July 26, 2010

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 9

Dear Mr. Trice:

By letter dated June 9, 2010, Shaw AREVA MOX Services 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 were initiated to incorporate additional operational phase controls necessary to support startup and operations of the Mixed Oxide Fuel Fabrication Facility (MFFF).

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).

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 component of NRC's Agency-wide 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).

If you have any questions related to this letter or our MPQAP review, please contact David Tiktinsky at 301-492-3229 or via e-mail at David.Tiktinsky@nrc.gov.

Sincerely,

/RA/

Marissa G. Bailey, Deputy Director
Special Projects and Technical
Support Directorate
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No: 70-3098

Enclosure: As stated

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

If you have any questions related to this letter or our MPQAP review, please contact David Tiktinsky at 301-492-3229 or via e-mail at David.Tiktinsky@nrc.gov.

Sincerely,

/RA/

Marissa G. Bailey, Deputy Director
Special Projects and Technical
Support Directorate
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No: 70-3098

Enclosure: As stated

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

DISTRIBUTION:
MOX r/f W. Gloersen, RII D. Seymour, RII

ML102020561

OFFICE	MODB	MODB	MODB	SPTSD
NAME	DTiktinsky	SAtack	LCampbell	MBailey
DATE	7/22/10	7/23/10	7/21/10	7/26/10

OFFICIAL RECORD COPY

SAFETY EVALUATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
APPROVAL OF THE MOX FUEL FABRICATION FACILITY QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION 9

1.0 INTRODUCTION

By letter dated April 19, 2010, 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). By letter dated June 9, 2010, MOX Services submitted further clarifications to the MPQAP, as documented in Revision 9, Change 1 to the MPQAP. The proposed changes include revisions to include guidance and additional requirements to support the startup and operations phases of the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF). All sections of the MPQAP underwent modification between Revision 8 and Revision 9, Change 1 to the MPQAP. As Revision 9, Change 1 includes all the changes submitted under Revision 9 to date and any reference to Revision 9 herein will include both Change 0 and Change 1.

2.0 REGULATORY EVALUATION

The applicant's quality assurance (QA) program applicable to the design, construction, and operation of the MFFF 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 1-18.

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 to 10 CFR Part 50 is to follow the 1994 edition of the ASME NQA-1, with the 1995 addenda.

3.0 TECHNICAL EVALUATION

In the Introduction to the MPQAP, the applicant identifies Shaw Project Services Group, Inc.; Shaw Environmental and Infrastructure; and AREVA Federal Services, LLC as the equity owners of MOX Services. The applicant revised its discussion of the use of subcontractor QA Programs to identify the following quality-affecting transportation activities that will be performed during Design, Construction, and Operations: (1) the design of shipping packages, (2) licensing and fabrication for the fresh MOX fuel assemblies to be transported between the MFFF and mission reactors, and (3) the design of equipment to load the fuel assemblies into the shipping packages. The applicant states that AREVA Federal Services, LLC, who will perform this work under the AREVA Federal Services LLC QA Plan as a subcontractor to the applicant, will be maintained as an approved supplier on the MOX Services Approved Suppliers List (ASL).

In the General statement of each individual MPQAP section, the applicant made changes such that each section (1) identifies the title for Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction);" and (2) includes a statement identifying that during

Operations, the MOX project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), "Quality Assurance Program Requirements (Operation)."

These changes were reviewed by the staff and were found to be acceptable on the basis that (1) changes to the Introduction material are not subject to NRC review and approval as they do not contain commitments on the part of the applicant, and (2) the addition of RG 1.33 adds information related to the resources MOX Services will use for guidance as it transitions from design and construction to operations, as provided in commitments in each section of the MPQAP.

3.1 Organization

3.1.1 General

The applicant defines the functional structure of the MOX Services organization in Figure 1-1 of the MPQAP. Figure 1-2 depicts the structure of the MOX Project Assurance Organization, including the lines of authority from the Regulatory Compliance Manager, Licensing Manager, and QA/QC Manager to the Project Assurance Manager to the MOX Services President/COO/Project Manager. The figure was revised in Revision 9 of the MPQAP to show that the QA Manager and the QC Manager have direct access to the MOX Services President/COO/Project Manager.

