

June 14, 2013

Mr. Kelly Trice
President and COO
Shaw AREVA MOX Services
P.O. Box 7097
Aiken, SC 29804-7097

SUBJECT: APPROVAL OF CHANGES TO THE MIXED OXIDE PROJECT QUALITY
ASSURANCE PROGRAM, REVISION 11, CHANGE 3

Dear Mr. Trice:

By letter dated May 31, 2012, with a final revision dated April 29, 2013, Shaw AREVA MOX Services submitted proposed changes to the Mixed Oxide Project Quality Assurance Plan (MPQAP) for the U.S. Nuclear Regulatory Commission's (NRC's) review and approval in accordance with paragraph 70.23(b) of Title 10 of the *Code of Federal Regulations* (10 CFR). The proposed changes include designation of a new category of Items Relied on for Safety with low safety significance defined as QL1-LR with an associated graded quality assurance that has been identified in the MPQAP revision.

The enclosed Safety Evaluation Report documents the NRC staff's conclusions that changes to the MPQAP continue to satisfy the criteria of Appendix B to 10 CFR Part 50 as required by Footnote 3 of 10 CFR 70.23(b).

In accordance to 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 System component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible through the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

K. Trice

2

If you have any questions related to this letter or our MPQAP review, please contact David Tiktinsky at 301-287-9155, or via e-mail to David.Tiktinsky@nrc.gov.

Sincerely,

/RA/

Marissa G. Bailey, Deputy Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No. 70-3098

Enclosure:
Safety Evaluation Report

If you have any questions related to this letter or our MPQAP review, please contact David Tiktinsky at 301-287-9155, or via e-mail to David.Tiktinsky@nrc.gov.

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SAFETY EVALUATION REPORT
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
PROPOSED CHANGES TO THE MIXED OXIDE PROJECT
QUALITY ASSURANCE PLAN, REVISION 11, CHANGE 3

1.0 INTRODUCTION

By letter dated May 31, 2012 (Ref. 1), Shaw AREVA MOX Services (MOX Services or the applicant) submitted proposed changes to the Mixed Oxide Project Quality Assurance Plan (MPQAP) for U. S. Nuclear Regulatory Commission (NRC) review and approval in accordance with Paragraph 70.23(b) of Title 10 of the *Code of Federal Regulations* (10 CFR). The changes included the proposal of a process for determining the relative importance to safety of items relied on for safety (IROFS) and an graded quality assurance (QA) program to be applied to IROFS whose relative importance to safety is determined to be low.

By letters dated July 31, 2012 (Ref. 2); March 11, 2013 (Ref. 4); and April 22, 2013 (Ref. 6), respectively, the NRC communicated requests for additional information (RAIs) to seek further clarification from the applicant on the ranking process and the application of graded QA to IROFS whose relative importance to safety is low. By letters dated September 24, 2012 (Ref. 3); April 1, 2013 (Ref. 5); and April 29, 2013 (Ref. 7), respectively, MOX Services submitted further clarifications to the MPQAP, as documented in Revision 11, Change 1; Revision 11, Change 2; and Revision 11, Change 3 to the MPQAP. As Revision 11, Change 3 includes all the changes submitted under Revision 11 to date, any reference to Revision 11 herein will include Change 1, Change 2, and Change 3.

2.0 REGULATORY EVALUATION

Footnote 3 of 10 CFR 70.23(b) identifies that the criteria in Appendix B of 10 CFR Part 50 (Appendix B) will be used by the Commission in determining the adequacy of the Mixed Oxide Fuel Fabrication Facility (MFFF) QA program. Criterion II, "Quality Assurance Program," of Appendix B requires, in part, that "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety."

NUREG-1718 "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," states that an acceptable means for meeting the requirements of Appendix B to 10 CFR Part 50 is to follow the 1994 edition of the ASME NQA-1, with the 1995 addenda (NQA-1-1994/1995a). Basic Requirement 2, "Quality Assurance Program," of NQA-1 1994/1995a states, in part, that "The [quality assurance] program shall provide control over activities affecting quality to an extent consistent with their importance."

The applicant's QA program applicable to the design, construction, and operation of the MFFF is described in the MPQAP. MOX Services has committed to comply with the guidance contained in NQA-1-1994/1995a. The predominant criteria of Appendix B and NQA-1-1994/1995a that are related to the proposed MPQAP changes and which may be affected are Criterion IV, "Procurement Document Control"; Criterion VII, "Control of Purchased Material, Equipment, and Services"; Criterion X, "Inspection"; and Criterion XVII, "Quality Assurance Records."

3.0 TECHNICAL EVALUATION

In Section 2 of the MPQAP, MOX Services identifies the quality levels that will be applied to systems, structures, and components (SSCs) at the MFFF. All SSCs that are designated as IROFS and that have been credited in the Integrated Safety Analysis (ISA) as being required to either (1) prevent or mitigate design basis events such that high-consequence events are made highly unlikely; (2) prevent or mitigate design basis events such that intermediate-consequence events are made unlikely; or (3) prevent criticality are assigned to quality level (QL) 1. Quality level 2 and 3 apply to non-IROFS that may be important to ensuring worker protection, managing radioactive waste, protecting IROFS from physical interactions, and ensuring that operational or mission critical goals are achieved.

In Revision 11 of the MPQAP, MOX Services identified a new QL, QL1-LR, which is a subset of QL-1. Quality level 1 LR applies to SSCs whose relative importance to safety has been determined by evaluation to be low. In its submittal, MOX Services provided a table of applicability detailing the manner in which existing, modified, and new MPQAP requirements will be applied to QL1-LR SSCs. Sections 1, 2, 3, 5, 6, 8, 9, 11, 12, 13, 14, 15, 16 and 18 of the MPQAP will be applied in full to QL1-LR IROFS, while the provisions of sections 4, 7, 10 and 17 of the MPQAP will apply to QL1-LR IROFS with exceptions and clarifications, as described in the following review discussion areas.

