March 11, 2013

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

SUBJECT: SECOND 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 your responses to the Staff's request for additional information dated July 31, 2012. Based on the review of your responses the staff needs additional information (See Enclosure) in order to complete its review and prepare a Safety Evaluation.
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.
The response should be provided within 30 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 (NRC) "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 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 Mr. David Tiktinsky at (301) 492-3229, or via e-mail to David.Tiktinsky@nrc.gov, if you have any questions.

Sincerely,

/RA/

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Patricia Silva, Chief
Conversion, Deconversion and
MOX 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

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SECOND REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE MOX PROJECT QUALITY ASSURANCE PLAN REVISION 11

RAI-1, Section 4.1, "Procurement Document Control/Control of Purchased Items and Services," of the proposed Revision 11, Change 1 to the MPQAP states that:

> *IROFS may be procured directly from suppliers based on nationally/internationally recognized independent accreditation from Underwriters Laboratory or Factory Mutual subject to the following:*
>
> - *The accreditation organizations test/qualification report for the item to be procured in conjunction with normal construction/preoperational/start-up testing is reviewed by MOX Services and has been determined to be sufficient to demonstrate that the item will perform its safety function.*
> - *The accreditation organizations evaluation of the technical and quality capability of the suppliers' process controls is reviewed by MOX Services and has been determined to be sufficient to provide reasonable assurance that the manufactured items are representative of the item tested.*
> - *If either of the conditions above cannot be met, MOX Services shall identify supplemental controls that are required to be established, consistent with section 7 of the MPQAP and documented in the purchase order per section 4 of the MPQAP. The supplemental requirements will be implemented by MOX Services or a MOX Services approved NQA-1 supplier.*
> - *The supplier provides to MOX Services a current certificate of accreditation, or equivalent, from the accreditation organization. This will be identified during MOX Services receipt inspection as part of item acceptance.*
> - *For the items procured the supplier shall provide a certificate of conformance. MOX Services quality control shall perform a receipt inspection and, where appropriate, MOX Services shall perform functional testing during start-up as a minimum.*
> - *The items will be designated as basic components upon acceptance. This will normally occur at QC receipt inspection.*
>
> *Factory Mutual and Underwriters Laboratories recalls will be reviewed as a part of the MOX Services Lessons Learned process.*

The regulation, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70.22(f), requires that the applicant describe the Quality Assurance (QA) program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI

a. *Please include in the MPQAP a description of (1) any technical and quality requirements that will be imposed on the supplier in the purchase order; (2) the criteria MOX Services will apply to review UL/FM test/qualification reports to determine that the testing is sufficient to demonstrate that the item will perform its safety function; (3) the criteria MOX Services will apply to review the accreditation organization's evaluation report for QL-1LR suppliers to determine whether the*

suppliers' process controls are sufficient to provide reasonable assurance that manufactured items are representative of item tested; (4) how certificates of conformance will be used to demonstrate compliance with Appendix B; and (5) information that will be documented by MOX Services to show that the UL or FM process is adequate for the category of item being procured (i.e., analysis of codes and standards applied, critical characteristics of item, adequacy of testing to verify characteristics, etc.). Supporting details may be provided in the justification for change as needed.

b. *Please describe how MOX Services will determine if functional testing is sufficient for product acceptance and verification of critical characteristics or, if further testing is required.*

c. *Please specify in the MPQAP the frequency upon which recalls will be reviewed as part of MOX Service's lessons learned process*.

RAI -2, The justification for change states that:

"Periodically, normally at least annually, follow-up visits are made to the manufacturing facility to ensure the QA process controls remain adequate and effective."

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met.

RAI
Please describe the basis for MOX Services' determination that the scope of the onsite inspections conducted by UL and FM for certifying suppliers are of sufficient frequency and breadth of program areas to ensure that the QA controls implemented by suppliers are adequate and effective and that manufactured items are representative of the items tested during the certification process.

RAI-3, The justification for change states that:

"A manufacturer wanting UL or FM approval of their respective product is required to submit the product description, sample products, specifications and related technical information. These are reviewed by UL or FM and appropriate is determined by their respective Engineering departments. The testing is documented in test procedures or standards.

The products are subjected to the required testing using appropriately qualified personnel from UL or FM respectively. If the testing is acceptable then an evaluation of the QA processes at the manufacturing location is performed. The objective of the site visit is to confirm adequate QA controls are in place to ensure future products are representative of the product samples tested."

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA

program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI

a. *Please clarify the wording in the excerpted text, "These are reviewed by UL or FM and appropriate is determined by their respective Engineering departments." It does not read logically.*

b. *Please describe the basis for MOX Services determination that UL and FM accreditation and testing services meet the graded QL-1R QA program requirements (i.e., graded Appendix B).*

c. *Please clarify if the UL and FM certification programs allow manufacturers to outsource the manufacture/production of certified items to another company or another facility location, and if yes, what controls are in place to confirm that the other company/location is manufacturing these items properly?*

RAI-4, Section 4.1, "Procurement Document Control/Control of Purchased Items and Services," of the proposed Revision 11, Change 1 to the MPQAP states that:

> *MOX Services may document the safety function, critical characteristics, verification method, acceptance criteria, and basis for selection in the procurement specification and will use the normal receipt inspection as the means to confirm/document completion of the verification requirements and the designation of the item as a basic component.*

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI

The statement "MOX Services may document…" is unclear. Please revise the statement to show the commitment that MOX Services will document the QL-1LR item's safety function, critical characteristics, verification method, acceptance criteria, and basis for selection in the procurement specification (or, if preferred, in a separate commercial grade dedication package) or provide information on why you would not document these items.

