

July 28, 2010

Mr. James A. Kay, Licensing Manager  
Eagle Rock Enrichment Facility  
AREVA Enrichment Services, LLC  
400 Donald Lynch Boulevard  
Marlborough, MA 01752

SUBJECT: APPROVAL OF AREVA ENRICHMENT SERVICES' PART 21 EXEMPTION REQUEST (TAC L32744)

Dear Mr. Kay:

On January 29, 2010, AREVA Enrichment Services, LLC (AES) transmitted a "Request for Exemption from 10 CFR 21.3, Definitions, for Commercial Grade Item, Basic Component, Critical Characteristic, Dedication, and Dedicating Entity" to the U.S. Nuclear Regulatory Commission (NRC) for review and approval.

In the exemption request, AES requested an exemption from the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR), Section 21.3, definitions for commercial grade item, "basic component," "critical characteristic," "dedication," and "dedicating entity." Approval of this exemption would enable AES the needed flexibility for procurement of components for construction of the Eagle Rock Enrichment Facility (EREF) in Bonneville County, Idaho. AES 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 AES, 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's interest. Therefore, the staff finds the request acceptable.

In the exemption request, AES committed to supplement its Quality Assurance Program Description to reflect the commitments made in this exemption request prior to implementing the 10 CFR Part 21 exemption. This supplement will incorporate the revised definition of commercial grade item—along with associated definition clarifications for basic component, critical characteristics, dedicating entity, and dedication—and implement a revised commercial grade item procurement strategy and dedication process, in which AES or its approved sub-contractor will assume full responsibility as the Dedicating Entity in cases where AES or its approved sub-contractor applies the commercial grade item procurement strategy.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(I).

This letter closes TAC L32744.

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 Breeda Reilly at (301) 492-3110 or via email to [breeda.reilly@nrc.gov](mailto:breeda.reilly@nrc.gov).

Sincerely,

**/RA/ Marissa Bailey for**

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

Enclosure: As stated

Docket No.: 70-7015

cc: Mr. James Curtiss, Curtiss Law  
Mr. Greg Harper, AES  
Mr. Sam Shakir, AES

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**\*via email**

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LICENSEE: AREVA Enrichment Services, LLC

SUBJECT: SAFETY EVALUATION REPORT: PART 21 EXEMPTION REQUEST, DATED JANUARY 29, 2010 (TAC L32744)

## BACKGROUND

By letter dated January 29, 2010, Byproduct, Source, and Special Nuclear Material license applicant, AREVA Enrichment Services, LLC (AES), submitted a request for exemption from the definitions in Title 10 of the *Code of Federal Regulations* (10 CFR) 21.3, for commercial grade item to enable AES to more effectively procure certain unique components for its gas centrifuge uranium enrichment facility. AES's submittal includes the proposed definitions for commercial grade item, basic component, critical characteristics, dedication, and dedicating entity that AES would use in lieu of the current 10 CFR 21.3 definitions. A conference call was held on April 27, 2010, and two items requiring clarification were discussed and resolved.

## DISCUSSION

AES is planning for the procurement of long-lead time components for the Eagle Rock Enrichment Facility (EREF) and wants to use the commercial grade dedication process for certain unique components.

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. The definition of commercial grade in 10 CFR 21.3 restricts AES's ability to use commercial grade dedication of items relied on for safety (IROFS). AES states 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 applicant states that the proposed definitions would allow AES to employ an equally controlled and safe approach to item procurement that is more economical. Additionally, the applicant stated that the proposed definitions will increase the flexibility to apply the definition of commercial grade item procurement strategy for equipment procurements where the equipment would not meet the definition applicable for Part 70 licensees; and in situations in which few or no suppliers are available with the U.S. Nuclear Regulatory Commission's (NRC) approved Quality Assurance (QA) Programs and Part 21 procedures.

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).

The 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. 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, QA Program. As a Part 70 facility, EREF will not have a Part 50 QA Program; however, the EREF Quality Assurance Program Description (QAPD) was reviewed and accepted by the NRC for application to the design, construction, operation , and decommissioning of the proposed EREF in a letter dated April 8, 2010. The applicant has stated that in all cases the applicable provisions of the EREF QAPD will be used to conduct the dedication process. 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 QA Level 1 and QA Level 2 requirements in accordance with the EREF QAPD and does not adversely affect public health and safety.

As discussed in the conference call on April 27, 2010, and referenced in the meeting summary dated May 6, 2010, AES considers all QA Level 1 IROFS and all QA Level 2 IROFS that involve hardware to be basic components. The NRC staff notes the change of the term “could” in reference to creating a substantial safety hazard to “would” in the proposed definition for basic component and does not identify a meaningful differentiation between the terms; the applicant is required to notify the NRC of any defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

AES has committed to revising its 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).

AES proposes replacing the definitions in 10 CFR 21.2 with 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 QA Level 1 or QA Level 2 requirements in accordance with the EREF QAPD. 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 hold points at the manufacturer's facility; and analysis of historical records for acceptable performance. In all cases, the applicable provisions of the EREF QAPD will be used to conduct the dedication process. 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.

Further, AES has committed to do the following: "In cases where AES or approved sub-contractors applies the commercial grade item procurement strategy and performs the dedication process, AES or its approved sub-contractor would assume full responsibility as the dedicating entity." These commitments are integral to successful performance of a commercial grade dedication process.

Prior to implementing the above commercial grade procurement strategy and dedication process, the applicant has committed to supplement its QAPD to reflect the commitments made in the exemption request dated January 29, 2010. The applicant shall submit the revised QAPD to NRC.

## ENVIRONMENTAL REVIEW

The NRC staff has determined that the changes are administrative in nature. The regulation in 10 CFR 51.22(c) (25)(vi)(I) allows for a categorical exclusion if the following requirements have been satisfied:

- (i) There is no significant change in the types, or significant increase in the amounts, of any effluents that may be released offsite;
- (ii) There is no significant increase in individual or cumulative occupational radiation exposure;
- (iii) There is no significant construction impact ; and
- (iv) There is no significant increase in the potential for, or consequences from, radiological accidents.

The changes to the definitions in 10 CFR Part 21 do not pose a significant change or increase in the parameters (i) through (iv), as identified above. There are no changes in the types of or increases in the amount of effluents. Occupational exposure is expected to remain the same. These changes involve no additional construction activity; and the potential for, and consequences from, radiological accidents are expected to be the same.

Based on this evaluation, the exemption request is eligible for categorical exclusion. Therefore, in accordance with 10 CFR 51.22(c)(25)(vi)(I), neither an environmental assessment nor an environmental impact statement is warranted for this action.

### CONCLUSION

Based on the above considerations, the staff finds that the use of the revised definitions related to commercial grade items does not adversely affect public health and safety. The use of commercial grade items by AES, which are properly dedicated, are deemed to be equivalent to those which would be designed and manufactured under the QA Level 1 or QA Level 2 requirements of the EREF QAPD. AES has committed to revising its QAPD and to assuming 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's interest. Therefore, the staff finds the request acceptable and approves the exemption.

### PRINCIPAL CONTRIBUTORS

Jeannette Arce  
Breeda Reilly  
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