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Director
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
11555 Rockville Pike
Rockville, MD 20852

Louisiana Energy Services, LLC
National Enrichment Facility
NRC Docket No. 70-3103

Subject: Re-Submittal of the Louisiana Energy Services' Request for Exemption from Definition of Commercial Grade Item

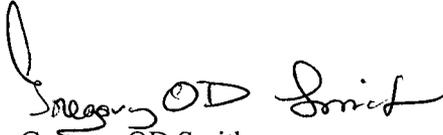
- Reference:
- 1) NEF-08-00162-NRC, Letter from LES to NRC, Request for Exemption from Definition of Commercial Grade Item, dated August 27, 2008.
 - 2) NRC Letter titled LES Request for Additional Information on Part 21 Exemption Request, dated October 27, 2008.
 - 3) NEF-08-00297-NRC, Letter from LES to NRC, Response to NRC Request for Additional Information (RAIs) for the NEF Request for Exemption for Exemption from Definition of Commercial Grade Item.

Louisiana Energy Services (LES) hereby submits its revised request for an exemption from 10 CFR 21.3 *commercial grade item*, as described in more detail in Enclosure 1 to this letter. In this revised request, LES adopts the definition of commercial grade item to that in 10 CFR 21.3 for nuclear power plants licensed under 10 CFR 50 (with the exception for substituting "Items Relied On For Safety (IROFS)" for "safety". The exemption request provided in Enclosure 1 has change bars in the margins to denote changes in text from the previous request. Other minor editorial changes were also incorporated. The requested exemption will provide needed flexibility in procurement for construction of the National Enrichment Facility (NEF) in Eunice, NM in a fiscally prudent and efficient manner.

The requested exemption is authorized by 10 CFR 21.7, "Exemptions," which provides for exemptions that are authorized by law, will not endanger life, property, or the common defense and security, and are otherwise in the public interest. Enclosure 1 to this letter demonstrates that the requested exemption meets each of these requirements. The enclosure also identifies the specific requirements of the regulation for which an exemption is requested and provides the associated justification. Approval of the exemption is requested by January 15, 2009 or as soon as possible thereafter to allow procurement of long lead-time components to proceed consistent with the construction schedule for the NEF.

If you have any questions, please contact Stephen Cowne, Director of Quality and Regulatory Affairs at (575) 394-5253.

Sincerely,



Gregory OD Smith
Chief Operating Officer and Chief Nuclear Officer

Enclosure: 10 CFR 21.3 Exemption Request

cc/ with enclosure:

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Enclosure 1: 10 CFR 21.3 Exemption Request

Background

Louisiana Energy Services (LES) is preparing for procurement of components for the National Enrichment Facility (NEF) in Eunice, NM. In accordance with 10 CFR 21.31, Procurement Documents, each procurement document for a basic component must specify that the provisions of 10 CFR Part 21 apply. Each supplier of a basic component for the NEF subject to 10 CFR Part 21, is required by 10 CFR 21.21 (a) to adopt procedures to evaluate deviations and failures to comply and notify the Commission of any deviations and failures to comply that are associated with a substantial safety hazard, unless an exemption applies. An exemption is provided by 10 CFR 21.7 for suppliers of commercial grade items.

LES is building a gas centrifuge enrichment facility using many components which are of European design and manufacture. Because of the high cost of maintaining and implementing an Appendix B quality assurance program, coupled with a relatively small demand, many of the manufacturers and suppliers of equipment necessary to construct the NEF presently neither implement or plan to implement quality assurance programs which fully meet US regulatory standards. These suppliers have quality programs which meet international standards and have provided products with a demonstrated high reliability to facilities similar to NEF in Europe. However they do not plan to deploy evaluation and notification procedures that satisfy the reporting requirements of Part 21.

Based on the current Part 21.3 (2) definition for Part 70 facilities, *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 product description (for example, a catalog).*

Parts (i) and (iii) are unnecessarily restrictive for defining commercial grade items. This definition of a commercial grade item for Part 70 facilities greatly complicates and in some cases prohibits necessary procurement of certain components to support the design, construction and safe operation of the NEF. Some NEF components will be subject to unique design or specification requirements, based upon their critical IROFS functions for their intended application in the NEF system.

For example, LES will need to procure centrifuge casings and process piping. These components possess unique characteristics and are available to the NEF from only one source, Enrichment Technology Corporation (ETC), a partially owned subsidiary of URENCO. URENCO is the parent company of LES. The casings and process piping will provide a confinement boundary as described in the Integrated Safety Analysis (ISA) therefore, must also be designed to satisfy our seismic requirements. ETC provides the design and specifications for these components direct

from ETC owned facilities or from subcontractors controlled by ETC. These components are unique to our Part 70 licensed facility. Given the dual use nature of many of these components they may not be ordered from the manufacturer/supplier on the basis of specifications set forth in a manufacturer's published product description, nor does the manufacturer publish a product catalog describing these components. The manufacturer/supplier can provide the components in full compliance with the NEF specifications (which in this case are ETC specifications) but only offer the item as a commercially available item not subject to 10 CFR 50, Appendix B Quality Assurance Criteria and Part 21.