In Revision 9 of the MPQAP, the applicant clarified the transition that its organizational structure will undergo as the facility shifts from construction to operations. The applicant stated that as the project progresses toward construction completion and the beginning of the operations phase, the focus of the organizational structure will shift from design and construction to operation. The applicant added to the MPQAP the statement that as the construction of systems is completed, the systems will undergo construction/commissioning testing, followed by preoperational testing, followed by turnover to Operations Start-up for completion of final acceptance testing.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes added clarity to (1) the reporting structure shown in Figure 1-2 and (2) the system testing that will be performed as part of the facility's transition from construction to operations.

3.1.2 Organizational Responsibilities

In Revision 9 of the MPQAP, the applicant revised the organizational descriptions of the following positions: MOX Services President/COO/Project Manager; Manager Project Assurance; Manager Quality Assurance/Quality Control; Licensing Manager; Regulatory Compliance Manager; Vice President Facility Design and Construction; Manager Environmental Safety & Health; Vice President Business Services; Vice President Operations; Vice President Project Services; Vice President Process Unit Design and Commissioning.

MOX Services President/COO/Project Manager

In Revision 9 of the MPQAP, the applicant revised the title for the MOX Services President and Project Manager to the MOX Services President/COO/Project Manager.

Manager Project Assurance

In Revision 9 of the MPQAP, the applicant revised the title for the Project Assurance Organization lead from Vice President Project Assurance to Manager Project Assurance. The applicant revised the position description as well. In Revision 9 of the MPQAP, the applicant states that the MOX Services Manager Project Assurance reports directly to the MOX Services President and is responsible for Quality Assurance, Licensing, and Regulatory Compliance. The applicant also states that the Manager of Quality Assurance/Quality Control, Licensing Manager, and the Regulatory Compliance Manager report to the Manager Project Assurance. The applicant also added a statement that the size of the Project Assurance Organization will be commensurate with the duties and responsibilities of the Organization.

The applicant states that the Manager of Quality Assurance/Quality Control will be independent of the managers responsible for performing quality-affecting work and will also be independent of cost and schedule considerations. The applicant states that the Manager of Quality Assurance/Quality Control will be responsible for maintaining the MPQAP and verifying its effective implementation at applicable MOX Services work locations.

The applicant further states that the manager responsible for the performance of controlled activities will approve the procedures used for those activities. As stated by the applicant, procedures that directly implement the QA Program requirements will obtain the concurrence of the quality assurance organization, and MOX Services Quality Assurance will witness and/or perform specified testing and inspections of items relied on for safety (IROFS).

The applicant added further descriptions of the responsibilities and interfaces of the QA and QC Managers. The applicant states that both Quality Managers will (1) be independent of the managers responsible for performing quality-affecting work, (2) be independent of cost and schedule considerations, (3) have the same access to the President as the line managers of the various functional areas of the project, (4) have an effective line of communication with other senior management, and (5) report to the Manager of Quality Assurance/Quality Control. The applicant commits to ensure that individuals who are assigned responsibility for ensuring effective execution of any portion of the QA program at any location have direct access to the Manager of Project Assurance.

In Revision 9 to the MPQAP, the applicant explains that although the Manager Quality Assurance/Quality Control may be assigned other duties, no duties will be allowed to compromise the independence of this function or to prevent needed attention to QA matters. The applicant commits to give the Manager Quality Assurance/Quality Control direct reporting access to the MOX Services President on quality-related matters.

As revised, the applicant describes the scope of responsibilities included in the Regulatory Compliance Manager position as the planning and execution of compliance activities, including interfaces with regulatory agencies. The applicant states that the Regulatory Compliance Manager will be responsible for regulatory compliance, direct interface with the NRC, and coordination between the DOE and the NRC, as required for MFFF regulatory compliance.

Vice President Facility Design and Construction

In Revision 9 of the MPQAP, the applicant identifies the reporting authority and organizational interrelationships of the Vice President Facility Design and Construction and states that the Vice President Facility Design and Construction reports to the MOX Services Project Manager during

design and construction and is responsible for the integration of MFFF engineering and construction activities. The applicant states that the Vice President Engineering and the Vice President Construction report to the Vice President Facility Design and Construction.