3.1 Staff Review of IROFS Safety Ranking Process

The stated purpose of the ranking process in the MPQAP is to define the relative importance of IROFS to the overall safety criteria for the application of graded QA controls. MOX Services Safety ranking considers the likelihood of failure and the consequence of that failure of the IROFS' safety function. IROFS whose importance to safety is high will be maintained as QL-1 IROFS with all associated QA controls as defined in the MPQAP. Those whose importance to safety is low will be identified as QL1-LR and QA controls will be applied commensurate with the IROFS importance to safety.

The IROFS ranking evaluations are prepared by MOX Services Nuclear Safety group which is within the Engineering organization. Each ranking criteria is evaluated according to its importance to safety with a justification provided. The overall importance to safety ranking for the IROFS is determined based on an evaluation of the criteria by the preparers, reviewed by a review group consisting of the Nuclear Safety Leads and approved by the Nuclear Safety Manager. All accident sequences (events) are evaluated individually. The highest ranking of all accident sequences establishes the IROFS ranking.

The Nuclear Safety group is solely responsible for the IROFS ranking process. This includes the identification of the IROFS, its safety function for each event as defined in the Nuclear Safety Evaluations/Nuclear Criticality Safety Evaluations, and the implementation of the IROFS Ranking Process. The results of the IROFS Ranking Process will be documented and reviewed by the Nuclear Safety group with approval by the Nuclear Safety Manager. The results of the IROFS ranking evaluations will be transmitted the Engineering group for implementation of the graded QA program. The QA is responsible for oversight and audits of the process. The evaluation is documented, reviewed, approved and maintained as a QA record. Design changes subsequent to the evaluation are reviewed to determine the impact on the importance to safety evaluation results. The likelihood criteria are:

- frequency of the initiating event
- reliability of the IROFS
- surveillance of the IROFS
- the safety margin from normal operations to the safety limit

The consequence criteria are:

- monitoring versus controlling function of the IROFS
- the consequences associated with the IROFS safety function failure
- the safety margin from the safety limit to the event consequences
- the additional protection features

The IROFS Ranking Process and implementation of the graded QA program will be controlled through project procedures (e.g., PP9-1, *SSC Quality Levels & Marking Design Documents*). MOX Services considers this process to be an acceptable method for determining importance to safety in the context of 10 CFR part 50 Appendix B and NQA-1.

The staff finds that the process for ranking IROFS and the commitments associated with the process for preparation, review and approval, and documentation are reasonable and should adequately provide a formalized, consistent and repeatable implementation of the process. To that end, the staff finds that the commitments associated with the process are acceptable.

In addition to the review of the revisions of the MPQAP, the staff also requested the procedure that would be used by MOX Services to perform the safety ranking evaluation, examples of individual IROFS evaluations, and a summary of the results of all IROFS that were evaluated for safety significance. The staff reviewed the procedure in context with the description of the process provided by MOX Services and the commitments associated with implementing the process. The staff review finds that the procedure provides adequate and applicable safety criteria for ranking IROFS, a reasonable process that adequately evaluates safety and possible impacts due to likelihoods of failure and potential consequences, and contains adequate measures for implementation of the process, including evaluation, review and approval. The staff also finds that the documentation associated with the process should provide staff a reasonable opportunity for review and inspection of the process and results.

The staff reviewed examples provided by MOX Services that used the safety ranking process. These examples contained both low and high ranked IROFS and were:

- Sintering furnace airlock doors
- Fire dampers
- High Depressurization Exhaust system temperature and differential pressure sensors
- Level controls
- Aqueous Polishing Fissionable Material Detecting Systems
- Favorable (criticality) geometry components

The staff review of these examples provided the staff a representative sample of safety ranking resulting in both low and high ranked IROFS using the safety ranking procedure provided by MOX Services. The staff reviewed detailed evaluations and justifications of the safety criteria specified in the safety ranking procedure. The staff review finds that the individual evaluations follow the procedure and seem reasonable, consistent and repeatable. Given the process, the staff feels that implementation is acceptable.

The staff also reviewed a listing provided by MOX Services that showed the Summary of Ranking Results for safety ranking of components that were evaluated up to the time of the request for additional data. Over 5000 IROFS were represented on the list. The staff reviewed the grouping of components on the list and the final rankings. In general, the staff finds that the results are reasonable and that components in individual processes and accident sequences have been evaluated independently.

The staff review has considered the following regarding the safety ranking process for IROFS:

- Revisions to the MPQAP
- Commitments in Plan
- Ranking Procedure
- Ranking Procedure implementation examples
- Results of ranking process

The staff finds that the process, implementation of the process, and results of the process are reasonable and acceptable for the given purpose. The staff understands that it is difficult to determine quantitatively, or even qualitatively, any impact that a reduction in application of a select group of QA controls would have on the overall likelihood of particular accidents sequences or individual performance of components. The staff also understands that this rating process is qualitative and relies on the knowledge and experience of MOX Services personnel. The staff believes that, based on their review, there is reasonable assurance that the safety function of individual components that are ranked of low safety significance will not significantly be affected such that meeting the performance requirements for assuring safety are unduly compromised. The staff further believes that the full complement of currently required QA controls are not needed to satisfy 70.61 performance requirements and the requirements of Appendix B as implemented in the MPQAP.

The staff review and conclusions only applies to select QA measures as included in this amendment. Additional grading of IROFS and the quality assurance program may require additional staff review based on criteria stated in the MPQAP change process.

3.2 Procurement Document Control

Criterion IV of Appendix B defines requirements for procurement document control. It requires that measures be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services. Criterion IV also requires, to the extent necessary, that procurement documents require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of Appendix B.

