



10 CFR 21.7

January 29, 2010

AES-O-NRC-10-00081-0

ATTN: Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

AREVA Enrichment Services LLC  
Eagle Rock Enrichment Facility  
NRC Docket No: 70-7015

Subject: Request for Exemption from 10 CFR 21.3, Definitions, for "Commercial Grade Item, Basic Component, Critical Characteristic, Dedication, and Dedicating Entity."

On December 30, 2008 (Ref. 1), as revised on April 23, 2009 (Ref. 2), AREVA Enrichment Services LLC (AES) submitted a License Application to construct and operate the Eagle Rock Enrichment Facility (EREF) to the U.S. Nuclear Regulatory Commission (NRC). Under the current regulations in 10 CFR 70, the needed flexibility for commercial grade dedication, as is allowed in 10 CFR 21.3 for nuclear power plants, is not provided.

Pursuant to 10 CFR 21.7, AES hereby submits a request for an exemption from 10 CFR 21.3 to modify the definition of "Commercial Grade Item, Basic Component, Critical Characteristic, Dedication, and Dedicating Entity", as described in more detail in the enclosure to this letter. The requested exemption will provide needed flexibility for procurement of components for construction of the EREF in Bonneville County, Idaho. Allowing AES to use the same flexibility for commercial grade dedication as is allowed in 10 CFR 21.3 for nuclear power plants will not adversely affect public health and safety.

The requested exemption, provided in the enclosure, concludes that modifications from the definitions contained in 10 CFR 21.3 for "Commercial Grade Item, Basic Component, Critical Characteristic, Dedication, and Dedicating Entity", is authorized by law, will not endanger life, property, or the common defense and security, and is in the public interest. The enclosure also identifies specific requirements of the regulation for which an exemption is requested and provides the associated justification.

NRC approval of the exemption is requested by June 2010 to allow procurement of long lead-time components to proceed consistent with the construction schedule for the EREF. The exemption request is similar to the exemption approved by the NRC on February 11, 2009 for Louisiana Energy Services, LLC (Ref. 3).

Following NRC approval of the exemption request, AES will 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 (1) incorporate the revised

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definition of commercial grade item, along with associated definition clarifications for basic component, critical characteristics, dedicating entity, and dedication, and (2) 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.

If you have any questions, or require additional information regarding this exemption request, please contact me at 508-573-6554.

Respectfully,



James A. Kay  
Licensing Manager

Enclosure: Request for Exemption from 10 CFR 21.3, Definitions, for Commercial Grade Item, Basic Component, Critical Characteristic, Dedication, and Dedicating Entity

References:

- 1) S. Shakir (AES) Letter to the U.S. Nuclear Regulatory Commission, Application for a Uranium Enrichment Facility License under 10 CFR 70, "Domestic Licensing of Special Nuclear Material," dated December 30, 2008.
- 2) S. Shakir (AES) Letter to the U.S. Nuclear Regulatory Commission, Revision 1 to License Application for the Eagle Rock Enrichment Facility, dated April 23, 2009.
- 3) D. Dorman (NRC) Letter to S. Cowne (LES), Approval of Louisiana Energy Services Part 21 Exemption Request and Amendment 13 to License, dated February 11, 2009.

cc: Breeda Reilly, U.S. NRC Senior Project Manager

**Enclosure to AES-O-NRC-10-00081-0**

**AREVA Enrichment Services LLC**

**Eagle Rock Enrichment Facility**

**Request for Exemption from 10 CFR 21.3, Definitions, for Commercial Grade Item,  
Basic Component, Critical Characteristic, Dedication, and Dedicating Entity**

## **Background**

On December 30, 2008 (Ref. 1), as revised on April 23, 2009 (Ref. 2), AREVA Enrichment Services LLC (AES) submitted a License Application to construct and operate the Eagle Rock Enrichment Facility (EREF) to the U.S. Nuclear Regulatory Commission (NRC). AES is planning for procurement of long lead-time components for the EREF at the Bonneville County, Idaho site, and desires to use the commercial grade dedication process for certain unique components for this facility. In accordance with 10 CFR 21.31, Procurement Documents, each procurement document for a basic component must specify that the provisions of 10 CFR 21 apply. Each supplier of a basic component for the EREF subject to 10 CFR 21, unless it is exempted, is required by 10 CFR 21.21(a) to adopt procedures to evaluate deviations and failures to comply and notify the Commission or the purchaser of any deviations and failures to comply that are associated with a substantial safety hazard. An exemption is provided by 10 CFR 21.7 for suppliers of commercial grade items.

