

January 31, 2012

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

SUBJECT: ISSUANCE OF REGULATORY GUIDE 3.74 "GUIDANCE FOR FUEL CYCLE FACILITY CHANGE PROCESSES"

Dear Mr. Rad:

The addition of Subpart H, to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70 over 10 years ago has resulted in an evolutionary process for both the review and regulatory oversight of fuel cycle facilities by the U.S. Nuclear Regulatory Commission (NRC) staff. This has been a learning process for both the NRC staff and all stakeholders, and has recently resulted in staff issuing new guidance regarding the fuel cycle facility change process to ensure the effective, efficient, and consistent oversight of licensees when reviewing compliance with 10 CFR 70.72.

Recently, a review by staff regarding a licensee's ability to make changes to its licensing basis documents, using the requirements of 10 CFR 70.72, has concluded that the use of this regulation for making changes to those documents and evaluating the need for prior NRC approval using that regulation is not applicable. Licensing basis documents are not part of 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.

Regulatory Guide¹ (RG) 3.74, "Guidance for Fuel Cycle Facility Change Processes," was issued, in final, on December 29, 2012. This guide addresses the 10 CFR 70.72 change process and provides guidance on its implementation, as well as a process for making changes to licensing basis documents. As a reminder, the NRC issues regulatory guides to describe and make available to the licensees (and in fact all stakeholders) methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations¹.

In this case, the issuance of this RG documents one acceptable way for a licensee to change, without prior NRC approval, licensing basis documents (such as their License Application (LA) and supporting documents). This method involves the licensee requesting an amendment to their license. This amendment would describe both the process and the criteria for evaluating whether changes would require prior NRC approval. It would also

¹ Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

describe the documentation requirements for the evaluation and the time period that a summary of the changes made would be provided to NRC.

If you chose to submit an amendment request, we suggest that you review the guidance in RG 3.74. As discussed in the RG, the licensee may choose to request that a license condition to be added to their license allowing them to make changes to licensing basis documents without prior NRC approval. The basis for such a license condition that the staff has found acceptable is if the change:

- Does not decrease the level of effectiveness of the design basis as described in the LA;
- Does not result in a departure from a method of evaluation described in the LA used in establishing the design bases;
- Does not result in a degradation in safety;
- Does not affect compliance with applicable regulatory requirements; and
- Does not conflict with an existing license condition.

A request for such a license condition should consider all the requirements of 10 CFR Part 70 and address the following:

1. The LA² should be maintained so that it is accurate and up-to-date. This should be controlled and documented by both approved methods and written procedures such as a configuration management processes.
2. Any change to the facility or its processes should be evaluated, before the change is implemented, to determine whether an application for an amendment to the LA is required.
3. If a change to the LA is made, the affected onsite documentation should, per written procedures, be updated promptly. The licensee should maintain records of changes to its facility, and these records should, at a minimum, include a written evaluation providing the bases for the determination that the changes to the LA did not require prior NRC approval. These records should be maintained until termination of the license.
4. Changes should be communicated to the NRC as follows:
 - For changes that require NRC pre-approval, the licensee should submit an amendment request to the NRC in accordance with 10 CFR 70.34.
 - For changes that do not require NRC pre-approval, the licensee should submit to the NRC on a periodic basis, generally annually or less, a summary of the changes to the licensing documents.

² LA also refers to all supporting documentation, not explicitly described in 10 CFR 70.72.

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/

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

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

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

Sincerely,
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Brian W. Smith, Branch Chief
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