July 31, 2012

Mr. Dealis W. Gwyn, Licensing Manager
Shaw AREVA MOX Services
P.O. Box 7097
Aiken, SC 29804-7097

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE REVIEW OF THE MOX PROJECT QUALITY ASSURANCE PLAN, REVISION 11 FOR THE MIXED OXIDE FUEL FABRICATION FACILITY

Dear Mr. Gwyn:

We have reviewed the document entitled “Revision 11 of the MOX Project Quality Assurance plan” dated May 31, 2012.

We have enclosed a list of additional information that is needed by the staff in order to complete the review of the Safety Evaluation (Enclosure 1). Please provide us with a response describing how our questions were addressed and any other changes to licensing documents that were necessary to incorporate the responses. In order for us to try and meet your requested date for this amendment, the response should be provided within 14 days of the date of this letter.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390, of the U.S. Nuclear Regulatory Commission’s (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 Documents 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).

Please contact me at (301) 492-3229 or via e-mail to David.Tiktinsky@nrc.gov, if you have any questions.

Sincerely,

/RA/

David Tiktinsky, Senior Project Manager
Mixed Oxide and Uranium
Deconversion Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-3098

Enclosure:
As stated

cc: See next page

Please contact me at (301) 492-3229 or via e-mail to David.Tiktinsky@nrc.gov, if you have any questions.

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REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE MOX PROJECT QUALITY ASSURANCE PLAN REVISION 11 DATED MAY 31, 2012

Requests for Additional Information (RAIs) related to revisions to the MOX Project Quality Assurance Plan (MPQAP) on the Items Relied On For Safety (IROFS) grading process:

RAI-1

The MPQAP revision makes reference to IROFS, IROFS control groups or structures, systems, and components, seemingly interchangeably. Please revise the plan to include an explanation of these terms and provide modifications for consistency and intent as applicable.

RAI-2

In the justification for change document provided with Revision 11 of the MPQAP, under the Title 10 of *Code of Federal Regulations* (10 CFR) 70.61 Review heading, please provide additional explanation/clarification of the following:

a. In 3), what data is being referred to that is collected and analyzed and how is that data used?
b. In 4), does complexity refer to the item in general or is this the complexity of the design or actions to perform the safety function?
c. In 6), what results are referred to that need to be reproduced?
d. Is prior or industry experience a consideration in determining the MPQAP requirements?

RAI-3

Please revise the justification document to describe the defined process and associated criteria used to evaluate the impact of augmented Quality Assurance (QA) of low safety significance ranked IROFS and meeting the requirements of 10 CFR 70.61.

RAI-4

Section 3.0 of the Augmented QA Program for IROFS provides brief descriptions of the purpose of the safety ranking process and how the process will be implemented. Revise the plan as applicable to address the following:

a) Is there a formal process used that describes in detail how the process will be implemented?
b) Is there a reference to this process that can be cited in the plan?
c) Are provisions made to evaluate and document changes to this process/methodology and do they include evaluating the need for possible U.S. Nuclear Regulatory Commission (NRC) prior approval of changes to the process?

RAI-5

In using the term failure in the justification document, is this any failure of the IROFS being referred to or only failure to perform its safety function? Please revise the justification document to clarify the terms.

RAI-6

The grading process as shown in the MPQAP revision calls for evaluation by Nuclear Safety to review design changes and their impact on the safety evaluation results. Revise the MPQAP and justification document to clarify the following:

a) Is there additional reviews performed to evaluate the impact on 10 CFR 70.61 requirements after a design change?
b) Are there any QA functional reviews?

RAI-7

Revise the MPQAP and justification document to clarify the following:

In the likelihood and consequence criteria for your IROFS grading evaluations, does frequency of the event and consequences of the event consider all possible accident sequences that the IROFS are included in? In the event of multiple accident sequences how is the process implemented?

RAI-8

Section 3 of Attachment B of the MPQAP submittal describes the IROFS Importance to Safety Ranking Process. Please provide text in the MPQAP that describes what disciplines (i.e., QA, engineering, etc.) will be involved in the performance, review, approval, and modification of IROFS ranking packages.

RAIs related to the QA program:

General

RAI-9

Section 4 of Attachment B of the MPQAP submittal states that "The provisions of sections 4, 7, 10, 17 and 18 of this QA plan apply with exceptions and clarifications as discussed in sections 5.0 thru 8.0." Please correct the reference provided to sections 5.0 through 8.0, given that these sections are identified as 4.1 through 4.4.

