

# **SAFETY EVALUATION REPORT RELATED TO THE EVALUATION OF AMENDMENT NUMBER MPQAP-2015-0002 OF THE “MIXED OXIDE PROJECT QUALITY ASSURANCE PLAN” DATED MAY 11, 2015, AS REVISED, FOR THE MIXED OXIDE FUEL FABRICATION FACILITY**

## **1.0 INTRODUCTION**

By letter dated May 31, 2012 (Ref. 1), CB&I AREVA MOX Services (MOX Services) submitted proposed changes documented in Revision 11 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 for items relied on for safety (IROFS) and a graded quality assurance (QA) program to be applied to IROFS whose relative importance to safety is determined to be low, designated as QL-1LR items. By letter dated June 14, 2013 (Ref. 2), NRC approved the proposed changes in Revision 11, Change 3, to the MPQAP.

By letter dated May 11, 2015 (Ref. 3), MOX Services submitted Amendment Number MPQAP-2015-0002 of the MPQAP to the NRC for review and approval in accordance with 10 CFR 70.23(b). In Amendment Number: MPQAP-2015-0002, MOX Services proposed revising the MPQAP to, among other things, reduce the required documentation for commercial grade items from suppliers who receive independent accreditation from Underwriters Laboratory (UL) or Factory Mutual (FM).

By letter dated September 8, 2015 (Ref. 4), the NRC sent a request for additional information to seek further clarification from MOX Services on the proposed changes to the MPQAP. By letter dated December 2, 2015 (Ref. 5), MOX Services provided clarification to the proposed changes in its response to the NRC staff's request for additional information.

## **2.0 REGULATORY EVALUATION**

Footnote 3 of 10 CFR 70.23(b) identifies that the criteria in Appendix B, “Quality Assurance Criteria For Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” (Appendix B) will be used by the Commission in determining the adequacy of the Mixed Oxide Fuel Fabrication Facility quality assurance (QA) program.

Appendix B, Criterion IV, “Procurement Document Control,” requires, in part, 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.

Appendix B, Criterion VII, “Control of Purchased Material, Equipment, and Services,” requires, in part, that measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. Appendix B, Criterion II, “Quality Assurance Program,” requires, in part, that the QA 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.

Enclosure

The requirements of 10 CFR 21.21(c) require that “A dedicating entity is responsible for (1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and (2) Maintaining auditable records for the dedication process.”

In Section 4 of the MPQAP, MOX Services describes procurement document control. In Section 7 of the MPQAP, MOX Services describes the control of purchased items and services. In MPQAP Attachment B, “Augmented QA Program for IROFS,” Section 4.1, “Procurement Document/Control of Purchased Items and Services,” MOX Services describes the procurement requirements for commercial grade items designated as QL-1LR, and procured directly from suppliers based on independent accreditation from UL or FM.

### 3.0 TECHNICAL EVALUATION

#### 3.1 Procurement Document Control

Criterion IV of Appendix B requires, in part, 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 that, to the extent necessary, procurement documents shall require contractors or subcontractors to provide a QA program consistent with the pertinent provisions of Appendix B. As mentioned above in Section 2.0, Criterion II of Appendix B allows grading the control over activities affecting quality to an extent consistent with their importance to safety.

By letter dated June 14, 2013, NRC approved the proposed changes in Revision 11, Change 3, to the MPQAP. Regarding procurement document controls, the NRC staff reviewed the controls described by MOX Services in Revision 11, Change 3, and supporting submittals to be applied to QL-1LR IROFS and found them 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 QL-1LR 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 QL-1LR items. Specifically, the NRC approved Revision 11, Change 3, based on the following controls.

1. MOX Services will perform a surveillance of UL or FM to verify the adequacy of their processes for supplier certification and item testing;
2. The supplier will provide certification documentation demonstrating that they hold a current UL or FM certification for the product to be procured;
3. The supplier will provide its QA manual;
4. The supplier will provide its UL or FM product qualification test report for the item to be procured; and
5. The supplier will provide its process evaluation report from UL or FM’s evaluation of the supplier’s process controls during the purchase requisition/bid evaluation phase.

In its acceptance of Revision 11, Change 3 to the MPQAP, the NRC staff determined that the controls listed above are already graded for procurement of commercial grade items directly from suppliers based on independent accreditation from UL or FM. The NRC staff determined these minimum controls are necessary for MOX Services to verify that the items will meet their intended safety function, and provide required supporting documentation and QA records. Since the NRC approved Revision 11, Change 3, to the MPQAP, MOX Services has been using such controls to perform commercial grade dedication of the items in order to designate the items as basic components and QL-1LR IROFS.

In Amendment Number MPQAP-2015-0002, MOX Services proposed to continue to procure commercial grade items directly from suppliers based on independent accreditation from UL or FM with the proposed modification to require less supporting documentation. MOX Services performs commercial grade dedication of the items and identifies them as basic components for use as QL-1LR IROFS. In Amendment Number MPQAP-2015-0002, MOX Services proposes to eliminate the procurement control for the supplier to submit its QA manual and its process evaluation report from UL or FM's evaluation of the supplier's process controls. MOX Services stated that it has performed one-time surveillances on UL and FM to verify their certification processes. Based on the results of the surveillances, MOX Services considers the technical and quality review/oversight performed by UL and FM sufficient to allow acceptance of their certification. However, the NRC staff has determined that MOX Services cannot delegate UL or FM as a third party dedicating entity to perform the dedication process because MOX Services:

- Has not performed formal audits of UL or FM;
- Does not intend to perform audits of UL or FM in the future;
- Has not qualified UL or FM as a third party dedicating entity; and
- Has not placed UL or FM on the MOX Services approved suppliers list.