As described in Revision 11 of the MPQAP, MOX Services will continue to include a description of the scope of work to be performed by the supplier in the procurement documents for QL1-LR items and services as well as technical requirements such as design bases, specifications, and codes/standards applicable to the items. For QL1-LR items, procurement documents may be used to specify the safety function, critical characteristics, verification method, acceptance criteria, and basis for selection for commercial grade items in lieu of documenting this information on a separate commercial grade dedication package.

Procurement documents for QL1-LR IROFS will not invoke Appendix B QA program requirements on suppliers or sub tier suppliers, and will not include a statement identifying the applicability of 10 CFR Part 21. Instead, as described in the response to an RAI (Ref. 5), purchase orders for QL1-LR IROFS will require that (1) the supplier submit certification documentation demonstrating that they hold a current Factory Mutual (FM) or Underwriter's Laboratory (UL) certification for the product to be procured; (2) the supplier will be required to notify MOX Services if there are any changes in the FM or UL certification status; (3) the supplier will be required to perform activities in accordance with their QA program/process as evaluated by UL or FM and any special provision(s) that may be imposed by MOX Services; (4) the supplier will be required, at the time of delivery, to provide a certificate of conformance (COC) to the requirements of the purchase order certifying that the work was performed in accordance with the QA program as evaluated by UL or FM; and (5) any nonconforming conditions that arise during the fabrication of products and their resolution for MOX Services shall be provided to MOX Services for review and, where appropriate, approval.

The RAI response letter (Ref. 5) and Rev.11 of the MPQAP (Ref. 7) also identified that UL and FM certified suppliers will be required to submit their QA manual, the FM or UL product qualification test report for the item to be procured, and the process evaluation report from UL or FM's evaluation of the supplier's process controls during the purchase requisition/bid evaluation phase. Based on the documented evaluation of these submittals performed by MOX Services, additional QA controls may be specified for specific procurements. Additionally, the commitments in Attachment B of Revision 11 of the MPQAP specify that any supplemental controls required for the procurement of QL1-LR items will be documented in the procurement specification.

Consistent with the treatment of other QL-1 IROFS, MOX Services will impose provisions in procurement documents for rights of access to the supplier's facility to conduct audit/surveillance activities as well as provisions for establishing hold points for the manufacturing process beyond which work cannot proceed by the supplier/subcontractor without MOX Services authorization. Procurement documents will also identify documents that are required to be submitted to MOX Services by suppliers and any requirements associated with the identification of technical and quality data needed for ordering spare parts or assemblies. MOX Services will also include requirements in procurement documents for QL1-LR suppliers to report adverse quality conditions resulting in work stoppages and non-conformances to MOX Services in writing.

The procurement document controls described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to QL1-LR IROFS were reviewed by the staff and were found to be acceptable on the basis that: (1) procurement documents will continue to specify appropriate regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality of QL1-LR items and services; and (2) MOX Services will continue to document the applicable elements inherent to the commercial grade dedication process for the dedication of commercial grade items to be used as QL1-LR items; however, the documentation will be done in a more streamlined approach that incorporates consideration of the testing and evaluation activities performed by UL and FM, as applicable. For the remaining elements of procurement document control, MOX Services will continue to apply the controls defined in Section 4 of the MPQAP in a like manner for QL-1 and QL1-LR IROFS. These controls are consistent with the requirements of Criterion IV of Appendix B for Procurement Document Control, the ability to apply QA controls commensurate with items' importance to safety, and the determination by MOX Services that QL1-LR items are of low safety significance relative to other IROFS.

3.3 Control of Purchased Material, Equipment, and Services

Criterion VII of Appendix B defines requirements for the control of purchased material, equipment, and services. It requires, in part, that measures be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to procurement documents. Criterion VII also requires that documentary evidence that material and equipment conform to the procurement requirements be available at the MFFF site prior to installation or use of such material and equipment, and be retained in sufficient detail to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. Further, Criterion VII requires that the effectiveness of the control of quality by contractors and subcontractors be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

a. Use of UL or FM Certification for QL1-LR Procurement

As described in Revision 11 of the MPQAP, MOX Services will procure QL1-LR IROFS directly from suppliers based on recognition of their accreditation¹ from UL or FM subject to certain provisions. As described in the basis for MOX Services' request to credit UL and FM accreditation as part of the supplier selection process for items of relatively low risk significance, MOX Services identified that suppliers that manufacture and supply UL or FM listed components are subject to UL or FM surveillance to establish their continued commitment to quality and consistency of supply. Subsequent to initial evaluation and certification, UL or FM certified/approved manufacturers receive periodic, unannounced inspections by representatives of UL or FM who audit production to determine the manufacturer's continued compliance to UL or FM's requirements. Furthermore, components manufactured by these suppliers are periodically tested to verify their design features and ensure their capability to meet their performance requirements (Ref. 7). Prior to use of UL or FM as the basis for supplier selection as part of the QL1-LR program, MOX Services will perform a surveillance of UL or FM to verify the adequacy of their processes for supplier certification and item testing (Ref. 7).