Procurement of IROFS/Qualification of Suppliers

RAI-10

The MPQAP Revision 11 Justification for Change states that (for IROFS ranked as having low relative safety significance) "MOX Services will rely on the national/international recognition to establish accreditation organizations capability to perform the accreditation.

Please revise your submittal to limit the scope of the request or provide additional information to support an expanded scope. For example,

- Please clarify who will be performing and what controls will be used for the evaluation of the supplier and/or subcontractor's technical and quality capability to

provide items or services based on a direct observation of his facility, personnel and implementation of their quality assurance program.

- Will the MPQAP be the basis for accreditation?
- Will MOX Services evaluate the national/international accrediting body and/or the supplier who is certified by the accrediting body based on the MPQAP?
- Please clarify the criteria that will be utilized (for review and acceptance) to determine that the evaluation performed by the accreditation body is sufficient. If the evaluation is not sufficient, what other supplemental controls/requirements will be used?

RAI-10

The MPQAP revision state that "Any characteristics requiring verification that cannot be verified at the time of receipt or later shall require source verification utilizing source inspection and/or source surveillance as appropriate."

Please revise the plan to clarify who will be responsible for the source inspections and/or source surveillances. Will these be performed under the MPQAP requirements?

RAI-11

The MPQAP revision states that the presented approach for other entities is similar to the use of Underwriters Laboratories, Inc. (UL) or Factory Mutual (FM). Please clarify how this approach is similar to the approved use of UL or FM.

Note that the use of UL or FM was approved by the NRC for specific fire protection components for the Louisiana Energy Services (LES) Enrichment Facility and that a detailed technical justification was provided by LES to identify (1) the scope of the IROFS to which the request applied, (2) the specific codes and standards that would be applied for the manufacture, installation, and use of the IROFS; and (3) how the UL and FM certification processes satisfied the criteria identified in the LES QA program. Further, LES committed to monitor the Consumer Product Safety Commission website periodically to ensure that product recalls had not affected any purchased items that had been procured for use as IROFS.

Please revise your submittal as appropriate to incorporate a comparable level of detail in the technical justification. Specifically, please identify (1) specific items or classes of items for which you seek approval to use a commercial supplier possessing certification from an accrediting body; (2) how the process used by the accrediting body will ensure the availability and reliability of the IROFS provided by certified suppliers; (3) how you will monitor for quality issues with certified suppliers or their products; (4) what measures MOX will implement to assess the capability of the accrediting body/bodies used; and (5) how the use of this process will satisfy the requirements of Appendix B to 10 CFR Part 50 and Nuclear Quality Assurance (NQA)-1.

RAI-12

The MPQAP Revision 11 Justification for Change states in multiple locations that (for IROFS ranked as having low relative safety significance) "Since the MOX MPQAP change is limited to items with low importance to safety, procured items are subject to independent validation of item by testing, and process by independent evaluation and compliance with MPQAP

requirements for procurement planning (RFPs), technical submittal review and acceptance, receipt inspection and construction/start-up testing, MOX considers the MPQAP change to meet the commitment to 10 CFR 50 Appendix B and NQA-1."

Please clarify if MOX Services will be responsible, using MPQAP requirements, for the independent validation of items by testing, the process by independent evaluation and compliance with MPQAP requirements for procurement planning, the technical submittal review and acceptance, the receipt inspection and the construction/start-up testing.

Please identify which Appendix B and NQA-1 criteria will provide the basis for the MPQAP changes to be considered not a reduction in commitments and therefore acceptable.

Laboratory Analysis Services and Suppliers for Items whose Importance to Safety is Low

RAI-13

The MPQAP Revision 11 Justification for Change states that (for IROFS ranked as having low relative safety significance) "MOX Services may use laboratory services from supplier's, both domestic and foreign that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA)." "The NRC endorsed the use of this accreditation approach for calibration in lieu of audit or commercial grade survey in a letter to Palo Verde on September 28, 2005."

The revision justification also states that (for IROFS ranked as having low relative safety significance) that "These IROFS may be procured directly from suppliers based on certificates from nationally/internationally recognized independent accreditation organizations (such as UL or FM) unless the engineer determines that additional requirements are necessary. MOX Services will rely on the national/international recognition to establish accreditation organizations capability to perform the accreditation."

The NRC staff notes that the referenced letter to Palo Verde does not endorse the use of laboratory services from domestic and foreign suppliers that are signatories to the ILAC MRA. The NRC letter and answers to the Office of New Reactors Vendor Workshop provides only that the NRC finds acceptable the use of commercial calibration laboratories accredited by one of the following 6 domestic accrediting bodies: NVLAP, A2LA, IAS, ACLASS, Perry Johnson, or LAB.

