SAFETY EVALUATION REPORT
LOUISIANA ENERGY SERVICES
PROPOSED MATERIALS LICENSE AMENDMENT
TO ADDRESS CHANGES TO LICENSING
DOCUMENTS AND THE NEED FOR
NUCLEAR REGULATORY COMMISSION PRIOR APPROVAL
LOUISIANA ENERGY SERVICES - DOCKET 70-3103

1.0 INTRODUCTION

By letter dated March 20, 2012, (LES-12-00074-NRC), Urenco USA (UUSA)/Louisiana Energy Services (LES) requested the U.S. Nuclear Regulatory Commission's (NRC's) review of a proposed amendment to the LES Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70 Materials License to address making changes to licensing basis documents and the need for NRC prior approval. In its letter, LES provided a detailed description of the proposed change, justification for the proposed change, a proposed modification of License Condition (LC) 30, and a summary of the implementing guidance associated with the proposed amendment process.

2.0 BACKGROUND

On December 29, 2011, the NRC issued Regulatory Guide (RG) 3.74, "Guidance for Fuel Cycle Facility Change Processes" (Agency wide Documents Access and Management System [ADAMS Accession] Number ML100890016). This RG addresses the 10 CFR 70.72 change process and provides guidance on its implementation. It also provides an acceptable method for making changes to licensing basis documents without prior NRC approval through use of a specific LC as described in the guide. This method involves the licensee requesting an amendment to their license to incorporate commitments for evaluation associated with determining the need for prior NRC approval of changes to licensing basis documents.

By letter dated January 31, 2012, the NRC informed LES of the recent issuance of RG 3.74. In its letter, the NRC stated that a recent NRC staff's review regarding a licensee's ability to make changes to its licensing basis documents, and specifically their Safety Analysis Report (SAR), using the requirements of 10 CFR 70.72, had concluded that the use of this regulation for making changes to those documents and evaluating the need for prior NRC approval using that regulation was not applicable. Further, the letter stated that licensing basis documents are not included in the items specified in 70.72(c) and the criteria for evaluating the need for prior NRC approval specified in 70.72(c)(1) is therefore not applicable for the types of changes expected to be made in licensing basis documents.

On March 20, 2012, LES provided a letter (LES-12-00043-NRC) to the NRC for a proposed amendment to their materials license. On April 3, 2012, the NRC staff and LES staff held a conference call to discuss and clarify the information provided in the January 31, 2012, letter, as well as to discuss comments the staff had regarding their preliminary review of the March 20, 2012, letter. The call was a discussion of the proposed LC from LES for making changes to the LES SAR and the associated implementation guidance provided as an attachment (Enclosure 1) to the request. The staff's opinion at that time was that the LC and wording in the LC seemed reasonable and consistent with commitments previously accepted by the staff and recommended in the regulatory guide. The staff did have questions regarding the implementation guidance provided by LES. The staff questioned the scope of changes as

defined by LES in their definition of change taken from the definition in 10 CFR Part 50. One major point of discussion was the LES proposal to rely on previously NRC-approved use of codes and standards as technical justification and precedent for LES not requesting an amendment for a change at their facility. The staff also questioned the proposed application for the use of previous NRC approval for methodologies and other safety commitments. The staff informed LES that these types of precedent may be more common for Part 50 licensees but are less common for Part 70 licensees and management consultation would be required before the staff would consider approval. The staff also discussed with LES the need for them to continue to adhere to the Condition 30 LC in their present license, and the suggestion was made to possibly add that condition, word for word, to the implementing guidance, as well as criteria for implementing changes to the NRC-approved Integrated Safety Analysis (ISA) methodology. Following the call, LES resubmitted a revised license amendment request on April 10, 2012, (LES-12-00054-NRC) following the guidance provided in RG 3.74 and clarifications and concerns discussed with the staff during the call. Lastly, on May 21, 2012, the NRC transmitted, via e-mail (ADAMS Accession Number ML12150A175), a request for clarification and comment on several points. We received your response, dated May 24, 2012, (LES-12-00074-NRC), which contained an updated version of the implementation guidance. It is the May 24, 2012, letter that provided the foundation for this Safety Evaluation Report.

3.0 AMENDMENT REQUEST

LES's letter requested the NRC to review and approve a proposed amendment to materials license SNM-2010, to incorporate a license condition (below) that would allow LES to make certain changes to their SAR without prior NRC approval. In its request, LES provided an amended LC (30) to address evaluating changes to the SAR and the criteria for determining whether such changes require prior approval. The LC criteria provided for evaluating changes to the SAR to determine whether an application for an amendment prior to implementation. LES requested that the proposed LC replace LC 30, currently in the license, in its entirety. LES also proposes to move the present LC 30 wording into the implementation guidance. The LC proposed by LES contains the commitment to evaluate changes to the SAR and evaluate these changes for the need for NRC prior approval with the criteria provided in the proposed LC. For changes that require prior approval, LES proposes to submit to the NRC for review and approval, an application to amend the license. LES proposes that changes to the SAR will be documented, maintained on site, and reported to the NRC every six months.