Subsequent to performing surveillances of UL and FM, MOX Services will implement a series of graded controls for specific items and suppliers. These controls will be implemented in lieu of the controls specified in Section 7.2.2, "Source Evaluation and Selection," of the MPQAP. For QL1-LR items, a MOX Services engineer will determine the safety function(s) of the item to be procured. For each safety function, the engineer will review the testing performed by FM/UL to determine whether the characteristics verified during the test and the method of testing is appropriate to demonstrate the safety function (Ref. 7). Specifically, Revision 11 of the MPQAP identifies that MOX Services will review the UL or FM test/qualification report for the item to be procured to determine if, in conjunction with normal construction, preoperational, and start-up testing, the testing performed by UL or FM is sufficient to demonstrate that the item will perform its safety function. In response to an RAI (Ref. 5) asking about the use of functional testing for product acceptance and verification of critical characteristics, MOX Services responded that it

¹ While the MPQAP uses the term "accreditation," UL identifies the services it offers as "certification," and FM identifies the services it offers as "approval." Specifically, UL's component certification program includes (1) testing of products to ensure their compliance with UL requirements, and (2) surveillance of the component manufacturer. FM's product approval program includes (1) FM testing of a product to a specification or drawing, and (2) FM review of quality control procedures at the manufacturer's facility. For the purposes of this SER, the term "accreditation," as used by MOX Services, will be used interchangeably with "certification" or "approval."

considers that functional testing by itself is not normally an acceptable basis for acceptance of a commercial item as a basic component. As discussed in RAI 1.a (2), MOX Services will determine the critical characteristics based on the safety function of the item to be procured. Appropriate verifications and verification methods will be required for each critical characteristic. The reference to functional testing was to indicate that if functional testing is required and the testing by the UL or FM is not sufficient to satisfy the critical characteristics, then MOX Services may rely on planned functional testing, if that will resolve the shortcoming of the UL or FM testing. Such functional testing is performed during Construction or Start-Up and, when appropriate, will be used as part of the basis for acceptance as opposed to imposing additional requirements on the supplier. MOX Services will also review UL or FM's evaluation of the technical and quality capability of the suppliers' process controls to determine if they are sufficient to provide reasonable assurance that the manufactured items are representative of the item tested.

As part of the supplier evaluation and selection process, PP3-12, *Supplier Evaluation*, a vendor surveillance report will be prepared documenting the technical evaluation of the UL or FM qualification testing and QA evaluation of the UL or FM Process evaluation. If successful, this evaluation will be the basis for adding the supplier to the approved commercial grade vendors' list (Ref. 7). As described in the MPQAP, if MOX Services determines that either the UL/FM testing or supplier evaluation are not sufficient during their evaluation, then they will identify supplemental controls that are required to be established to ascertain product quality. The supplemental requirements will be implemented by MOX Services or a MOX Services approved NQA-1 supplier.

Suppliers of QL1-LR IROFS will be required to provide a current certificate of accreditation, or equivalent, from UL or FM, and a COC that confirms that the work has been performed in accordance with the technical and quality requirements of the purchase order and the Supplier's QA Program as evaluated by UL or FM (Ref. 7). These documents, along with any inspection reports, test reports, and other documentation demonstrating compliance with the acceptance requirements specified by engineering in the purchase order, will be reviewed by MOX Services as part of receipt inspection (Ref. 7). As described in Revision 11 of the MPQAP, QL1-LR items will be designated as basic components upon acceptance, which typically occurs at receipt inspection.

In order to continuously monitor for product quality issues, MOX Services indicated in RAI responses (Ref. 5) that it will act immediately whenever it receives information indicating a potential recall for items used in a QL-1 (including QL1-LR) application. MOX Services indicated that it will apply the lessons learned process and, when appropriate, the corrective action process. Revision 11 of the MPQAP identifies that MOX Services will review UL and FM recalls at least quarterly as part of the MOX Services Lessons Learned process. MOX Services committed to reevaluate use of UL or FM for supplier selection in the event that recall results indicate an adverse trend with UL or FM products (Ref. 5).

The measures described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to the control of QL1-LR material, equipment, and services purchased from UL or FM accredited suppliers were reviewed by the staff and were found to be acceptable on the basis that Appendix B requirements for the control of purchased material, equipment, and services may be graded commensurate with the items' importance to safety. QL1-LR items have been determined to be of low safety significance relative to other IROFS; therefore, the use of UL or FM certification/approval processes as part of a graded QA program provides sufficient control of item quality. The graded QA program includes surveillance of UL and FM

prior to the use of accredited suppliers, review of supplier furnished documentation by MOX Services as part of bid/supplier selection and receipt inspection, satisfaction of the elements of commercial grade dedication, and periodic monitoring of procured items for recalls. These controls and oversight mechanisms provide an acceptable level of QA to ensure the availability and reliability of QL1-LR IROFS consistent with Criterion VII of Appendix B.

b. Laboratory Materials Testing and Calibration Services

Revision 11 of the MPQAP incorporated provisions for the use of foreign laboratories accredited by le Comité français d'accréditation (COFRAC) and Swiss Accreditation Services (SAS) for materials testing and calibration services associated with foreign procurements. MOX Services committed to ensure that foreign material testing and calibration suppliers provide a current COFRAC/SAS certificate of accreditation to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." MOX Services will also verify the certificate during receipt inspection and ensure that the certification covers the analysis scope as described in the purchase order.

For foreign calibration suppliers, MOX Services identified that the requirements of Section 7.2.2.C(4) of the MPQAP will be met, except that use of specified foreign suppliers is authorized. Section 7.2.2.C.(4) states that source selection for suppliers of calibration services will include verification of their accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), the American Association for Laboratory Accreditation (A2LA) or other accreditation agencies accepted as signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA). The MPQAP also identifies that procurement documents for calibration services will: (1) impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements; (2) require reporting of as-found calibration data when calibrated items are found to be out-of-tolerance; and (3) require identification of the laboratory equipment/standards used.

As described in the MPQAP (Ref. 7), MOX Services will submit any prospective laboratory (calibration or testing) to blind sample testing as part of the initial supplier selection basis, quarterly for the first year, and annually thereafter. The sample and basis will be documented in MOX Services procedures. In the conduct of blind sample testing, MOX Services will send five known samples to the laboratory for testing and will compare the results to the known samples to verify the adequacy of the testing services (Ref. 5).

For foreign laboratory materials testing, Revision 11 of the MPQAP states that in addition to requiring the supplier to furnish a valid certificate of accreditation, the purchase document will impose additional technical and administrative requirements needed to satisfy MPQAP and will require identification of standards used, as applicable (Ref. 7).