RAI-5, The MPQAP justification for change pertaining to the use of UL/FM suppliers states that:

> *"…the safety performance of these items [IROFS-like items procured in France based on accreditation of the supplier] is equivalent to that assumed in the MFFF ISA. This is based on no significant events at the reference facilities (INES Reportable) involving failure of these items to perform. The events reported under the INES reporting for each facility for the past two years were reviewed."*

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI
MOX Services' justification for UL and FM approach to accreditation included a discussion of what was done at the AREVA LaHague and Melox facilities. Please provide additional details regarding the use of accredited suppliers at those facilities. The additional details should include:

a. *A discussion of why a performance history of two years of INES Reportable events is sufficient to support MOX Services assumptions regarding performance of accredited items.*

b. *A description of the types of components that were procured for the French facilities using the accreditation supplier process. Additionally, provide a comparison of the types of items that were procured for the French facilities using an accreditation process to those that may be procured under the QL-1R program using UL/FM.*

c. *A description of the qualification processes of the accreditation entities that were used at the French facilities and a discussion of how they are comparable to what UL/FM does as part of their accreditation processes.*

RAI-6, MOX Services technical justification states that:

> *"MOX services will place COFRAC and SAS accredited laboratories on the approved suppliers list based on COFRAC or SAS accreditation certificate when needed. Prior to use of the laboratory MOX Services shall verify that the needed services are included within the scope of accreditation including range and uncertainties. Upon first use and periodically thereafter (not to exceed yearly if active), independent sampling will be performed."*

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met to the extent consistent with their importance to safety.

The NRC is actively reviewing implementation strategies to consider (1) expanding NRC's recognition (beyond domestic accreditation bodies) to international accreditation bodies on the basis that they are all full signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) and (2) including testing laboratories accredited under the requirements of International Standard Organization (ISO) International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," as part of the agency's recognition of the ILAC MRA process (ML12137A440). Until such time as that review has been completed, the request to use international calibration and testing suppliers based on their accreditation by ILAC-accredited bodies (SAS and COFRAC) cannot be approved without supplemental controls. Further, accreditation may not be used to add suppliers to the Approved Suppliers List (see NUREG-0800); rather, the NRC has approved its use in lieu of a commercial grade survey as part of the dedication process for domestic suppliers.

RAI
a. *Please revise the MPQAP and supporting documents related to international calibration to (1) reflect the limitation that accreditation can only be used in lieu of a*

commercial grade survey (not to add suppliers to the approved suppliers list) and (2) describe the complementary controls/actions, such as independent sampling, that will be used to dedicate international calibration services. For the use of independent sampling, please specify the periodicity in the MPQAP (i.e., "not to exceed yearly, if active") and identify if sampling will be done for each supplier or only a sample of all the accredited suppliers used.

b. *Please revise the MPQAP and supporting documents related to international testing to (1) describe the basis for international testing lab capabilities. Because the NRC has not yet provided direct review of international testing supplier performance or compliance with ILAC and SAS/COFRAC requirements and oversight, further justification is needed by MOX Services to describe the basis for supplier performance beyond their accreditation status. This justification can include the results of MOX Services audits and surveys of international testing suppliers, their demonstrated performance history, or a commitment to perform more rigorous sampling of testing services during initial use of suppliers to establish performance capability, and (2) describe the complementary controls/actions, such as independent sampling, that will be used to dedicate international testing services. For the use of independent sampling, please specify in the MPQAP the initial and subsequent periodicity and sample size for testing services, or describe how MOX Services will determine the initial and subsequent periodicity and sample size. Please ensure that, whether documented in the MPQAP or an alternate QA Record, the basis for selection of initial and subsequent sample size and periodicity for testing suppliers is documented.*

c. *Please describe how MOX Services will adjust the periodicity and sample size of independent sampling for international calibration and testing suppliers based on supplier performance.*

RAI-7, With respect to the oversight provide by ILAC of SAS/COFRAC, the MPQAP justification for change states that:

> *"Once accredited, laboratories accredited by COFRAC or SAS are subject to regular on site evaluation to confirm continued satisfactory performance of their management systems (QA Program). COFRAC and SAS are also subject to regular evaluations by ILAC to ensure their accreditation approaches meet minimum ILAC standards."*

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI

a. *Please confirm that the scope and frequency of these on site evaluations at both levels (ILAC evaluations of SAS/COFRAC and SAS/COFRAC evaluations of suppliers) meet minimum ILAC standards.*

b. *Please confirm that the requirements for initial accreditation for SAS/COFRAC are comparable to those applied by ILAC to domestic calibration suppliers.*

RAI-8, Section 4.1.B of Attachment B of the MPQAP states that:

"For other laboratory services the MOX Services or approved supplier purchase documents require identification of the laboratory equipment/standards used."

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI

Please clarify what is meant by "other laboratory services."

RAI-9, Section 4.0 of Attachment B of the MPQAP states that:

"The provisions of sections 1, 2, 3, 5, 6, 8, 9, 11, 12, 13, 14, 15, 16 and 18 of this QA Plan apply without exception."

Section 16.2.1 of the MPQAP states that:

"Significant conditions adverse to quality related to QL-1 SSCs shall be evaluated for reportability under 10CFR21 to determine if the defects or non-compliances are reportable to the NRC."

The regulation, 10 CFR Part 70.22(f), requires that the applicant describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of § 70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met, to the extent consistent with their importance to safety.

RAI

Please revise Section 16.2.1 of the MPQAP to include references to QL-1R, in addition to QL-1, in the discussion of invoking of the requirements of 10 CFR Part 21 for the reporting of defects and non-compliances. Please include in your response a discussion of the measures that will be used, if any, to ensure that MOX Services is notified of defects and deviations associated with QL-1LR calibration and testing services (including any measures imposed on sub-suppliers who provide calibration services to a MOX approved supplier)?