The applicant defines the responsibilities of the Vice President Engineering and states that this function will provide the engineering and design services throughout the life of the MFFF Project and is responsible for safety analysis activities and nuclear criticality safety. The applicant also states that the Vice President Engineering is responsible for design authority and engineering program management/configuration control.

The applicant states that, during the design phase, the process design function will provide the MFFF process design, and during operations, it will provide process design support of MFFF construction and equipment fabrication and installation. The applicant states that the process design function will also support Plant Operations in the development and performance of in-plant startup testing and the development of operating and maintenance procedures. In Revision 9 to the MPQAP, the applicant also states that the software function, process unit function, and the laboratory function will report to the VP Process Unit Design and Commissioning. The applicant states that although these groups will receive functional direction and day-to-day priorities from the VP Process Unit Design and Commissioning, they will receive technical direction from the VP Engineering.

As part of its description of the responsibilities and function of the Vice President of Construction, the applicant added information about construction acceptance testing to the MPQAP. The applicant commits to perform construction acceptance testing, which is performed to confirm proper installation of components and readiness for startup testing, in accordance with approved procedures.

Manager Environmental Safety & Health

In Revision 9 to the MPQAP, the applicant clarified that the Manager Environmental Safety & Health reports directly to the MOX Services President. The applicant also added that, in addition to being responsible for Environment, Safety, and Health (ES&H) requirements, the Manager ES&H will be responsible for Environmental Management, Industrial Safety, Environmental Health, Emergency Preparedness, and Radiation Protection to ensure consistent interpretation of ES&H requirements, support licensing, perform design reviews, and manage development of the Environmental Report. The applicant also added that the Manager Environmental Safety & Health will continue to ensure compliance with ES&H requirements during the operations phase.

Vice President Business Services

The applicant revised the position title from Vice President Business Systems to Vice President Business Services.

Vice President Operations

The applicant made a complete revision to the description of the Vice President of Operations between Revisions 8 and 9 of the MPQAP. As revised, the MPQAP states that the Vice President Operations will develop and implement a comprehensive Project Management Program for the MFFF Physical Security, Startup, Operations, Fuel Services, and Material Control & Accountability (MC&A).

The applicant defines the responsibilities of the Plant Operations function, which include: (1) fuel qualification, (2) fuel assembly mechanical design, (3) development and implementation of the plan for the design, manufacture, and transportation of lead assemblies, (4) operability reviews for design and licensing support of the MFFF, (5), development and qualification of processes and procedures for operations and maintenance activities, (6) providing input with respect to functional testing needed as preparation for start-up testing and the transition to operations, (7) directing all start-up activities, test programs, and test procedures for onsite Cold Start-up Tests, and (8) operation and maintenance of the MFFF. MOX Services identifies configuration management, preparation of operating procedures, staffing and training of qualified plant personnel, implementation of a maintenance program and preparation of maintenance procedures, implementation of safe work practices and emergency response programs as functions performed by plant Operations during the operation and maintenance of the MFFF. The applicant also states that the Plant Operations function will report directly to the President during the operations phase.

The applicant states that the Vice President Operations will also be responsible for Irradiation Services and Packaging & Transportation for the project. The applicant explains that the Irradiation Services and Packaging & Transportation function provides oversight of programs executed within and for the MFFF Project, oversight and control of the change management processes, and independent review of overall project performance. The applicant also identifies the Irradiation Services and Packaging & Transportation organization as the lead for interfacing with the Department of Energy for scope, cost, and schedule performance.

The applicant states that the Irradiation Services function provides support for core design, core physics, license modifications to the mission reactors, and development of the irradiation plan during the design phase. The applicant states that during construction, the Irradiation Services function will provide the interface between the mission reactors and MOX Services and as such, is responsible for coordination with the mission reactors on implementation of modifications for use of the MOX fuel.

The applicant states that the Packaging & Transportation function supports the development and implementation of the MOX fresh fuel package planning, transportation integration planning, MOX fuel package design, and lead assembly transportation. The applicant further states that during the operations phase, the Irradiation Services function will continue to provide the interface between MOX Services and the mission reactors, coordinating transportation and logistics, as necessary, to deliver the MOX fresh fuel assemblies to the mission reactors for irradiation.

Vice President Project Services

Between Revisions 8 and 9 of the MPQAP, the applicant revised the position title from Vice President Fuel Services to Vice President Project Services and made a complete revision to the position description.

