

**SAFETY EVALUATION REPORT RELATED TO THE APPROVAL OF AMENDMENT
NUMBER: MPQAP-2015-0001 OF THE “MIXED OXIDE PROJECT QUALITY ASSURANCE
PLAN” FOR THE MIXED OXIDE FUEL FABRICATION FACILITY**

1.0 INTRODUCTION

By letter dated May 11, 2015 (Agencywide Documents Access and Management System [ADAMS] Accession No.ML15132A199), as revised on June 15, 2015 (ADAMS Accession Number 151156B372) and July 7, 2015 (ADAMS Accession Number 15188A460), CB&I AREVA MOX Services (MOX Services) submitted Amendment Number: MPQAP-2015-0001 of the MOX Project Quality Assurance Plan (MPQAP) (ADAMS Accession No. ML) to the U.S. Nuclear Regulatory Commission (NRC) for review and approval in accordance with Paragraph 70.23(b) of Title 10 of the *Code of Federal Regulations* (10 CFR). MOX Services proposed revising the MPQAP to use International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatories as described in Nuclear Energy Institute (NEI) NEI 14-05, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1 (ADAMS Accession No. ML14245A392). NEI 14-05, Revision 1, describes a process for purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by ILAC MRA signatories for basic components in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process. The NRC endorsed NEI 14-05, Revision 1, via “Final Safety Evaluation Report For Technical Report NEI 14-05, ‘Guidelines For The Use Of Accreditation In Lieu Of Commercial Grade Surveys For Procurement Of Laboratory Calibration And Test Services,’ Revision 1,” (Safety Evaluation Report) on August 28, 2014 (ADAMS Accession No. ML14322A535).

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 program. Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B 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.”

NUREG-1718 (NRC, 2000), “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 is to follow the 1994 edition of the ASME NQA-1, with the 1995 addenda (NQA-1-1994/1995a). Basic Requirement 7, “Control of Purchased Items and Services,” of NQA-1 1994/1995a states, in part, that the procurement of items and services shall be controlled to assure conformity with specified requirements.

MOX Services has committed to comply with the guidance contained in NQA-1-1994/1995a. The predominant criterion of Appendix B and NQA-1-1994/1995a that is related to the proposed MPQAP changes and which may be affected is Criterion VII, “Control of Purchased Items and Services.” Section 7 of the MOX Services MPQAP describes the control of purchased items and services. NEI 14-05 provides an approach for licensees and suppliers of basic components for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the ILAC

Enclosure

MRA in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

On the basis of its review, the NRC staff concluded in its SER that NEI 14-05, Revision 1, provides an acceptable approach for licensees and suppliers subject to Appendix B for using laboratory accreditation by ABs that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

3.0 TECHNICAL EVALUATION

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.

The NRC staff reviewed MOX Services proposed changes to the MPQAP identified in Amendment Number: MPQAP-2015-0001 finds them acceptable to meet the requirements of Criterion VII of Appendix B. The revised Section 7.2.2C4 of the MPQAP provides controls for purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by ILAC MRA signatories using the ILAC accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process in accordance with the guidance in NEI 14-05, Revision 1. The revised Section 7.2.2C4 provides a process for verifying that suppliers of calibration and testing services from domestic and international calibration and testing laboratories are accepted as signatories to the ILAC MRA. Specifically, the revised Section 7.2.2C4 requires, among other things:

1. A documented review of the laboratory's accreditation to verify that accreditation is performed by an AB recognized by the ILAC MRA, the accreditation encompasses ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," for calibration services, that the published scope of accreditation covers the needed measurement parameters, ranges, and uncertainties, and for testing services, that the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty;
2. That the purchase document requires certification by the laboratory, that the service has been provided in accordance with the laboratory's accredited ISO/IEC 17025:2005 accredited program and is within the scope of accreditation, that the purchase document imposes additional technical and administrative requirements to satisfy necessary quality assurance program and technical requirements, that the purchase document requires, for calibration services only, that the certificate of calibration include the as-found calibration data (for calibrated items found to be out-of-tolerance) and identification of

the laboratory equipment/standards used, and that the purchase document requires notification by the laboratory of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation; and

3. Receipt inspection will be performed to verify that the laboratory's documentation certifies that the contracted calibration or test service has been performed in accordance with their ISO/IEC 17025:2005 program, that the service has been performed within the scope of the accreditation, and that the purchase order's requirements are met.

CONCLUSIONS

The NRC staff has reviewed the changes requested by MOX Services in Amendment Number: MPQAP-2015-0001 and finds them acceptable on the basis that the provisions of Sections 7 of the MPQAP, as revised, continue to meet the requirements of Appendix B when purchasing commercial-grade calibration and testing services from calibration and testing laboratories accredited by ILAC MRA signatories in lieu of performing commercial-grade surveys.

Specifically, the measures described by MOX Services continue to provide sufficient controls to verify (1) that the calibration or test laboratory holds accreditation by an AB recognized by the ILAC MRA encompassing ISO/IEC 17025:2005 and that the procured service is within the scope of the accreditation; (2) that purchase documents require documentation of the laboratory's certification that the service was performed within the scope of the accredited program, necessary quality assurance program and technical controls, as-found calibration data for out-of-tolerance calibrated items, laboratory equipment and standards used, and notification provided to MOX Services of any condition that adversely impact the laboratory's accreditation; and (3) that receipt inspection will be conducted to verify that the laboratory's documentation certifies that the service has been performed within the scope of the accreditation and that the purchase order requirements are met.