

June 15, 2009

Mr. David Stinson
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 7, CHANGE 1

Dear Mr. Stinson:

By letters dated January 14 and June 11, 2009, Shaw AREVA MOX Services (MOX Services, 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 proposed changes would (1) provide for acceptance of accreditation of commercial-grade calibration services by a nationally-recognized accrediting body in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, (2) revise organizational titles and functional responsibilities, and (3) make various editorial and clarifying changes.

The enclosed safety evaluation documents the NRC staff's conclusion 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) and does not result in a reduction of commitments.

If you have any questions related to this letter or our MPQAP review, please contact David Tiktinsky at (301) 492-3229.

Sincerely,

/RA/

Margie Kotzalas, Chief
MOX Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No: 70-3098

Enclosure: Safety Evaluation

cc w/enclosure:

S. Glenn, NNSA/SRS

J. Olencz, NNSA

S. Jenkins, SC Dept. of HEC

D. Silverman, Esq., MOX Services

G. Shell, MOX Services

A.J. Eggenberger, DNFSB

L. Zeller, BREDL

G. Carroll, Nuclear Watch South

D. Curran, Esq., Nuclear Watch South

D. Gwyn, MOX Services

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SAFETY EVALUATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
PROPOSED CHANGES TO THE MIXED OXIDE PROJECT
QUALITY ASSURANCE PLAN, REVISION 7, CHANGE 1

1.0 INTRODUCTION

By letters dated January 14 and June 11, 2009, Shaw AREVA MOX Services (MOX Services, 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 proposed changes would (1) revise organizational titles and functional responsibilities, (2) make various editorial and clarifying changes, and, (3) provide for acceptance of accreditation of commercial-grade calibration services by a nationally-recognized accrediting body in lieu of a supplier audit, commercial-grade survey, or in-process surveillance. This method for qualifying the calibration supplier and accepting its calibration services would be applied only to commercial-grade services.

2.0 REGULATORY EVALUATION

The applicant's quality assurance (QA) program for design and construction of the Mixed Oxide Fuel Fabrication Facility is described in the MPQAP. The MPQAP identifies the regulatory guides and standards to which the applicant has committed in satisfying the criteria of Appendix B to 10 CFR Part 50 as required by Footnote 3 of 10 CFR 70.23(b). The predominant criteria of Appendix B that are related to the proposed MPQAP changes and which may be affected are Criteria 1, 4, 7, 12, 17, and 18.

Criterion 1, "Organization," allows for the delegation of authorities and duties for carrying out portions of the MPQAP to others. Delegation of commercial-grade services would be controlled through procurement documents and purchasing requirements.

Criterion 4, "Procurement Document Control," requires that measures be established to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure quality are stipulated or referenced in procurement documents.

Criterion 7, "Control of Purchased Material, Equipment, and Services," requires that measures be established to assure that purchased material, equipment, and services conform to the procurement documents.

Criterion 12, "Control of Measuring and Test Equipment," requires that measures be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

Criterion 17, "Quality Assurance Records," requires that records that furnish documentary evidence of quality be specified, prepared, and maintained and that records be protected against damage, deterioration, or loss.

Criterion 18, "Audits," requires that a comprehensive system of planned and periodic audits be carried out by appropriately trained personnel not having direct responsibility in the areas being audited.

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 10 CFR Part 50 Appendix B is to follow the 1994 edition of the American Society of Mechanical Engineers, Nuclear Quality Assurance Standard (ASME NQA-1) with the 1995 addenda.

3.0 TECHNICAL EVALUATION

3.1 MPQAP, Section 1 "Organization"

The applicant proposed the following changes to MPQAP, Section 1 "Organization."

- Add receipt inspection functions to the responsibilities of the Quality Control Manager.
- Add document control and record management functions to the responsibilities of the Vice President of Engineering.
- Revise title of "Vice President and Chief Administrative Officer" to "Vice President Business Systems." Delete document control, records management, finance and accounting, and facilities management functions and add communications functions.
- Make various editorial and organizational title changes without corresponding changes in functional responsibilities.

ASME NQA-1, Basic Requirement 1, "Organization" states that "[p]ersons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to: (a) identify quality problems; (b) initiate, recommend, or provide solutions to quality problems through designated channels; (c) verify implementation of solutions; and (d) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred." The staff has reviewed the proposed functional changes, including the organizational chart, and has determined that the organizational freedom to identify and correct quality problems would continue to exist. Because the proposed changes meet the requirements of ASME NQA-1, Basic Requirement 1, the staff has determined that this proposed change is acceptable.

3.2 MPQAP, Sections 2 "Quality Assurance Program," 4 "Procurement Document Control," 5 "Instructions, Procedures, and Drawings," and 6 "Document Control"

The proposed changes in these sections are editorial and do not affect the technical adequacy of the MPQAP. For this reason, the staff has determined that these sections of the MPQAP continue to meet the requirements of ASME NQA-1 Basic Requirement 2, Basic Requirement 4, Basic Requirement 5, and Basic Requirement 6 and are acceptable.