Please revise the submittal to provide a more focused scope that will align with the NRC's approved approach for the use of domestic calibration suppliers possessing accreditation from one of the six bodies identified above or provide specific information to support an expanded scope of (1) procurement directly from suppliers based on certificates from nationally/internationally recognized independent accreditation organizations and (2) laboratory services from supplier's, both domestic and foreign that are signatories to the ILAC MRA.
Additional information needs to be provided in the justification to support the expanded scope. Some examples that may help the staff understand the requested changes for suppliers include:

(a) identification of the specific accrediting body to be used; (b) IROFS and/or IROFS categories or services that would be procured; (c) description of accrediting body's

accreditation (e.g., FM, UL) program for accepting or qualifying suppliers (this description should contain an analyses of the accreditation program as compared to the applicable MPQAP provisions including addressing differences and providing the rationale why these differences are acceptable and d) a description of MOX Services review and oversight of an accrediting body of suppliers, limitations of their use, etc.

Some examples for calibration services include:

(a) A description of the ILAC/MRA calibration program (this description should contain an analyses of the calibration program as compared to the applicable MPQAP provisions, including addressing differences and providing the rationale why these differences are acceptable), and (b) a description of MOX Services review and oversight of an accrediting body of calibration services, limitations of their use, etc.

Commercial Grade Dedication for Items whose Importance to Safety is Low

RAI-14

The MPQAP Revision 11 Justification for Change states that (for IROFS ranked as having low relative safety significance) “The MPQAP change clarifies that for items whose importance to safety is low the technical evaluation and the verification that dedication requirements have been satisfied will be integrated into the procurement specification and receipt inspection respectively.”

a) Please specify the dedication requirements that will be required to be in the procurement specifications and those that will be required at the receipt inspection.

b) Please expand on the review, approval, and documentation process for the dedication activities/requirements for the IROFS discussed and identify how the process will differ from that used for Quality Level (QL)-1 IROFS. (e.g., will signoffs on QL-1LR dedication forms (disciplines reviewing and levels of authority approving) be comparable to those performed for QL-1 dedication packages?; will the information documented for QL-1LR dedication activities be the same as for QL-1 IROFS with the exception of *where* the information is documented?)

Peer Inspection during Installation and Fabrication of items whose importance to safety is low

RAI-15

The MPQAP Revision 11 Justification for Change states that (for IROFS ranked as having low relative safety significance) "The only difference will be that the personnel will report to Construction or Assembly as opposed to Quality Control."

Please clarify how this change will maintain reporting independence from cost and schedule.

Audits

RAI-16

The MPQAP Revision 11 Justification for Change states that (for IROFS ranked as having low relative safety significance) "MOX Services will focus the use of audits on items whose importance to safety is high. Items whose importance to safety is low will be primarily evaluated by assessment, surveillance or performance monitoring."

Please provide the personnel qualifications, frequency, documentation, and any other appropriate requirements for the assessment, surveillance or performance monitoring that will be performed on "items whose importance to safety is low." Please identify what measures will be taken to ensure that graded QA controls are being effectively implemented and are sufficient to ensure the availability and reliability of IROFS (the NRC staff notes that programmatic reviews, such as assessing the implementation of graded QA controls, are typically accomplished through the use of audits. Please describe how assessment, surveillance or performance monitoring activities will accomplish this function).

Industry Precedent Discussion

RAI-17

Should MOX Services wish to rely on nuclear industry precedent in the application of QA requirements for its proposed augmented programs, please clarify how the references that were provided for American Centrifuge Plant and Eagle Rock Enrichment Facility specifically relate to the approach presented in the submittal (e.g. how this submittal satisfies the level of detail, technical justification, and information provided by previous submittals for a graded approach).

Additionally, the Plan should contain a provision similar to the following: The rationale for the use of a graded quality assurance alternative, exception, or precedent approved by an NRC safety evaluation must be documented and include a discussion on the applicability of that alternative, exception or precedent to the MFFF.

Other Factors Discussion

RAI-18

The MPQAP states that "MOX services has a robust corrective action program and lessons learned program that provide timely feedback from internal lessons learned or lessons

learned from other facilities that may require MOX Services to reassess the QA program controls."

Please clarify how the corrective action and lessons learned program will capture (and/or trend) the results of assessments, surveillances or performance monitoring that will be performed on "items whose importance to safety is low." Further, please identify what actions will be taken in the event that the results of assessments, surveillances, or performance monitoring indicate quality issues associated with QL-1LR IROFS

Please also clarify if the information will focus on issues identified at the Mixed Oxide Fuel Fabrication Facility or if information from other facilities will also be used.