In Revision 9 to the MPQAP, the applicant identifies the responsibilities of the Vice President Project Services and states that the Vice President Project Services is responsible for implementing a comprehensive schedule and risk management program for the MFFF project. The applicant explains that the Project Services function (1) provides technical direction and oversight of the Construction Project Control function, (2) manages the performance

measurement process, and (3) ensures effective implementation and operation of the MOX Services Earned Value Management System.

The applicant defines the scope of the Project Services function and states that the function is responsible for document control files and the distribution and maintenance of all project records associated with the administration, operation, and maintenance of the MFFF in the Electronic Document Management System. The applicant states that the Project Records Center group (1) maintains and stores all Project Records and Quality Assurance Records, (2) controls the revision of engineering, licensing, quality assurance, procurement, vendor, and project management records, (3) transmits and periodically inventories all controlled documents, and (4) performs archival storage of official project records that produce objective evidence of project activities.

The applicant identifies additional responsibilities of the Project Services function. The applicant states that the function is responsible for software development, certification, rollout, and support of IT systems and is responsible for all Information Technology design tools used by the project to support engineering, construction, startup, and operations.

Vice President Process Unit Design and Commissioning

Between Revisions 8 and 9 of the MPQAP, the applicant renamed the Vice President Projects as the Vice President Process Unit Design and Commissioning. The applicant also made a complete revision to the position description for the now-titled Vice President Process Unit Design and Commissioning.

The applicant identifies the function of the Vice President Process Unit Design and Commissioning and states that the Vice President Process Unit Design and Commissioning is responsible for (1) commissioning (in-advance testing) as well as design, procurement, fabrication, assembly, functional component, and equipment checkouts of the MFFF process units in the U.S. and Europe, (2) oversight of the Process Unit, Software, and Lab design group functions, and (3) ensuring effective interface with Construction, Engineering, Quality Assurance, and Start-Up to meet overall project technical, cost, and schedule performance.

In Revision 9 of the MPQAP, the applicant explains that although the software function, process unit function, and laboratory function report to and receive functional direction and day to day priorities from the VP Process Unit Design and Commissioning, these functions receive technical direction from the VP Engineering.

MOX Services states that the software design function, which is responsible for the design of the software needed to operate the integrated control system for the MFFF, also provide support to other facility activities. The software design function supports Plant Operations in the performance of equipment acceptance and start-up testing and the development of operating procedures, operator training modules, equipment acceptance tests, and start-up tests. MOX Services also states that the software design function will transition to Plant Operations in the operations phase in order to support maintenance and maintain configuration control of the operations software.

MOX Services also added a description of the process unit design function in Revision 9 to the MPQAP and states that the function (1) performs design of the MFFF Process Units, Laboratory Units, Chemical Units, and AP and MP Units, including internal equipment/subassemblies and

associated mechanical, electrical, and long lead equipment, (2) coordinates with Procurement and QA to ensure engineering and QA requirements are included in procurement documents and are satisfied by the suppliers of purchased equipment, (3) holds responsibility for glove box and equipment technical specifications, (4) provides support to Plant Operations for the development of operating procedures, operator training modules, equipment acceptance tests, and start-up tests, (5) coordinates equipment installation and design support for construction, and (6) supports the performance of equipment acceptance and start-up testing.. As stated in the MPQAP, the design managers have a technical reporting relationship with the VP Engineering. This function also transitions to Plant Operations once the operations phase of MFFF begins.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes added clarity and detail to the organizational positions and structure that will be implemented as the MFFF project progresses from design and construction to operations.

3.1.3 Requirements

As part of its description of controls for the delegation of work in Section 1.3.3 of the MPQAP, the applicant added the requirement to perform periodic evaluations when work is delegated.

The NRC staff evaluated this change and found that it was acceptable because it enhances the MFFF QA Program by establishing measures to ensure the quality of delegated work.

Based on its review of the changes described above to Sections 1.1, 1.2, and 1.3 of the MPQAP, the staff concluded that the reporting structure, system testing requirements, position descriptions, and controls for the evaluation of delegated work described in the MPQAP for the MFFF Organization, as revised, are consistent with the requirements of Criterion I of Appendix B to 10 CFR Part 50.

