March 20, 2008

Dealis Gwyn, Licensing Manager
Shaw Areva MOX Services
Savannah River Site - F Area
Building 706-1F
Aiken, SC 29808

SUBJECT: REQUEST FOR AN EXEMPTION FROM 10 CFR Part 21.3 "COMMERCIAL GRADE ITEM"

Dear Mr. Gwyn:

We have received your request dated December 20, 2007, for an exemption from the definition of commercial grade item under 10 CFR Part 21.3 for the Mixed Oxide Fuel Fabrication Facility (MFFF), which is under construction at the Savannah River Site in Aiken, South Carolina. In accordance with 10 CFR Part 21.7, the U.S. Nuclear Regulatory Commission staff (Staff) grants the exemption. A "Safety Evaluation Report for Exemption Request to 10 CFR Part 21.3" explaining the Staff's recommendations is attached.

After careful review, the Staff determined that Shaw AREVA MOX Services (MOX Services) provided sufficient information to conclude that an exemption from the definition of commercial grade item for the MFFF under the current 10 CFR Part 21 definition for Part 70 facilities will not endanger life or property or the common defense and security, and are otherwise in the public interest (10 CFR Part 21.7). As a result, the Staff authorizes an alternate definition of commercial grade item for the MFFF as follows:

> *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).*

Additionally, the Staff expects MOX Services to fulfill the following commitments: 1) to revise the MOX Project Quality Assurance Plan to specify the revised definition of commercial grade item, along with associated definition clarifications (i.e., basic component, critical characteristics, dedicating entity, and dedication); and 2) to assume full responsibility as the dedicating entity, in cases where MOX Services applies the commercial grade item procurement strategy and performs the dedication process.

If you have any questions regarding this matter, please contact David Tiktinsky, of my staff, at (301) 492-3229 or by e-mail at dht@nrc.gov.

In accordance with 10 CFR Part 2.790 of the U.S. Nuclear Regulatory Commission's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the Public Document Room or from the Publicly Available Records component of the document system Agencywide Documents Access and Management System (ADAMS) of the USNRC. ADAMS is accessible from the website at http://www.nrc.gov/NRC/ADAMS/index.html (The Public Electronic Reading Room).

Sincerely,

/RA/

Joseph G. Giitter, Deputy Director
Special Projects and Technical
Support Directorate
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No.: 70-3098

Enclosure: Safety Evaluation Report

cc: w/o enclosure
G. Smith, NNSA
J. Olencz, NNSA
S. Jenkins, SC Dept. Of HEC
D. Silverman, Esq., MOX Services
D. Gwyn, MOX Services
A.J. Eggenberger, DNFSB
L. Zeller, BREDL
G. Carroll, Nuclear Watch South
D. Curran, Esq., Nuclear Watch South

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Safety Evaluation Report for Exemption Request to 10 CFR Part 21.3, "Definitions," Commercial Grade Item for the Mixed Oxide Fuel Fabrication Facility being Constructed by Shaw AREVA MOX Services on the Savannah River Site in Aiken, SC

DOCKET: 70-3098

1.0 Background

In February 2001, Shaw AREVA MOX Services (MOX Services or Applicant), formerly known as Duke Cogema Stone and Webster (DCS), submitted a Construction Authorization Request (CAR) to build a Mixed Oxide Fuel Fabrication Facility (MFFF) on the U.S. Department of Energy's Savannah River Site, near Aiken, South Carolina. The U.S. Nuclear Regulatory Commission (Staff) conducted environmental and safety reviews of the MFFF CAR and supporting documentation. In March 2005, the Staff issued a Construction Authorization (CA) to DCS for the MFFF. The Staff's technical basis for issuing the CA is set forth in NUREG-1821, "Final Safety Evaluation Report on the CAR for the MFFF" in March 2005. Nuclear construction at the site began on August 1, 2007.

In September 2006, MOX Services submitted a license application (LA) to possess and use radioactive material and an Integrated Safety Analysis (ISA) Summary. The Staff completed its acceptance/acknowledgment review and sent a letter to MOX Services on December 20, 2006, indicating that the application was acceptable for docketing. The LA and ISA Summary are currently undergoing a technical review.

2.0 Request for an Exemption

In a letter dated December 20, 2007, MOX Services requested an exemption from the definition of "commercial grade item" as provided in 10 CFR Part 21.3. Citing the impact on its procurement of long lead-time components for the MFFF as a basis, MOX Services proposed alternate language for a "commercial grade item", which would apply specifically to the MFFF. In response to the request, the Staff issues this Safety Evaluation Report.

3.0 Regulatory Requirement

The applicable regulatory requirement is:

10 CFR Part 21.7 Exemptions

> "The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations of this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest…"

Enclosure

4.0 Staff Review and Analysis of Exemption Request

According to MOX Services' request, they are in the process of preparing procurements for long-lead time components for the MFFF and desire to use the commercial grade dedication process as may be appropriate, for this facility. The MFFF is unique among fuel cycle facilities due to the large numbers of items relied upon for safety (IROFS) compared to other fuel cycle facilities. This is largely due to the need to provide confinement for the plutonium.

The definition of commercial grade items in 10 CFR Part 21.3, which applies to a 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 MFFF has unique requirements for equipment that are safety significant (i.e., IROFS), the definition restricts severely MOX Service's ability to use commercial grade dedication. The Applicant also stated, in its exemption request, that items (i) and (ii) 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 MFFF. As support the Applicant stated that many of the manufacturers and suppliers of equipment that are needed to construct the MFFF (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 MFFF is the only planned MOX facility 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), 60 Fed. Reg. 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. In order to provide greater flexibility in using commercial grade items for safety-related service by nuclear power plant licensees, the 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 the 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 MFFF, 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 impact public health and safety.

MOX Services has committed to revising the MOX Project Quality Assurance Plan (MPQAP) 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, MOX Services committed to do the following: "In cases where MOX Services applies the commercial grade item procurement strategy and performs the dedication process, MOX Services would assume full responsibility as the dedicating entity." These commitments are integral to successful performance of a commercial grade dedication process at MFFF.

5.0 Conclusion

Based on the foregoing analysis, the Staff finds that the use of a revised definition of commercial grade item for the MFFF does not impact public health and safety. When properly and successfully dedicated, a commercial grade item is deemed by the 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 MFFF, 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 and does not impact public health and safety. MOX Services is committing to revise its Quality Assurance plan 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 will not endanger life or property and is otherwise in the public interest. Therefore, the Staff finds the request acceptable, and recommends approval of the exemption.

6.0 Finding

The definition for "commercial grade" item for the MFFF shall state:

> *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).*

Additionally, MOX Services committed to revising its MPQAP 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, MOX Services committed to the following: "In cases where MOX Services applies the commercial grade item procurement strategy and performs the dedication process, MOX Services would assume full responsibility as the dedicating entity." These commitments are integral to successful performance of a commercial grade dedication process at MFFF.