Therefore, as an NRC 10 CFR Part 70 licensee, MOX Services is required to perform commercial grade dedication for the items that are procured directly from suppliers based on independent accreditation from UL or FM to be identified as QL-1LR IROFS. Eliminating the commitment for MOX Services' to receive and review the supplier's QA manual and its process evaluation report from UL or FM's evaluation of the supplier's process controls would result in insufficient information for MOX Services to assure that the item will perform its safety function.

In Amendment Number MPQAP-2015-0002, MOX Services also proposes to add the note, "If UL or FM approves an item to a standard and engineering determines that meeting that standard meets the needed safety requirements, then the UL or FM [qualification test] report is no longer required." However, as discussed above, eliminating the UL and FM qualification test reports would not be acceptable because MOX Services must review these reports as part of its commercial grade dedication process to assure that the item will meet its intended safety function.

The NRC staff reviewed the procurement document controls described by MOX Services in Amendment Number MPQAP-2015-0002 of the MPQAP and supporting submittals to be applied to QL-1LR IROFS and were found to be not acceptable on the basis that: (1) procurement documents will not continue to specify appropriate documentation requirements which are necessary to assure adequate quality of QL-1LR items and services; and (2) by eliminating receipt and formal review of proposed documents, MOX Services would not continue

to document the applicable elements inherent to the commercial grade dedication process for the dedication of commercial grade items to be used as QL-1LR IROFS.

### 3.2 Control of Purchased Items and Services

Criterion VII of Appendix B 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 the procurement documents. Criterion VII also states that these measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

By letter dated June 14, 2013, the NRC approved the proposed changes in Revision 11, Change 3, to the MPQAP. Regarding control of purchased items and services, the NRC staff reviewed the controls described by MOX Services in Revision 11, Change 3, and supporting submittals to be applied to QL-1LR IROFS and found them 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. The graded QA program includes review of supplier furnished documentation by MOX Services as part of bid/supplier selection and receipt inspection and satisfaction of the elements of commercial grade dedication. These controls provide an acceptable level of QA to ensure the availability and reliability of QL-1LR IROFS consistent with Criterion VII of Appendix B.

As discussed above, in Amendment Number MPQAP-2015-0002, MOX Services proposes to eliminate the procurement control for the supplier to submit its QA manual and its process evaluation report from UL or FM's evaluation of the supplier's process controls. However, eliminating the UL and FM qualification test reports would not be acceptable because MOX Services must review these reports as part of its commercial grade dedication process to assure that the item will meet its intended safety function. In addition, MOX Services would not be able to maintain necessary QA records required for the dedication of procured commercial grade items and reporting of defects and noncompliance in accordance with the requirements of 10 CFR Part 21.

The NRC staff reviewed the control of purchased items and services described by MOX Services in Amendment Number MPQAP-2015-0002 of the MPQAP and supporting submittal to be applied to QL-1LR IROFS and found the proposed changes are not acceptable on the basis that: (1) the graded QA program does not include review of all necessary supplier furnished documentation by MOX Services as part of bid/supplier selection and receipt inspection necessary for commercial grade dedication; (2) does not maintain auditable records for the dedication process so that MOX Services, as the dedicating entity, can identify and evaluate deviations and report defects and failures to comply associated with substantial safety hazards for dedicated items; and (3) does not maintain auditable records for the dedication process in accordance with the requirements of 10 CFR Part 21.

### 4.0 CONCLUSIONS

The NRC staff has reviewed the changes requested by MOX Services in Amendment Number: MPQAP-2015-0002 and supporting document and finds them not acceptable. The NRC staff determined that the controls approved by NRC in Revision 11, Change 3, to the MPQAP are already graded for procurement of commercial grade items directly from suppliers based on

independent accreditation from UL or FM. By reducing the documentation requirements further: (1) procurement documents would not continue to specify appropriate documentation requirements which are necessary to assure adequate quality of QL-1LR items and services; (2) MOX Services would not continue to document the applicable elements inherent to the commercial grade dedication process for the dedication of commercial grade items to be used as QL-1LR items; (3) the graded QA program would not include review of all necessary supplier furnished documentation by MOX Services as part of bid/supplier selection and receipt inspection necessary for commercial grade dedication: and (4) auditable records for the dedication process would not be maintained.

## 5.0 REFERENCES

1. Letter from MOX Services to the NRC, "Submittal of Revision 11, Change 3, of the MOX Project Quality Assurance Plan," May 31, 2012, Agencywide Documents Access and Management System (ADAMS) No. ML12159A262.
2. Letter from NRC to MOX Services, "Approval of Changes to the Mixed Oxide Project Quality Assurance Program, Revision 11, Change 3, Change 3," June 14, 2013, ADAMS No. ML13127A456.
3. Letter from MOX Services to the NRC, "Submittal of Amendment Number MPQAP-2015-0002 of the MOX Project Quality Assurance Plan," May 11, 2015, ADAMS No. ML15132A212.
4. Letter from NRC to MOX Services, "U.S. Nuclear Regulatory Commission Request For Additional Information Related To Amendment MPQAP-2015-0002 Of The "Mixed Oxide Project Quality Assurance Plan" For The Mixed Oxide Fuel Fabrication Facility," September 8, 2015, ADAMS No. ML15232A112.
5. Letter from MOX Services to the NRC, "Response to Request for Additional Information Regarding MOX Project Quality Assurance Plan (MPQAP) Amendment Number: MPQAP-20 15-002," December 2, 2015, ADAMS No. ML15337A313.