3.2 QUALITY ASSURANCE PROGRAM

MOX Services added a new subsection, Section 2.1.3, “Transition to Operational MPQAP Requirements,” as part of Revision 9 of the MPQAP. The section states that full implementation of the Operational QA requirements will be enforced after each System or Area Turnover as the MFFF transitions from Construction to Startup and Operations. Section 2.1.3 also added the commitment that the Operating Limits Manual will be in place and functioning prior to the introduction of Special Nuclear Material into the MFFF Process Systems.

In Section 2.2.6, “Personnel Indoctrination, Training, and Qualification,” the applicant added requirements for indoctrination and training records. The applicant added the requirement that records relating to the implementation of indoctrination and training include formal classroom training lesson plans and records of the objectives and content of training. These requirements will supplement the existing requirements of maintaining training attendance sheets and personnel training records.

The applicant also added further requirements for the content of procedures for the certification of inspection and test personnel. The applicant added clarification of procedural requirements for on the job training and initial certification of personnel. In Section 2.2.6.H.3, MOX Services identified that when on-the-job training is to be implemented as part of the formal training program, the training will emphasize first-hand experience gained through actual performance of

inspections and tests *under the direct observation and supervision of a qualified person and verification of conformance is by the qualified person until certification is achieved.* Section 2.2.6.H.4 was clarified to state that MFFF procedures will provide for the initial evaluation of candidate capability through evaluation of the candidate's education, experience, training, and either test results or capability demonstration *in performing the type of inspection or test commensurate with the job*.

Section 2.2.6.H.5 was clarified to state that MFFF procedures will require that any person who has not performed inspection or testing activities in his or her qualified area for a period of 1 year will be reevaluated by a re-determination of required capability *prior to performing inspection and test activities*. Section 2.2.6.H.6 was revised to allow the list of qualification records (i.e., employer's name; identification of person being certified; activities certified to perform; basis used for certification, etc.) to be applied "as appropriate" to the circumstances of the individual being trained. Also, an additional criterion was added to the list of possible qualification records: examination results.

As part of Section 2.2.7, "Management Assessments," of the MPQAP, MOX Services revised the requirement to perform annual assessments of quality-affecting activities to state that quality-affecting activities will be evaluated annually or at least once during the life of the activity, which ever is shorter. MOX Services also added the provision that management assessments of operational activities may be extended to once every two years.

In Section 2.2.9 of the MPQAP, "Provisions for Continuing QA," the applicant revised the description of how changes to the MPQAP are submitted to and approved by the NRC. In Revision 9 of the MPQAP, MOX Services states that changes to the MPQAP will not be regarded as accepted by the NRC until a letter to this effect is received from the appropriate reviewing office of the NRC.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes set forth more robust expectations for indoctrination and training records and procedures, management assessments, and for maintenance of the MPQAP. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion II of Appendix B to 10 CFR Part 50.

3.3 DESIGN CONTROL

In Section 3.1, "General," of the MPQAP, the applicant added a statement to ensure that design control is maintained in the selection of materials for the design and construction of IROFS. Specifically, the applicant committed to establish controls for the selection and suitability of application of design methods, materials, parts, equipment and processes that are essential to the functions of structures, systems and components.

In Section 3.2.3, "Design Analysis," of the MPQAP, the applicant added requirements for documentation of design analyses related to computer calculations. In addition to requiring the computer type, computer program (e.g., name), revision identification, inputs, outputs, and bases for use of the program to be documented, the applicant added the requirement to document evidence of or provide reference to the computer program verification. This provision is consistent with the requirements identified in Supplement 3S-1 of NQA-1-1994, which requires that documentation of design analyses include the "identification of any computer calculation, including computer type, computer program (e.g.,name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or

reference thereto) supporting application of the computer program to the specific physical problem." As revised, the MPQAP includes all the requirements identified in Section 3.1(b) of Supplement 3S-1 to NQA-1-1994 for design analysis documentation.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes provided a more thorough description of MOX Services controls that will be applied to the application of design control in the (1) selection of materials, parts, equipment, and processes to ensure the functionality of IROFS and (2) the demonstration that the suitability of computer programs used in safety-related applications has been verified. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50.