The definition of commercial grade items in 10 CFR 21.3, which applies to a 10 CFR 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 AES facility has unique requirements for equipment that are safety significant (i.e., Items Relied On For Safety (IROFS)), the definition restricts AES' ability to use commercial grade dedication. Additionally, 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.

Many of the manufacturers and suppliers of equipment that are needed to construct the facility (including foreign suppliers) do not have an NRC approved quality assurance program because of the high cost of maintaining and implementing such a program, and the relatively small demand of 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 21.

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. To provide added flexibility in using commercial grade items for safety-related service, the Commission adopted a new definition of commercial grade item for nuclear power plants. 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. See Federal Register, Volume 60, pp. 48369 - 374 (Sept. 19, 1995). No such changes have been adopted.

AES is requesting an exemption from certain definitions of 10 CFR 21.3, Definitions, that are consistent with the added flexibility given to nuclear power plants and to support procurement of long lead-time components for the EREF. AES desires to use the commercial grade dedication process for certain unique components for this facility in a fiscally prudent manner and not adversely impact the EREF construction schedule. The exemption request is similar to the

exemption approved by the NRC on February 11, 2009, for Louisiana Energy Services, LLC (Ref. 3).

### **Introduction**

In accordance with 10 CFR 21.7, Exemptions, AES requests NRC approval of an exemption from the requirements of 10 CFR 21.3, Definitions, for "*Commercial grade item, Basic component, Critical characteristics, Dedication, and Dedicating entity.*" In lieu of the current definitions for facilities and activities licensed under 10 CFR 70, AES will, upon exemption approval, revise the AES Quality Assurance Program Description (QAPD) to specify different definitions for commercial grade item, basic component, critical characteristics, dedication, and dedicating entity, based on the definitions presented below, and (2) 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. The revised QAPD would provide the same added flexibility in procuring commercial grade items for IROFS as the Commission provided for nuclear power plant licensees when it amended the definition of commercial grade item in September 1995.

AES would use the following definitions for commercial grade item, basic component, critical characteristic, dedication, and dedicating entity. These are the same definitions that the NRC utilized in the Safety Evaluation Report associated with the approval of the exemption request for Louisiana Energy Services (Ref. 3) except for the definition of *Dedication* where the NRC approved EREF QAPD is used in place of a 10 CFR 50, Appendix B quality assurance program:

*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.

The ability to employ these proposed definitions would provide AES with increased flexibility to apply the commercial grade item procurement strategy for equipment procurements where the equipment would not meet the definition applicable for Part 70 licensees. This flexibility is particularly necessary in situations in which few or no suppliers are available with NRC approved QA Programs and Part 21 procedures. The proposed definitions for commercial grade item, basic component, critical characteristic, dedication, and dedicating entity would remove unnecessary restrictions and allow AES to employ an equally controlled and safe approach to item procurement that is more economical.

When applying the requested exemption, AES will 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, for compliance with identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process. For the EREF, 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.

#### **The Requested Exemption is Authorized By Law**

The NRC has the authority under the Atomic Energy Act to grant exemptions from 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," were adopted at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt the specific provisions from which AES 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. See Federal Register, Volume 60, page 48372 (September 19, 1995). Since then, procurement of commercial grade items using the more flexible definition of commercial grade item has been successfully implemented by 10 CFR 50 licensees. As a result, implementation of a similar procurement process by AES under Part 70 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 AES to implement a controlled and safe approach to item procurement that will support AES's goal of constructing the EREF in a timely and cost efficient manner. The overall result of not granting the exemption will be increased cost, delayed completion of procurement activities, and the associated economic losses, without any safety benefit.

Therefore, granting the requested exemption is in the public interest.

**Conclusion**

As demonstrated above, 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 AES, which are properly dedicated, would be equivalent to those which would be manufactured under an NRC approved quality assurance program. AES is committing to revise its QAPD and to apply this exemption in our commercial grade item procurement strategy. Further, 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.

Since the provisions of 10 CFR 21.7 are satisfied, the requested exemption should be granted. Approval of the exemption is requested by June 2010 to allow procurement of long lead-time components to proceed consistent with the construction schedule for the EREF.

**Commitments**

AES makes the following commitments if the requested exemption is approved:

1. Prior to implementing the above commercial grade item procurement strategy and dedication process, AES will submit a revision to the QAPD to specify the different definitions for commercial grade item, basic component, critical characteristics, dedication, and dedicating entity, based on the definitions presented in the above exemption request.
2. When applying the requested exemption, 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, for compliance with identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process.

### References

1. S. Shakir (AES) Letter to the U.S. Nuclear Regulatory Commission, Application for a Uranium Enrichment Facility License Under 10 CFR 70, "Domestic Licensing of Special Nuclear Material," dated December 30, 2008.
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