LES clarified that exception to these audit frequencies are those audit intervals defined by codes or regulations as committed to by the LES license and applicable to specific functional areas (Ref. 2). LES indicated that the 90 days extension period is applicable to internal and external audits. LES also clarified that 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 was started. This provision for audit start date extension will also be applicable to supplier audit, surveys, and evaluations (Ref. 2).

4.0 TECHNICAL EVALUATION

The NRC staff evaluated the changes proposed in LAR 12-01 and found that they were acceptable as they did not present a reduction in commitments made by LES. In addition, the NRC staff found that the changes are consistent with the regulatory requirements in 10 CFR Part 70 for management measures as well as the requirements of Appendix B to 10 CFR Part 50.

5.0 CONCLUSIONS

The staff finds that the proposed changes do not present a reduction in commitment and are consistent with the regulatory requirements in 10 CFR Part 70 for management measures. In addition, the QA audit frequency change as described in the revised portions of the SAR and Section 18 of the QAPD continue to be consistent with the requirements provided in Appendix B to Part 50 and with the requirements provided in the American Society of Mechanical Engineers QA Standard NQA-1-1994 with 1995 Addenda, as well as updated guidance provided in NQA-1-2008 with 2009 Addenda.

PRINCIPAL CONTRIBUTOR

Soly I. Soto Lugo

SUBJECT: QUALITY ASSURANCE PROGRAM DESCRIPTION UPDATE

1.0 BACKGROUND

By letter dated February 16, 2012, "Quality Assurance Program Description," Louisiana Energy Services (LES), LLC, submitted changes to the LES Quality Assurance Program Description (QAPD) made in accordance with Section 19 of its QAPD (Ref. 3). Revision 32d of Section 17, "Quality Assurance Records," includes guidance for electronically generated Quality Assurance (QA) records. By letter dated April 13, 2012, "Response to Request for Additional Information on License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change," LES submitted further clarification regarding QA electronic records requirements (Ref. 2).

2.0 REGULATORY REQUIREMENTS

Under Title 10 of the *Code of Federal Regulations* (10 CFR) 70.62, a licensee is required to establish and maintain a safety program, including management measures, that demonstrates compliance with the performance requirements of 10 CFR 70.61. The licensee's management measures are required to ensure that engineered and administrative controls and control systems that are identified as items relied on for safety (IROFS) are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function when needed to comply with the performance requirements of 10 CFR 70.61.

In its application, LES committed to comply with the requirements of Appendix B to 10 CFR Part 50; and, as such, is required to establish a QA program to be applied to the design, fabrication, construction, and testing of structures, systems, and components of a facility.

Title 10 CFR Part 70, Section 70.72(c), identifies changes that may be made to license basis documents without prior U.S. Nuclear Regulatory Commission (NRC) review and approval. Changes that do not meet the criteria established in Section 70.72(c) require a LAR in accordance with Section 70.34.

3.0 CHANGES IN QAPD

By letter dated February 16, 2012, LES added additional requirements for electronically generated QA records to Section 17 of its QAPD (Ref. 3). LES indicated they will continue to commit with the requirements provided in Supplement 17S-1 of NQA-1-1994 Part 1 for receiving, storing, safekeeping and preserving QA records. In addition, LES committed to develop a process for safe storage of electronic QA records in accordance with approved procedures requiring both media and compatible processing systems to ensure a retrievable and legible format for the entire retention period of the record (Ref. 3).

Furthermore, LES added a subsection to Section 17 of the QAPD to include specific requirements for electronic records (Ref. 3). In this section, LES indicated that 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. Additionally, LES committed to provide a process, within approved procedures, for electronic records authorization by electronic signatures, electronic approvals, or any other means that ensures traceability to a specific individual or organization of authorization with an associated date. The revision also included commitment for authentication information. LES indicated that

authentication information must be identified on the media or contained within or linked to the document itself.

By letter dated April 13, 2012, LES provided additional clarification information on QA electronic records. In this letter, LES indicated that the process for creation and management of electronic QA records has not been developed or tested at this time. However, LES also indicated that 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, (Ref. 4) which endorses the Nuclear Information and Records Management Association (NIRMA) guidelines listed 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").

According to letter dated April 13, 2012, LES specified that: (1) the controls needed for electronically generated QA records will only be developed independently of the current controls and the controls for electronic and hard copy will be aligned to ensure appropriate guidance of QA records in either format; (2) if the electronic process that is developed does not support the commitments required for QA records, 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; (3) 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; (4) QA records will be stored on electronic storage media in accordance with NIRMA guidelines specified in RIS 2000-18; and (5) periodic media inspections will also be conducted in accordance with NIRMA guidelines or the media manufacturer's recommendations. In addition, LES also indicated in this letter that backup copies of electronic QA records will be maintained in multiple, physically-independent electronic locations until such time as the QA records are copied and verified to an appropriate electronic storage medium. Furthermore, a copy of the electronic storage media will then be stored in two separate physical locations.

4.0 TECHICAL EVALUATION

In accordance with Section 19 of its QAPD, LES is required to submit non-substantive changes to the QAPD to the NRC within 30 days of implementation of such changes. On February 7, 2012, LES approved changes under its own approval authority and the NRC was notified on February 16, 2012 (Ref. 3). The NRC staff evaluated these changes to ensure that they are in compliance with Section 19 of the LES QAPD.

5.0 CONCLUSION

The NRC staff found that the changes were acceptable as long as the process to generate, control, store, and maintain QA electronic records are in accordance to guidance provided in RIS 2000-18. LES committed to this in the response to request for additional information letter dated April 13, 2012, "Response to Request for Additional Information on License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change." Upon review of the changes, the staff found that the changes are consistent with the regulatory requirements in 10 CFR Part 70 for management measures and concludes that the changes are acceptable as they did not reduce any commitments made by the licensee in Revision 32d of Section 17 of its QAPD. The descriptions provided in Section 17 of the LES QA program continue to be consistent with the requirements of Criterion 17 of Appendix B to 10 CFR Part 50, as well as the requirements provided in Basic Requirement 17 of NQA-1-1994.

PRINCIPAL CONTRIBUTOR

Soly I. Soto Lugo

REFERENCES

1. Letter from Jay Laughlin, Louisiana Energy Services, LLC, "License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change," February 10, 2012. Agencywide Documents Access and Management Systems (ADAMS) Accession Number ML12045A290.
2. Letter from Russell Williams for Jay Laughlin, Louisiana Energy Services, LLC, "Response to Request for Additional Information on License Amendment Request (LAR) 12-01 Quality Assurance (QA) Audit Frequency Change," April 13, 2012. ADAMS Accession Number ML12109A087.
3. Letter from Jay Laughlin, Louisiana Energy Services, LLC, "Quality Assurance Program Description (QAPD) Update," February 16, 2012. ADAMS Accession Number ML12053A135.
4. Regulatory Issue Summary RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," October 23, 2000, ADAMS Accession Number ML100160003.