Proposed License Condition, LC 30

The licensee is granted the special authorization as requested in correspondence dated May 24, 2012, (LES-12-00074-NRC). Specifically:

a) The licensee shall not make changes to the Safety Analysis Report (SAR), without prior NRC approval unless the criteria in paragraph b are satisfied. For changes requiring prior NRC approval, the licensee shall submit to the NRC, for review and approval, an application to amend the license. Such changes shall not be implemented until approval is granted unless prior written authorization is provided by the NRC.

b) Upon documented completion of a change request for a facility or process, the licensee may make changes in the facility or process as presented in the SAR, or conduct tests or activities not presented in the SAR that would normally be described therein, without prior NRC approval, subject to the following conditions:

1. There is no decrease in the level of effectiveness of the design basis for safety functions as described in the SAR, and
2. The change does not result in a departure from a method of evaluation described in the SAR used in establishing the design bases for safety functions, and
3. The change does not result in a decrease in effectiveness of safety commitments as described in the SAR, and
4. The change does not affect compliance with applicable regulatory safety requirements, and
5. The change does not conflict with any condition specifically stated in LES Materials License SNM-2010.

Changes to the SAR shall be evaluated, documented and reported in accordance with the commitments in Enclosure 1 of correspondence dated May 24, 2012 (LES-12-00074-NRC). Records of such changes shall be maintained, including technical justification and management approval, in dedicated records to enable NRC inspection upon request at the facility. A periodic report containing a description of each such change, and appropriate revised sections to the license application, shall be submitted to the NRC every six months

4.0 STAFF REVIEW

The NRC staff evaluated the proposed LC from the May 24, 2012, LES letter against the guidance in RG 3.74 and similar previously approved LCs to determine if LES's proposed LC would be adequate to address changes to their SAR and determine if prior NRC approval would be required.

The NRC staff also reviewed LES's proposed implementation guidance, to evaluate whether the process met the expectations of the staff and to assure that the current LC 30 was adequately addressed within the enclosed process for evaluating SAR changes.

The NRC staff noted that the proposed LC was drafted following closely the guidance in RG 3.74, Section 5(c). The NRC staff reviewed LES's proposed LC to evaluate the criteria for making changes to licensing basis documents, the provisions for documenting the evaluations for determining the need for prior approval of changes to the licensing basis documents, and how those changes would be communicated to the NRC following LES's determination on whether or not prior NRC approval is required before implementation of the change. In addition, the NRC staff noted that the proposed LC was similar to other LCs for addressing changes to licensing documents and the determination of whether prior approval was required that have been previously approved by the NRC for other applicants and licensees.

The staff also reviewed the implementation guidance contained in Enclosure 1 to your May 24, 2012, letter. This enclosure provided a summary of the implementing process for evaluating changes to the SAR and contains the commitments from LC 30 of the present LES license. The enclosure provides an outline of the process that will be used by LES to evaluate SAR changes. This enclosure also contains the following:

- A definition of change that now incorporates safety commitments within the scope of changes needing evaluation as well as physical changes to the facility.
- A commitment to follow Section 4.3.8.2 of Nuclear Energy Institute (NEI) 96-07, "Guidance for 10 CFR 50.59 Implementation," Revision 1, November, 2000. This guidance was previously endorsed by the staff in RG 1.187. This guidance is

referenced in the licensee's process for evaluating whether there is a decrease in the level of effectiveness of the design basis safety functions described in the SAR. This guidance provides detailed criteria for use by Part 50 licensees for evaluating whether codes and standards previously approved by the NRC are "approved for the intended application" and can be used without submitting an amendment for approval. Guidance is provided in this reference section for evaluating the type of analysis being performed and the applicable terms, conditions, and limitations for use consistent with the basis for prior NRC approval. Given the level of detail provided in this reference, and the fact that this guidance is established guidance that has been previously endorsed by the staff, the staff finds that the applicability of this guidance for the intended purpose proposed by LES to be acceptable.