3.4 PROCUREMENT DOCUMENT CONTROL

The only change to Section 4, "Procurement Document Control," of the MPQAP between Revision 8 and Revision 9 was the inclusion of the statement that "During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*." The staff reviewed this inclusion, as discussed in Section 3.0 of this SER and found it acceptable as it provides relevant information regarding the basis used by the applicant to ensure compliance with regulatory requirements during operations.

3.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The applicant added a statement to Section 3.5.1, "General," of the MPQAP to clearly state that MOX Project Procedures will be approved by the MOX Services Project Manager.

The applicant refined its description of implementing documents in Section 5.2.1 of the MPQAP such that the applicant now states that implementing documents include QA procedures and specifications, and, in some cases, QA Program requirements may be included in other documents, such as drawings.

In Section 5.2.2, "Content of Implementing Documents," the applicant clarified the requirements for information to be contained in implementing documents. Specifically, the Section 5.2.2.C requires that implementing documents contain a sequential description of the work to be performed, including controls for altering the sequence of required inspections, tests, and other operations. In Revision 9 to the MPQAP, MOX Services modified this statement to clarify that the inspections, tests, and other operations referred to in this subpart are those that are relied on for safety. The applicant also clarified that any alteration of the sequential description of work to be performed will be subjected to the same change controls as those for the original review and approval.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes constituted improvements to the MPQAP. Specifically, the revision: (1) clearly identified the approval authority for MOX Project Procedures, (2) clarified the expectation of which implementing documents are subject to QA requirements, (3) limited the cross-section of implementing documents identified as quality-related documents that such that only documents containing safety-related QA specifications are controlled, rather than all documents (e.g., drawings), and (4) refined the wording related to the control of implementing documents to make clear that the requirements apply to implementing documents issued for IROFS inspections, tests, and operations, and (5)

established revision control for any changes to the sequence of IROFS inspections, tests, and operations that is equivalent to the control implemented for the initial issuance of the sequence. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion IV of Appendix B to 10 CFR Part 50.

3.6 DOCUMENT CONTROL

The applicant revised Section 6.2, "Requirements," of the MPQAP to increase the level of detail used to define its document control program. In Section 6.2.1 of the MPQAP, the applicant commits to control the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality in order to ensure that the correct documents are used onsite. In Revision 8 to the MPQAP, the applicant identified exampled of these documents as including project procedures, Design Requirements documents, Basis of Design documents, engineering specifications, drawings, calculations, and procurement documents. In Revision 9 to the MPQAP, the applicant clarified and added additional examples of documents that specify quality requirements or prescribe activities affecting quality. The new and revised examples include: engineering design specifications, design drawings, as-built drawings, engineering calculations, purchase orders and related documents, vendor-supplied documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, inspection and test reports and all such documents made electronically available.

In Section 6.2.2 of the MPQAP, the applicant commits to ensure that documents are reviewed for adequacy and approved for release. As part of Revision 9, the applicant clarified that the documents must be reviewed and approved by authorized personnel. The applicant also added that the reviewing organization will have access to pertinent background data or information necessary to base their approval.

Section 6.2.7 of the MPQAP requires that changes to MFFF documents be reviewed for adequacy, correctness, and completeness prior to approval and issuance. The applicant revised the description of the organization responsible for reviewing the changes. Instead of changes being reviewed by the organizations or disciplines affected by the change, as revised, the MPQAP requires that changes be reviewed by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable. The applicant also added that the reviewing organization would have access to pertinent background data or information necessary to base their approval.

The applicant added three new subsections to Section 6, "Document Control," of the MPQAP: Section 6.2.10, Section 6.2.11, and Section 6.2.12.

Section 6.2.10, "Procedure Use," of the MPQAP requires that procedures used during the operational phase be reviewed by an individual knowledgeable in the area affected by the procedure at least every two years to determine if changes are necessary or desirable. The applicant provides an exemption from the requirement to conduct the two-year review if all of the following five criteria are satisfied:

(1) Procedures have been updated during upon identification of any discrepancies.
(2) Procedures undergo a review prior to use if they have not been used in the previous two years.
(3) A QA program audit of procedures is conducted every two years.
(4) Applicable procedures undergo a review following any modification to a system.

(5) Applicable procedures are reviewed following an unusual incident, such as an accident, significant operator error, or equipment malfunction.