As described in RAI responses, MOX Services has performed a commercial grade survey of a French laboratory certified by COFRAC, Laboratoire Pourquery. The survey entailed verification of the lab's accreditation by COFRAC and evaluation of QA elements, including the lab's Organization; QA Program; Procurement Document Control; Instructions, Procedures and Drawings; Control of Purchased Material, Equipment, and Services; Handling; Storage and Shipping; Inspection, Test, and Operating Status; Control of Measuring and Test Equipment; Nonconforming Material, Parts, or Components; Corrective Action; Records; and Audits. The survey also assessed the lab's QA Manual (Laboratoire Pourquery Quality Management Plan) and the lab's proficiency and ability to comply with technical documents for material testing activities. The survey found the QA controls developed and implemented by Laboratoire

Pourquery to be adequate and the laboratory certification to be the same format and equivalent content to domestic calibration laboratory certificates (Ref. 5). The Laboratoire Pourquery certificate of accreditation indicated that the supplier holds accreditation to ISO 17025 and specified the analytical techniques, including limitations where applicable, that were accredited (Ref. 5).

As part of a corrective action for an NRC-identified violation, MOX Services was required to recertify 99 commercial certified material test reports (CMTRs) because MOX Services had incorrectly specified the use of Positive Material Identification (PMI) equipment for verification of 304L stainless steel material for the commercial grade dedication of QL-1 materials. The PMI equipment was not capable of distinguishing 304L stainless steel from 304 stainless steel, therefore, MOX Services had to validate the material properties by other means (Ref. 16). MOX Services either performed optical emission spectroscopy on-site under their Appendix B QA program to verify the properties of the material or sent samples to an approved lab that complies with Appendix B for analysis to confirm chemical elements. The results were compared to the commercial CMTRs, which had been provided by laboratory materials testing suppliers that included Laboratoire Pourquery and MECASEM Group, both of which are accredited by COFRAC, and Laboratoire d'essais Metallurgiques, which holds accreditation from SAS. During the review, there were no unsatisfactory CMTRs identified (Ref. 5).

The measures described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to the control of QL1-LR calibration and testing services performed by SAS and CORFAC accredited suppliers were reviewed by the staff and were found to be acceptable on the basis that Appendix B requirements for the control of purchased material, equipment, and services may be graded commensurate with the items' importance to safety. QL1-LR items have been determined to be of low safety significance relative to other IROFS; therefore, the use of calibration and testing suppliers who are accredited by accrediting bodies who are signatories to the ILAC MRA as part of an graded QA program provides sufficient control of item quality.

The NRC has accepted the ILAC process domestically for calibration suppliers. Specifically, in September of 2004, Arizona Public Services (APS) requested NRC to, pursuant to 10 CFR 10.54(a)(4), provide acceptance of accreditation to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," by a nationally-recognized accrediting body in lieu of a supplier audit, commercial grade survey, or in-process surveillance during performance of the accredited calibration services. The request limited the extension of this method for qualification and acceptance to commercial-grade calibration services. In September 2005, based on NRC review of the NVLAP and A2LA accreditation programs and the ILAC Mutual Recognition Arrangement, NRC accepted the APS request and concluded that NVLAP and A2LA accreditation provide an acceptable alternative for qualification of commercial-grade calibration service suppliers. NRC's approval of APS request was based on assessment of NVLAP's internal administrative process, comparison of the NVLAP and NUPIC suppliers' evaluation processes, and observation of an NVLAP accreditation assessment. The NRC found the A2LA process to be an acceptable alternative to support the use of commercial grade calibration services based on NVLAP's recognition of A2LA through the ILAC MRA; similarity of A2LA and NVLAP accreditation processes; NRC meeting with A2LA staff; review of publicly available and internal administrative procedures; openness and completeness of A2LA responses to NRC's questions; open invitation to participate in future A2LA accreditation assessments; and ILAC assessments of the A2LA program. The basis for recognizing the ILAC process is described in the APS Palo Verde safety evaluation report (SER) (Agencywide Documents Access Management System [ADAMS])

Accession Number ML052710224). Since the issuance of the Palo Verde SER, NRC has extended approval of domestic commercial calibration laboratories to include laboratories accredited by any of the following domestic accrediting bodies: NVLAP, A2LA, International Accreditation Service, Inc, ANSI-ASQ National Accreditation Board, Perry Johnson, and Laboratory Accreditation Bureau.

Participation in the ILAC MRA entails requirements applicable to all signatories. Each accreditation body must abide by the ILAC evaluation procedures; maintain conformance with the current version of ISO/IEC 17011, "Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies," related ILAC guidance documents, and supplementary requirements; and ensure that all accredited laboratories comply with ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories." Acceptance of an accreditation body into the ILAC MRA requires successful evaluation by peers from other accreditation bodies in accordance with the relevant rules and procedures contained in ILAC publications. ILAC Regional Cooperation Bodies coordinate peer evaluations to maintain confidence in the accreditation bodies that are signatories to regional MRAs. Each Regional Cooperation Body is required to abide by ILAC's procedures and requirements and undergo routine peer evaluations by members of another Regional Cooperation Body or ILAC (Ref. 10). In this case, the European Cooperation for Accreditation, an ILAC recognized Regional Cooperation Body and signatory to the MRA, performs on-site evaluations of COFRAC and SAS upon initial certification and at least annually thereafter.

This evaluation includes oversight of a COFRAC or SAS certification evaluation at a material supplier (Ref. 9). Because SAS and COFRAC are signatories to the ILAC MRA, measures defined by ILAC will ensure adherence to ISO/IEC standards and oversight of program implementation on a regular basis. In addition, accreditation certificates issued by COFRAC or SAS will explicitly identify each laboratory's capabilities for testing services by listing the analytical services that were evaluated and approved during accreditation and identifying any limitations for those services.

