



Nuclear Regulatory Commission
Exhibit # - NRC000115-MA-BD01
Docket # - 07003103 | 07007015
Identified: 01/25/2011

Admitted: 01/25/2011
Rejected:

Withdrawn:
Stricken:

NRC000115

February 11, 2009

Mr. Stephen Cowne, Director
Quality and Regulatory Affairs
Louisiana Energy Services, LLC
P.O. Box 1789
Eunice, NM 88231

SUBJECT: APPROVAL OF LOUISIANA ENERGY SERVICES PART 21 EXEMPTION
REQUEST AND AMENDMENT 13 TO LICENSE

Dear Mr. Cowne:

On August 27, 2008, Louisiana Energy Services (LES) transmitted a "Request for Exemption from Definition of Commercial Grade Item" to the U.S. Nuclear Regulatory Commission (NRC) for review and approval. On November 21, 2008, resubmitted its request for exemption and on November 24, 2008, responded to an NRC request for additional information transmitted to LES on October 27, 2008.

In the exemption request, LES requested an exemption from the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR), Section 21.3, for modification of the definition of "commercial grade item" to enable LES to more effectively procure certain unique components for its gas centrifuge uranium enrichment facility. LES requested that it be allowed the same definition for "commercial grade item" as is allowed in the 10 CFR 21.3 for nuclear power plants.

A Safety Evaluation Report of the staff's review of the exemption request is attached in Enclosure 1. Based on its review, the staff finds that the use of a revised definition of commercial grade item does not adversely affect public health and safety. Therefore, the use of commercial grade items by LES, which are properly dedicated, is acceptable. Further, the staff considered the requirements of 10 CFR Part 21.7 and finds that granting this exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest. Therefore, the staff finds the request acceptable and is attaching Amendment 13 of the License.

In the exemption request, LES committed to amend its Quality Assurance Program Description to incorporate new definitions applicable to the exemption request and to assume full responsibility as the dedicating entity. New License Condition 28 has been added to the License to reflect the requested revised definitions applicable to commercial grade items and require the Licensee to submit a license amendment request to modify the Quality Assurance Program Description in accordance with the above commitments. The amended License is attached under Enclosure 2.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(11).

S. Cowne

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Document Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions, please contact Mr. Timothy C. Johnson at (301) 492-3121.

Sincerely,

/RA/

Daniel H. Dorman, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Safety Evaluation Report
2. Amendment 13 to License

Docket No.: 70-3103

License No.: SNM-2010

cc:

William Szymanski/DOE
Gary Don Reagan/Hobbs
Cindy Padilla/NMED
Glen Hackler/Andrews
Gary Schubert/Lea County
Michael Marriotte/NIRS
Jon Goldstein/NMED
Tannis Fox/NMED
Lindsay Lovejoy/NIRS

Alton Dunn/Jal
Daniel Stenger/H&H
Betty Rickman/Tatum
John Parker/NMED
Richard Ratliff/Texas
CO'Claire/Ohio
Joseph Malherek/PC
Patricia Madrid/NMAG
Clint Williamson/LES

Gregory Smith/LES
David Trujillo/Lovington
Reinhard Hinterreither/LES
Matt White/Eunice
Lee Cheney/CNIC
Roger Mulder/Texas
Ron Curry/NMED
Glen Smith/NMAG

S. Cowne

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Lindsay Lovejoy/NIRS	Clint Williamson/LES	

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NAME	TCJohnson	VWilliams	JDeJesus	BJones	BSmith	MTschiltz	DDorman
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OFFICIAL RECORD COPY

DOCKET: 070--3103

LICENSEE: Louisiana Energy Services, LLC
Eunice, New Mexico

SUBJECT: SAFETY EVALUATION REPORT: PART 21 EXEMPTION REQUEST, DATED
AUGUST 27, 2008 (TAC L32462)

BACKGROUND

On August 27, 2008, Louisiana Energy Services (LES) requested an exemption from the requirements in Title 10 of the Code of Federal Regulations (10 CFR), Section 21.3, for modification of the definition of "commercial grade item" to enable LES to more effectively procure certain unique components for its gas centrifuge uranium enrichment facility. In response to a U.S. Nuclear Regulatory Commission (NRC) request for additional information (RAI), dated October 27, 2008, on November 21, 2008, LES re-submitted its exemption request proposing alternate language for the definition of "commercial grade item." On November 24, 2008, LES provided a response to the RAI.

DISCUSSION

LES is in the process of preparing procurements for long-lead time components for their uranium enrichment facility and desire to use the commercial grade dedication process for certain unique components for this facility.