Section 6.2.11, "Temporary Procedures (during Operations Phase)," sets forth requirements that govern the use of temporary procedures at the MFFF during operations. As stated in Revision 9 of the MPQAP, the applicant requires temporary procedures to identify the time period during which they will be valid for use. For changes made to temporary procedures that are consistent with the original intent of the procedure, the applicant commits to ensure that two members of the staff who are knowledgeable in the areas affected by the procedure perform a review of the changes.

In Section 6.2.12 of the MPQAP, MOX Services states that it will continually improve work instructions through reviews and incorporation of feedback from users.

The NRC staff evaluated these changes and found that they were acceptable. The changes do not reduce the commitments made by the applicant in Revision 8 to the MPQAP and enhance the guidance provided for the operations phase of the facility. The revision amplified the examples of documents that specify quality requirements or prescribe activities affecting quality, which should enable MFFF personnel to more ably identify quality-related documents and apply QA requirements to the development, review, approval, and maintenance of these documents. Further revisions to this section designated which personnel are able to review and approve quality documents, including changes thereto, and identified that these personnel will have access to requisite information needed to grant approval. The revision also added measures to ensure that (1) procedures are kept up to date, (2) temporary procedures are used only while valid and are appropriately reviewed and approved when revised; and (3) feedback mechanisms will be employed to continually improve work instructions for maximum effectiveness. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion VI of Appendix B to 10 CFR Part 50.

3.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Subpart A of Section 7.2.2, "Source Evaluation and Selection," of the MPQAP sets forth requirements for the evaluation of suppliers to verify the supplier's capability to provide items or services in accordance with the technical and quality requirements identified in the procurement document. In Revision 9 of the MPQAP, the applicant modified this requirement to allow the procurement of certain items without an audit. These items include those that are relatively simple and standard in design, manufacturing, and testing and those that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. The ability to accept items with no supplier audit required is consistent with the requirements of RG 1.28, Revision 3, which states that after the award of a contract and based on an evaluation, supplier audits may be omitted provided that the items procured are relatively simple and standard in design, manufacturing, and testing and those that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. Furthermore, Section 4.2, "Receiving Inspection," of Appendix 7A-1, Nonmandatory Guidance for Control of Purchased Items and Services," of NQA-1-1994, allows acceptance of these simple/easily verifiable items based solely on receiving inspection so long as the receiving inspection does not require operations which could adversely affect the integrity, function, or cleanness of the item.

Section 7.2.2.C contains MOX Services' commitment to identify measures for evaluating and selecting suppliers in QA procedures. The section also identifies methods available for the

selection and evaluation of entities providing items or services to the MFFF. One method identified for the selection of suppliers of calibration services is the verification that such suppliers have been accredited by the National Voluntary Laboratory Accreditation Program or the American Association for Laboratory Accreditation to ANSI/ISO/IEC 17025 and that the scope of required services is bounded by the accreditation parameters, ranges, and uncertainties. For such procurements, the applicant identifies additional requirements that must be included in the purchase order, such as identification of laboratory equipment and standards used and the imposition of technical and administrative requirements necessary for QA program compliance. In Revision 9 of the MPQAP, the applicant added an additional requirement that must be noted in procurement documents for calibration services that recognize the laboratory accreditation. This requirement states that the procurement document must specify that the use of the alternative method limited to domestic suppliers of calibration services. This change is consistent with the requirements for verifying accreditation for use of calibration suppliers identified in other NRC staff safety evaluation (Palo Verde Nuclear Generating Station QA Plan, September 28, 2005, ML052710224) and guidance contained in NUREG 0800.

In Revision 9 of the MPQAP, the applicant renumbered Sections 7.2.6-7.2.9 to reorganize the content of those sections under the existing Section 7.2.6, "Acceptance of Items or Services." The applicant added Subpart B to Section 7.2.6.1, "General," to provide controls for the acceptance of services from suppliers. As revised, the applicant identifies three methods that may be used, as appropriate to the circumstances, to accept services such as third party inspections; engineering and consulting services; and installation, repair, overhaul, or maintenance work, shall accept the service by any or all of the following methods, as appropriate to the services being procured: (1) Technical verification of the product produced; (2) Surveillance and/or audit of the activity or work; and (3) Review of objective evidence (such as certifications, stress reports or personnel qualifications) for conformance to procurement document requirements. The addition of controls for the acceptance of services only is consistent with the provisions of Subpart 8.3, "Acceptance of Services Only," of NQA-1-1994, Supplement 7S-1.