3.3 MPQAP, Section 7 "Control of Purchased Materials, Equipment, and Services"

The proposed change would provide for acceptance of accreditation of commercial-grade calibration services by a nationally-recognized accrediting body, using procedures consistent

with international standards and guidelines, specifically those found in ANSI/ISO/IEC 17025 “General Requirement for the Competence of Testing and Calibration Laboratories.” The scope of services would be bound by the accreditation parameters, ranges and uncertainties. To implement this change, the applicant would impose additional requirements in procurement documents, such as (1) additional technical and administrative requirements to satisfy QA program and technical requirements, (2) reporting as-found calibration data when calibrated items are found to be out-of-tolerance, and (3) identification of the laboratory equipment and standards used. The accreditation process would be credited in lieu of a supplier audit, commercial-grade survey, or in-process surveillance. This method for qualifying the calibration supplier and accepting its calibration services would be applied only to commercial-grade calibration services.

Use of an accreditation process as an alternative to audits, surveys, or surveillances has been accepted by the NRC and documented in a September 28, 2005, letter to G. R. Overbeck (Palo Verde Nuclear Generating Station, ML052710224). The bases of the NRC’s approval are as follows:

- Alternative method is documented in the QA program
- Accreditation is to ANSI/ISO/IEC 17025
- Approval is limited to National Voluntary Laboratory Accreditation Program (NVLAP) and American Association for Laboratory Accreditation (A2LA)
- Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements
- Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance, and
- Purchase documents require identification of the laboratory equipment and standards used.

The applicant’s proposed change meets the NRC’s bases for approval and is therefore acceptable.

3.4 MPQAP, Sections 15 “Nonconforming Materials, Parts, or Components,” 16 “Corrective Action”

The proposed changes in these sections are editorial and do not affect the technical adequacy of the MPQAP. For this reason, the staff has determined that these sections of the MPQAP continue to meet the requirements of ASME NQA-1 Basic Requirement 15 and Basic Requirement 16 and are acceptable.

3.5 MPQAP, Section 17 “Quality Assurance Records”

The applicant has proposed changes to the description of records repositories and temporary storage to clarify the ASME NQA-1 requirements for records retention by providing examples of the types of records and their storage requirements prior to entering permanent storage. For example, the applicant stated that “documents used for acceptance or rejection which remain in use for more than one shift shall be placed in temporary storage by the originating organization until completion.” The applicant also clarified requirements for the temporary storage of electronic records (i.e., storage will be on project computer shared drives or in a container or facility with a fire rating of one hour). The staff has reviewed these changes

against the requirements of ASME NQA-1 Basic Requirement 17 and determined that the changes are acceptable.

3.6 MPQAP, Section 18 “Audits”

The applicant proposed additional information to address requirements for lead auditor certification when the individual has previously been certified as a lead auditor. The additional information is consistent with the supplementary requirements for the qualification of QA program audit personnel of ASME NQA-1, Supplement 2S-3, Section 4.2 and is acceptable.

3.7 MPQAP, Attachment 1 “ASME/NQA-1-1994 through 1995a, Part II Applicability to MOX Project

The applicant proposed an attachment to describe the applicable sections of ASME NQA-1 Part II. In prior revisions of the MPQAP, this information was described in Section 2 in tabular form. Additionally, the applicant added clarifying language on the use of Subpart 2.1, Planning. The applicant stated that planning is frequently performed on a generic basis for application to many systems and component installations and that individual plans are not normally prepared unless the work operations are unique. The staff has reviewed this clarifying information against the requirements of ASME NQA-1 Part II, Subpart 2.1 and determined that it is acceptable.

3.8 Augmented QA Program

In MPQAP, Revision 5, dated June 20, 2007, the applicant stated that it would transmit to the NRC a list of QL-1 items relied on for safety (IROFS) that use augmented QA programs. This commitment was being tracked by the NRC as an open item. However, the list of QL-1 IROFS that are subject to augmented QA is not necessary for the staff to make a regulatory finding on the acceptability of the MPQAP and therefore, this item is closed.

4.0 CONCLUSIONS

The NRC staff has reviewed the proposed changes to the quality assurance program as documented in MPQAP, Revision 7 Change 1 and evaluated the changes against the requirements of the 1994 edition of ASME NQA-1 with the 1995 addenda. Based on its review, the staff determined that the proposed changes meet the requirements of ASME NQA-1 and that changes to the MPQAP continues to satisfy the criteria of Appendix B to 10 CFR Part 50 as required by Footnote 3 of 10 CFR 70.23(b). Therefore, the changes are not a reduction of commitments and MPQAP Revision 7 Change 1 is acceptable for design and construction activities at the Mixed Oxide Fuel Fabrication Facility.