In addition to crediting adherence to the ILAC MRA for establishing the competence of accredited laboratories and maintaining their reliability, MOX Services provided a descriptive basis for the use of international calibration and testing suppliers. This basis included prior performance history demonstrated by CMTR validations, onsite assessment of supplier capabilities from commercial grade survey results, and commitments to perform blind sample testing periodically to verify the ability of calibration and testing suppliers to provide accurate, reliable services. Based on NRC's review of the domestic ILAC accreditation process, MOX Services demonstration of the capability of SAS and COFRAC-accredited laboratories, and commitments by MOX Services to perform blind sample testing and monitor supplier performance, as described in the following section, the NRC staff finds the use of material testing and calibration labs accredited by SAS and COFRAC acceptable for QL1-LR IROFS and consistent with the graded application of Criterion VII of Appendix B.

c. NCA-3800

Revision 11 of the MPQAP was modified to allow MOX Services to add suppliers that have an American Society Mechanical Engineers (ASME) NCA-3800 certified program to the Approved Commercial Grade Vendor List based on their accreditation. In order to apply this provision, the supplier must submit a certificate of accreditation, or equivalent, and MOX Services will perform an audit or surveillance of the supplier after work has commenced to verify implementation of

the supplier's QA program as it applies to the supply of QL1-LR IROFS (Ref. 7). ASME Section III NCA 3800, "Metallic Material Organization's Quality System Program," provides requirements for certificate holders, material organizations, and approved suppliers that are involved in supplying material. Material organizations are certified by ASME and obtain a Quality System Certificate after verification of the adequacy of the organization's Quality System Program (Ref. 14). In Information Notice (IN) 86-21, "Recognition of American Society of Engineers Accreditation Program for N Stamp Holders" (Ref. 11), the NRC informed holders of operating licenses and construction permits that the NRC recognizes the ASME Accreditation Program for N, NA, NPT, and NV stamps and associated certificates of authorization and quality system certificates as evidence that the holder of the certificate of authorization has a documented QA program that meets the requirements of Appendix B. IN 86-21 and IN 86-21, Supplement 1, (Ref. 12) stated that the NRC's recognition of the ASME Accreditation Program applied only to the programmatic aspects of the QA programs and that holders of operating licenses or construction permits, and their subcontractors, are still responsible for ensuring that the suppliers are effectively implementing their approved QA programs. IN 86-21, Supplement 2 (Ref. 13), further clarified the NRC expectations for implementation of IN 86-21 by identifying that the licensee should schedule and perform periodic audits when the supplier is performing a sufficient quantity of work to demonstrate that the supplier is adequately performing the functions defined in the QA program for the purchase of items and that implementation audits are not necessary for procuring items that are (1) relatively simple and standard in design, manufacturing, and testing; and (2) adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.

As part of Revision 11 of the MPQAP, MOX Services identified that the small item exclusion per NCA-3810 does not apply, and that NCA-3855.5 upgrades must be accompanied by an analysis to demonstrate that critical characteristics have been satisfied (Ref. 7). The small item exclusion of NCA-3810 [since moved to NCA-3812] allowed material of a certain size (typically less than one inch in diameter) including piping, bolting material, and bars to be exempted from certain QA provisions. NRC IN 96-40, "Deficiencies in Material Dedication and Procurement Practices and in Audits of Vendors" (Ref. 15), identified that some licensees accepted material under the ASME Code small parts exemption apparently without review for suitability of application by an N Certificate holder as required by the ASME Code. The NCA-3855.5 upgrade allows use of unqualified source material if certain requirements identified in the Code are met.

The NRC staff reviewed the controls described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to QL1-LR IROFS and found them to be consistent with the requirements of Criterion VII of Appendix B for Control of Purchased Material, Equipment, and Services and the content of IN 86-21 and Supplements. Consistent with IN 86-21 and Supplements, MOX Services will add suppliers that have an ASME NCA-3800 certified program to the Approved Commercial Grade Vendor List based on their accreditation and will perform an audit or survey to verify supplier implementation of its QA program after work has commenced. MOX Services addressed the small parts exemption of NCA-3810 by identifying that they would not apply any such provisions. MOX Services also committed to perform a documented analysis to show that critical characteristics associated with material that has been upgraded in accordance with NCA-3855.5 have been satisfied. The NRC staff has reviewed these commitments and found them acceptable to satisfy Appendix B requirements and NRC guidance for the use of ASME NCA-3800 certified suppliers for QL1-LR IROFS.

d. Supplier Approval, Performance Monitoring, and Dedication Documentation

Consistent with existing MPQAP requirements that are applicable to QL-1 and QL1-LR IROFS in a like manner, MOX Services will plan and document procurement activities; evaluate proposals using technically qualified personnel from the QA, procurement, and responsible organizations to determine if the proposal meets procurement document requirements; and establish measures to interface with the supplier/subcontractor and to verify supplier performance. The MPQAP identifies that MOX Services will implement measures to control, process, and accept supplier generated documents and that MOX Services will implement measures for the acceptance of supplier furnished material and equipment, such as review of COCs and performing source verifications, receiving inspections or post-installation tests. The MPQAP also describes provisions for the control of supplier non-conformances. Specifically, MOX Services will require suppliers of QL1-LR IROFS to submit reports of non-conformance to MOX Services identifying supplier/subcontractor disposition, technical justification, and verification of implementation of the disposition. MOX Services and the supplier will establish and document the process for disposition of items that do not meet procurement document requirements, and suppliers will be required to evaluate nonconforming items according to the applicable requirements of Section 15, "Nonconforming Materials, Parts, or Components," of the MPQAP.