When applying the requested Specific Exemption Request discussed below, LES proposes to procure these items as a commercial grade item and assume full responsibility as the dedicating entity for compliance with the evaluation and reporting requirements of Part 21. As the dedicating entity, LES would evaluate identified potential defects or failures to comply for creation of a substantial safety hazard. For LES, a substantial safety hazard is a deviation that affects the ability of an IROFS to meet the applicable performance criteria of 10 CFR 70.61.

In 1995, in response to a petition filed on behalf of operators of nuclear power plants, the Commission determined that the definition of commercial grade item was unnecessarily restrictive, and resulted in very limited use of the commercial grade item designation. The Commission adopted a new definition of commercial grade item for nuclear power plants to provide added flexibility in using commercial grade items for safety-related service.

The amended definition added flexibility only for nuclear power plants and did not change the requirements applicable to other facilities and activities. In response to a comment from the public that the new definition should also apply to such other facilities and activities, the Commission stated that proposed changes for nonreactor licensees are currently being considered. (60 Fed. Reg. 48,370 -371 Sept. 19, 1995). No such changes have been adopted. LES has identified the urgent need for, and is requesting, an exemption from paragraph (2) of 10 CFR 21.3 "Commercial grade item" that is consistent with the added flexibility given to Nuclear Power Plants. This exemption request will support procurement of components for the NEF in a fiscally prudent manner and not adversely impact the NEF construction schedule.

Specific Exemption Request

In accordance with 10 CFR 21.7, "Exemptions," LES requests NRC approval of an exemption from the requirements of 10 CFR 21.3, "Definitions," *Commercial grade item*, paragraph (2). In lieu of the definition of commercial grade item for facilities and activities licensed under Part 70, LES will, upon exemption approval, revise the NEF Project Quality Assurance Plan (QAP) to specify a different definition of commercial grade item along with associated definition clarifications, based on the definition applicable to nuclear power plants in 10 CFR 21.3, "Definitions," *Commercial grade item*, paragraph (1). The revised QAP would provide the same added flexibility in procuring commercial grade items for safety related (or IROFS) service as the Commission provided for nuclear power plant licensees when it amended the definition of commercial grade item in September 1995. LES would use the following definition of 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)."

As described above, some NEF components are designed and specified by vendors such as ETC. Where such components are designated as Items Relied On_For Safety (IROFS), LES will commercially dedicate the items using one or more acceptance methods to verify the critical characteristics related to the IROFS function of the item. Inspections, tests and special process verifications performed by the vendor may be credited for control of critical characteristics on the basis of a commercial grade survey performed in accordance with the LES Quality Assurance Plan.”

Other terms in Part 21 also need clarification to provide consistency with the above definition of commercial grade item. These terms (basic component, critical characteristics, dedicating entity and dedication) are defined below consistent with their applicability to the NEF.

Basic component. (2) When applied to LES NEF licensed under 10 CFR 70, 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 70.6 1).

(3) In all cases, basic components includes 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. When applied to LES NEF licensed pursuant to 10 CFR 70, 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. When applied to LES NEF licensed pursuant to 10 CFR 70, 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. When applied to LES NEF licensed pursuant to 10 CFR 70, 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 failures to comply for the dedicated item, and maintaining auditable records of the dedication process. 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.

The ability to employ the proposed definition of commercial grade item along with associated definition clarifications would provide LES with increased flexibility to apply the commercial grade item procurement and dedication strategy for equipment procurements where the equipment would not meet the present definition applicable for Part 70 licensees. This flexibility is particularly necessary in situations, in which, few or no suppliers are available with appropriate 10 CFR 50 Appendix B QA Programs and Part 21 procedures. The proposed definition would remove unnecessary restrictions and allow LES to employ an equally controlled and safe approach to item procurement.

The Requested Exemption is Authorized by Law

The NRC has the authority under the Atomic Energy Act to grant exemptions for its regulations if doing so would not violate the requirements of law. This exemption is authorized by law as is required by 10 CFR 21.7. No law exists that precludes the activities covered by this exemption request. The provisions of 10 CFR 21.3, "Definitions," Commercial grade item, paragraph (2) were adopted at the discretion of the Commission consistent with its statutory authority. No statute requires the NRC to adopt the specific provisions from which LES seeks an exemption. Rather, the NRC may determine that alternative means are adequate to provide reasonable assurance of safety. The Requested Exemption Will Not Endanger Life, Property, or the Common Defense and Security in adopting the revised definition of commercial grade item for nuclear power plants in 1995, the Commission determined that a commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or similar item designed and manufactured under a Part 50 Appendix B quality assurance program. 60 Fed Reg. 48,372 (Sept. 19, 1995). Since then, procurement of commercial grade items using the more flexible definition of commercial grade item has been successfully implemented by Part 50 licensees. As a result, implementation of a similar procurement process by LES also will not endanger life, property, or the common defense and security.

The Requested Exemption is in the Public Interest

The requested exemption is in the public interest because it will allow LES to implement a controlled and safe approach to item procurement that will support the LES goal of constructing the NEF in a timely and cost efficient manner. The overall result of not granting the exemption will be the delayed completion of procurement activities, and associated economic losses, without any safety benefit. Therefore, granting the requested exemption is in the public interest.

Conclusion

As demonstrated above, the requested exemption is authorized by law, will not endanger life, property, or the common defense and security, and is otherwise in the public interest. Since the provisions of 10 CFR 21.7 are satisfied, the requested exemption should be granted.