The definition of commercial grade items in 10 CFR Part 21.3, which applies to a 10 CFR Part 70 facility, states that a "commercial grade" item means an item that is: (i) not subject to design or specification requirements that are unique to those facilities or activities; (ii) used in applications other than those facilities or activities; and (iii) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published description. Because the LES facility has unique requirements for equipment that are safety significant (i.e., Items Relied On For Safety), the definition restricts LES' ability to use commercial grade dedication. The Licensee also stated in its exemption request that items (i) and (iii) stated above, are unnecessarily restrictive for defining commercial grade items and would greatly complicate, and in some cases, prohibit necessary procurement of certain components to support the design, construction, and safe operation of the facility. The Licensee stated that many of the manufacturers and suppliers of equipment that are needed to construct the facility (including foreign suppliers) do not have a 10 CFR Part 50, Appendix B, quality assurance program because of the high cost of maintaining and implementing such a program, and the relatively small demand (the facility is one of only two gas centrifuge uranium enrichment facilities currently under construction in the United States). Additionally, these manufacturers and suppliers do not have the evaluation and notification processes in place that would satisfy the requirements of 10 CFR Part 21.

In 1995, in response to a petition filed on behalf of nuclear power plant operators, NRC revised 10 CFR Part 21 to add more flexibility in using commercial grade items for safety-related services for nuclear power plants. See Statements of Consideration (SOC), Federal Register, Volume 60, page 48369 (September 19, 1995).

NRC determined that the definition of commercial grade item previously used for nuclear power plants, which is currently in place for fuel cycle facilities, resulted in very limited use of the commercial grade item designation. In order to provide greater flexibility in using commercial grade items for safety-related service by nuclear power plant licensees, NRC replaced the previous definition with a new definition. Additionally, the SOC stated that “for facilities licensed pursuant to 10 CFR Part 70, the existing definition is retained, although proposed revisions to Part 21 for application to these facilities and activities are under consideration in a separate rulemaking” (p. 48372).

The SOC also stated that “the commercial grade item”, when properly and successfully dedicated, is deemed by NRC to be equivalent in its safety function performance to the same or a similar item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program”. Therefore, the use of commercial grade items for the facility, which are properly dedicated, are deemed to be equivalent to those which would be manufactured under a 10 CFR Part 50, Appendix B, quality assurance program and does not adversely affect public health and safety.

LES has committed to revising its Project Quality Assurance Plan Description (QAPD) to specify the revised definition of commercial grade item, along with associated definition clarifications (i.e., basic component, critical characteristics, dedicating entity, and dedication).

Further, LES committed to do the following: “In cases where LES applies the commercial grade item procurement strategy and performs the dedication process, LES would assume full responsibility as the dedicating entity.” These commitments are integral to successful performance of a commercial grade dedication process.

Based on the above, NRC is imposing the following license condition:

“The Licensee is exempted from the definitions of “commercial grade item,” “basic component,” “critical characteristics,” “dedicating entity,” and “dedication” in 10 CFR 21.3, as replaced by the following:

Commercial grade item: A commercial grade item means a structure, system, or component, or part thereof that affects its Items Relied on for Safety (IROFS) function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

Basic component: A basic component means a structure, system, or component, or part thereof that affects their IROFS function, that is directly procured by the licensee or activity subject to the regulations in part 70 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission would create a substantial safety hazard (i.e., exceed performance requirements of 10 CFR 70.61). In all cases, basic components include IROFS-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Critical characteristics: Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended IROFS function.

Dedication: Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

Dedicating entity: Dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where the Licensee applies the commercial grade item procurement strategy and performs the dedication process, the Licensee would assume full responsibility as the dedicating entity.

Prior to implementing the above commercial grade procurement strategy and dedication process, the Licensee shall submit a license amendment request to the NRC for approval amending its QAPD to include its commitments described in its exemption request submittals dated November 21, 2008, and November 24, 2008.”

With the above proposed license condition, the staff finds the exemption request acceptable.

ENVIRONMENTAL REVIEW

The changes are considered administrative in nature. The staff has determined that the changes are categorically excluded from the requirement to prepare a site-specific environmental assessment. Therefore, in accordance with 10 CFR 51.22(c)(11), neither an environmental assessment nor an environmental impact statement is warranted for this action.

CONCLUSION

Based on the above considerations and the proposed license condition, the staff finds that the use of the revised definitions related to commercial grade items does not adversely affect public health and safety. Therefore, the use of commercial grade items by LES, which are properly dedicated, are deemed to be equivalent those which would be manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. LES is committing to revise its QAPD and to assume full responsibility as the dedicating entity. Further, the staff considered the requirements of 10 CFR Part 21.7, and finds that granting this exemption is authorized by law

and will not endanger life or property or the common defense and security and is otherwise in the public interest. Therefore, with the proposed license condition above, the staff finds the request acceptable, and recommends approval of the exemption.

PRINCIPAL CONTRIBUTORS

Jonathan DeJesus
Paul Bell
Wilkins Smith