Requirements for maintenance of the Commercial Grade Item Approved Suppliers List were added in Revision 11 of the MPQAP. The Commercial Grade Item Approved Suppliers List will be used for QL1-LR procurements and for those suppliers whose QA Programs have been evaluated and accepted by MOX Services for items that will be procured in accordance with approved procedures, as opposed to procurement in accordance with Appendix B. MOX Services will use the Commercial Grade Item Approved Suppliers List to document approval of suppliers certified/approved by UL or FM; accredited by SAS or COFRAC; or who have an ASME NCA-3800 certified QA program. Revision 11 of the MPQAP includes the commitment to perform a documented evaluation of commercial grade suppliers every 12 months. Suppliers of QL1-LR items and services whose evaluation is satisfactory will be maintained on the Commercial Grade Item Approved Suppliers List, whereas those who have unacceptable evaluations will have appropriate restrictions identified on the list.

Attachment B of Revision 11 of the MPQAP identifies that for QL1-LR IROFS, the procurement specification may be used in lieu of a separate commercial grade dedication package to document the safety function, critical characteristics, verification method, acceptance criteria, and basis for selection. In such cases, MOX Services 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 controls for supplier approval, performance monitoring, and dedication documentation for QL1-LR IROFS described by MOX Services in Revision 11 of the MPQAP and supporting submittals were reviewed by the staff and were found to be acceptable to meet the graded application of Appendix B, Criterion VII, on the basis that (1) performance of commercial grade suppliers will be monitored annually and status maintained on the Approved Commercial Grade Suppliers List; (2) the attributes of commercial grade dedication will be documented, although flexibility will exist with respect to whether documentation is captured in the procurement specification or a separate commercial grade dedication package; and (3) the majority of the elements of control of purchased material, equipment, and services, as defined in Section 7 of the MPQAP, will be applied in a like manner for QL-1 and QL1-LR IROFS. These elements include measures for evaluation of procurement proposals, interfacing with suppliers, processing of supplier generated documents, and the control of supplier non-conformances. Specific controls associated with the commercial grade dedication of QL1-LR IROFS (including

services) procured from UL and FM certified suppliers, SAS and COFRAC accredited laboratories, and ASME NCA-3800 certified suppliers are described in Attachment B of the MPQAP, and the staff's review of those controls is described in detail in Sections 3.3.a, 3.3.b, and 3.3.c, respectively, above.

3.4 Inspection

Criterion X of Appendix B provides requirements for inspection and states, in part, that an inspection program shall be established and executed to verify conformance of activities affecting quality with documented instructions, procedures, and drawings. Appendix B requires that these inspections be performed by individuals other than those who performed the activity being inspected.

The applicability table included in Revision 11 of the MPQAP identified that the requirements of Section 10, "Inspection," of the MPQAP apply in full as supplemented by provisions in Attachment B. The requirements of the MPQAP for inspection include commitments to plan inspection activities and control them in accordance with instructions, procedures, drawings, checklists, travelers or other appropriate means. The MPQAP also includes requirements for the use of inspection hold points, sampling, in-process monitoring, final inspection, item acceptance, and documentation of inspection attributes and results.

Attachment B of Revision 11 to the MPQAP identified that for QL1-LR IROFS, inspections may be performed by MOX Services qualified construction or assembly personnel in lieu of quality control (QC) inspectors. Personnel performing QL1-LR inspections will be independent of the work activity and will receive the same training and qualification as a Level II QC inspector (per MPQAP section 2.2.6.H), but will not receive certification as a Level II inspector and may not report through the QA/QC organization.

The measures described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to the inspection of QL1-LR IROFS were reviewed by the staff and were found to be acceptable on the basis that Appendix B requirements for inspection may be graded commensurate with the items' importance to safety, and QL1-LR items have been determined to be of low safety significance relative to other IROFS. Therefore, the use of appropriately trained craft-persons for inspection of QL1-LR IROFS is appropriate as long as the inspectors are independent of the work activity being inspected. MOX Services has committed to ensure that inspections are performed by personnel other than those who performed or directly supervised the work being inspected and who do not report directly to the immediate supervisor responsible for the work being inspected. Further, MOX Services will continue to satisfy the QL-1 training and qualification requirements for these personnel, with the exception of QL1-LR inspection personnel receiving certification as Level II inspectors. MOX Services will continue to plan, document, and conduct QL1-LR inspections in the same manner as QL-1 inspections. These inspection controls provide an acceptable level of QA to ensure the capability and independence of inspection personnel and the proper conduct of inspections necessary to ensure the availability and reliability of QL1-LR IROFS consistent with Criterion X of Appendix B.

3.5 Quality Assurance Records

Criterion XVII of Appendix B requires that sufficient records be maintained to furnish evidence of activities affecting quality. Criterion XVII requires that records be identifiable and retrievable and that requirements be established for record retention.

The applicability table included in Revision 11 of the MPQAP identified that the requirements of Section 17, "Quality Assurance Records," of the MPQAP apply in full as supplemented by provisions in Attachment B. The requirements of the MPQAP for records include provisions for the use of a records management system and controls for the generation, classification, retrieval, storage, and preservation of records. MOX Services defines lifetime records as those records that are of significant value in (1) demonstrating capability for safe operation; (2) maintaining, reworking, repairing, replacing or modifying an item; or (3) determining the cause of an accident or malfunction of an item. Lifetime records also include records that provide required baseline data for in-service inspections (Ref. 7).

Attachment B of Revision 11 to the MPQAP identifies that for QL1-LR IROFS, IROFS ranking evaluations will be maintained as lifetime records.

The measures described by MOX Services in Revision 11 of the MPQAP to be applied to records associated with QL1-LR IROFS were reviewed by the staff and were found to be acceptable on the basis that IROFS ranking evaluations will be retained as lifetime records, making them available for the life of the facility should they be needed for any future evaluations or reviews. Other records associated with QL1-LR IROFS will continue to be managed in accordance with the full set of existing MPQAP requirements for records. These controls meet the requirements of Appendix B and provide an acceptable level of QA to ensure the availability of records associated with QL1-LR IROFS.