- Provision to evaluate an increase in the frequency of occurrence of an accident previously evaluated in the ISA. The implementing guidance defines what a negligible effect on the frequency of occurrence is and under what circumstances an increase is considered not to occur. The guidance provided by LES is consistent and applicable to currently established practices for evaluating changes to frequency of occurrence for an accident and therefore is acceptable to the staff.
- Provision to evaluate an increase in the likelihood of occurrence of a malfunction of items relied on for safety (IROFS) previously evaluated in the ISA. The implementing guidance proposed by LES provides reference to NEI 96-07, Section 4.3.2. Section 4.3.2 provides guidance on determining when more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component important to safety results. The implementing guidance also defines what a negligible effect on the likelihood of occurrence of a malfunction of an IROFS is and under what circumstances an increase is considered not to occur. The guidance provided by LES is consistent and applicable to currently established practices for evaluating changes to the likelihood of occurrence of a malfunction of an IROFS and therefore is acceptable.
- Provision to evaluate an increase in the consequences of an IROFS malfunction or an accident previously evaluated in the ISA. The implementing guidance proposed by LES provides reference to NEI 96-07, Section 4.3.3. Section 4.3.3 provides guidance for determining when more than minimal increases in the consequences of an accident results. The implementing guidance also contains reference to the Part 70 performance requirements and specifies that consequences not meeting those thresholds are not considered increases for the purpose of determining the need for a license amendment. The staff believes that the guidance provided by LES is consistent and applicable to currently established practices for evaluating an increase in consequences for an accident and provides reasonable criteria for evaluation and therefore is acceptable.
- Provision to evaluate whether the change creates a possibility for a different type of accident than previously evaluated in the ISA. The staff believes that inclusion of the criteria for evaluating the effectiveness of a change to the SAR supports the intent of the guidance in RG 3.74 for determining whether changes require submittal of a license amendment and is acceptable.
- Provision to evaluate whether the change could result in a departure from a method of evaluation described in the SAR used in establishing the design bases for safety functions. The implementing guidance proposed by LES provides reference to NEI 96-07, Section 3.4. Section 3.4 provides guidance for determining when previously approved NRC methods can be used without prior NRC approval. Similar to Section 4.3.8.2, this guidance provides detailed criteria for use by Part 50 licensees for evaluating whether methods of evaluation previously approved by the NRC are

"approved for the intended application" and can be used without submitting an amendment for approval. LES also commits that no changes to the NRC approved ISA methodology described in the SAR can be made without submitting an amendment. The staff believes that the guidance provided by LES is consistent and applicable to currently established practices for evaluating whether the change could result in a departure from a method of evaluation and limits changes not requiring prior approval to changes in methods not including the ISA methods for evaluation and therefore is acceptable.

- Provision to evaluate if a change does not result in a decrease in the effectiveness of safety commitments described in the SAR. This commitment is also consistent with the RG 3.74 guidance with similar criteria provided by LES in their proposed LC. The staff believes inclusion of the criteria in the implementation process is consistent with the provisions provided in the proposed LC 30 provided by LES and is acceptable.
- Provision to evaluate whether the change does not conflict with current regulations or any condition specifically stated in the license. The staff believes that evaluation of these criteria is consistent with the guidance provided in RG 3.74, Section 5, and is reasonable and applicable. Inclusion of these criteria is therefore acceptable to the staff.
- A commitment to document the evaluations for determining whether NRC prior approval is required and maintain records of the evaluations on site. This commitment is recommended in the guidance in RG 3.74 Section 5. This commitment allows the staff to assess implementation of the process proposed by LES for changes to the SAR and is acceptable.
- With the commitment to submit a summary of changes that were made that did not require NRC prior approval to the NRC every six months. This commitment is also consistent with the recommended guidance in RG 3.74, Section 5, and is therefore acceptable.

5.0 CONCLUSION

The NRC staff has reviewed the information provided by LES in its March 20, 2012, and May 24, 2012, letters and finds that the proposed LC has been drafted in accordance with the guidance in RG 3.74, "Guidance for Fuel Cycle Facility Change Processes," and the information provided in the February 3, 2012, NRC letter to LES. In addition, LES's proposed LC is similar to LCs to address this matter that have been previously approved by the NRC for other applicants and licensees. The NRC staff finds that the process for tracking changes to the licensing basis documents, the timeliness required for updating the onsite documentation, and the timeframe for reporting changes not needing NRC prior approval to the NRC are reasonable and consistent with the guidance in RG 3.74. The NRC staff finds that the commitment to perform and document the evaluation for determining the need for prior approval of changes is acceptable. The staff also performed a review of the implementing process for evaluating the need for NRC prior approval. The staff finds that the description of the process that will be used to evaluate changes is reasonable and contains sufficient detail to adequately evaluate the need for prior NRC approval of changes to the SAR. The implementing guidance proposed by LES is similar in many cases to the criteria in 10 CFR 50.59(c)(2) that addresses evaluation of changes to the final safety analysis report at nuclear power stations. Therefore, the NRC staff finds that LES's proposed amendment and LC for making changes to the licensing basis documents is acceptable and, provides reasonable assurance for the health and safety of the public, workers, and the environment. The staff acceptance requires that additional text be added to LC 30 to include the commitment to follow the guidance and commitments described in Enclosure 1 of

the May 24, 2012, letter (Amendment 56 to SNM-2010). The staff finds that the implementing guidance process proposed by LES is reasonable, comprehensive, consistent with current guidance, and provides reasonable assurance that, if implemented properly, will meet staff expectations and regulatory requirements.

Principal Contributors:

Kevin Morrissey, NMSS/FCSS/MODB
Michael Raddatz, NMSS/FCSS/UEB