3.6 Additional Changes

Criterion II of Appendix B requires, in part, that a QA program be established, documented by written policies, procedures, or instructions and carried out throughout plant life. Appendix B requires that the structures, systems, and components to be covered by the QA program be identified and controlled in a manner consistent with their importance to safety.

Revision 11 of the MPQAP revised Section 2 to remove a previously existing commitment for MOX Services to submit a list of IROFS subject to an graded QA program to the NRC. The requirement was removed since a description of the graded QA program, including the criteria for determining QL1-LR IROFS, was provided as Attachment B to the MPQAP (Ref. 5). The NRC Staff has reviewed this change and finds it acceptable on the basis that (1) the Staff has found the process described by MOX Services for determining and classifying the relative safety significance of IROFS acceptable (as described in this SER), and (2) documentation of those IROFS that are identified as QL1-LR will be maintained at the MFFF and will be available for NRC review as part of regular, ongoing inspections. Therefore, the removal of the commitment to submit this list to the NRC is acceptable as the information will still be maintained by MOX Services onsite and will be readily accessible to NRC for review. These commitments are consistent with the graded application of requirements of Appendix B for QA program controls.

3.7 QA Program Conclusions

The NRC Staff has reviewed the QA program changes requested by MOX Services in Revision 11 of the MPQAP and finds them acceptable on the basis that the provisions of Sections 4, 7, 10 and 17 of the MPQAP, as revised, provide an acceptable level of QA control commensurate with the safety significance of QL1-LR IROFS. Specifically, the measures described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to procurement document control; control of purchased material, equipment, and services; inspection; and maintenance of records associated with QL1-LR IROFS are satisfactory for the graded application of Appendix B for low risk IROFS at the MFFF.

4.0 CONCLUSIONS

The regulatory requirements of Appendix B allow the application of QA controls to be graded commensurate with the importance of items to safety. As described by MOX Services and reviewed by the staff in Section 3.1 of this SER, QL1-LR items have been determined to be of low safety significance relative to other IROFS.

The NRC staff has reviewed the QA program changes requested by MOX Services in Revision 11 of the MPQAP and finds them acceptable on the basis that the provisions of Sections 4, 7, 10 and 17 of the MPQAP, as revised, provide an acceptable level of QA control commensurate with the safety significance of QL1-LR IROFS. Specifically, the measures described by MOX Services in Revision 11 of the MPQAP and supporting submittals to be applied to procurement document control; control of purchased material, equipment, and services; inspection; and maintenance of records associated with QL1-LR IROFS are satisfactory for the graded application of Appendix B for low risk IROFS at the MFFF.

5.0 ADDITIONAL STATEMENT REGARDING APPLICABILITY OF APPROVAL

The approval of this request is specific to the MOX fuel fabrication facility that may be licensed to possess special nuclear material under 10 CFR Part 70, if all the required licensing requirements contained in the regulations are met.

6.0 REFERENCES

1. Letter from MOX Services to the U.S. NRC, "Submittal of Revision 11 of the MOX Project Quality Assurance Plan," May 31, 2012, ML12159A262.
2. Letter from David Tiktinsky to Dealis Gwyn, "Request for Additional Information Regarding the Review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility," July 31, 2012, ML12198A062.
3. Letter from MOX Services to the U.S. NRC, "RE: NRC-DCS-000642, letter from David Tiktinsky to Dealis Gwyn, dated July 31, 2012, Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility," September 24, 2012, ML12271A225.
4. Letter from David Tiktinsky to Dealis Gwyn, "Second Request for Additional Information Regarding the Review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility," March 11, 2013, ML13059A150.

5. Letter from MOX Services to the U.S. NRC, "RE: NRC-DCS-000669, letter from David Tiktinsky to Dealis Gwyn, dated March 11, 2013, Second Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility, April 1, 2013, ML13092A389.
6. Email from David Tiktinsky to Dealis Gwyn, "MPQAP Revision 11 Change 2 RAI Follow-up," dated April 22, 2013 (ADAMS Accession No. ML13115A208).
7. Letter from MOX Services to the U.S. NRC, "RE: NRC-DCS-000671, Email from David Tiktinsky to Dealis Gwyn, dated April 22, 2013, MPQAP Revision 11 Change 2 RAI Follow-up," April 29, 2013 (ADAMS Accession No. ML13120A278).
8. Letter from Arizona Public Service Company to the U.S. NRC, "Palo Verde Nuclear Generating Station Quality Assurance Program Reduction in Commitment," September 5, 2004, Accession No. ML042590501.
9. Safety Evaluation Report, "Palo Verde Nuclear Generating Station, Units 1, 2, and 3 – Approval of Change to Quality Assurance Program (Commercial-Grade Calibration Services) (TAC NOS. MC4402, MC4403, AND MC4404)," September 28, 2005, Accession No. ML052710224.
10. International Laboratory Accreditation Cooperation Brochure B7:05/2011, "The ILAC Mutual Recognition Agreement," Copyright 2010.
11. U.S. NRC Information Notice 86-21, "Recognition of American Society of Engineers Accreditation Program for N Stamp Holders."
12. U.S. NRC Information Notice 86-21, "Recognition of American Society of Engineers Accreditation Program for N Stamp Holders," Supplement 1.
13. U.S. NRC Information Notice 86-21, "Recognition of American Society of Engineers Accreditation Program for N Stamp Holders," Supplement 2.
14. ASME Boiler and Pressure Vessel Code III, Subsection NCA, General Requirements for Division 1 and Division 2," 2010 Edition.
15. U.S. NRC Information Notice 96-40, "Deficiencies in Material Dedication and Procurement Practices and in Audits of Vendors."
16. U.S. NRC Inspection Report No. 70-3098/2012-002, dated July 20, 2012 (ADAMS Accession No. ML12202B056).