In Section 7.2.6.2, "Certificate of Conformance," of the MPQAP, the applicant added clarification of MFFF requirements for the use of certificates of conformance (CoCs) to accept material, equipment, or services. In Section 7.2.6.2.A, the applicant stated that CoCs must identify the purchased material, equipment, or service that is applicable to the specific procurement document. As part of Revision 9 of the MPQAP, the applicant clarified that the CoC must be also be linked to the purchase order number. Linking the purchase order number to the CoC is consistent with the requirements contained in Subpart 8.2 of NQA-1-1994, Supplement 7S-1, which states that "The certificate shall identify the purchased material or equipment, such as by the purchase order number."

In Section 7.2.6.2.B, the applicant requires CoCs to identify the specific procurement requirements that must be met by the purchased material, equipment, or service. In the revision, the applicant added examples of the procurement requirements that may apply, which include codes, standards, pre-installation tests, and other specifications. The applicant also added that the identification of procurement requirements may be satisfied by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. This additional information is consistent with the requirements contained in Subpart 8.2 of NQA-1-1994, Supplement 7S-1, which states that "The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by

providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate." The results of pre-installation tests are also a valid example of information that MOX Services may require its suppliers to document on CoCs for purchased material, equipment, or services in order to verify that the item or service satisfies requirements established by the MFFF in procurement documents.

Section 7.2.6.4, "Receiving Inspection," sets forth requirements for the use of receiving inspections to accept items at the MFFF. As part of Revision 9 to the MPQAP, MOX Services added Subpart F to Section 7.2.6.4 to discuss supplier evaluation requirements related to receipt inspections. As revised, the MPQAP requires that the results of receipt inspection, operating experience, and supplier evaluation programs be reviewed on an ongoing basis and considered with respect to any potential effect on supplier qualification. Section 7.2.6.4.F requires that these results take into consideration the need for (1) corrective actions, (2) adjustments to supplier audit plans, (3) additional actions required in the event that a periodic review determines that, as a whole, the results constitute a significant condition adverse to quality, and (4) adjustments needed for the supplier qualification.

Revision 9 to the MPQAP also requires, in Section 7.2.6.4.F, an annual evaluation to be performed if there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve months. The MPQAP requires the evaluation to include a review of (1) supplier-furnished documents and records, (2) results of previous source verifications, audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources (e.g., customer or NRC audits). The requirements set forth in Revision 9 of the MPQAP related to the use of receiving inspections are appropriate to verify the quality and acceptability of items procured for the MFFF and are consistent with the provisions of NQA-1-1994, Basic Requirement 7, "Control of Purchased Items and Services."

The NRC staff evaluated the changes to Section 7 of the MPQAP and found that they were acceptable. The changes do not reduce the commitments made by the applicant in Revision 8 to the MPQAP and enhance the guidance provided for (1) the evaluation, selection, and verification of continued performance of suppliers, (2) the acceptance of services, (3) the use of CoCs to accept material, equipment, and services, (4) the use of receipt inspections for item acceptance, and (5) the review of receipt inspections, operating experience, and supplier evaluations for consideration of continued supplier qualification. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion VII of Appendix B to 10 CFR Part 50.

3.8 IDENTIFICATION AND CONTROL OF MATERIAL PARTS, AND COMPONENTS

In Revision 9 of the MPQAP, the applicant added a statement to Section 8.1, "General," to clearly state that the MOX Services QA Program procedures will establish the necessary controls to ensure that only correct and accepted materials, parts and components including the use of consumables and items with limited shelf life and partially fabricated assemblies are used or installed.

In Section 8.2.1, "Identification," of the MPQAP, the applicant clarified the identification requirements for items, as described in Section 8.2.1.B. In Revision 9 of the MPQAP, MOX Services clarified that the items that must be identified through initial receipt, fabrication, installation, and end use are those items that are "of production," such as items produced in batches or lots or items produced on a component or part basis. MOX Services also clarified in

this revision that the identification of these items shall relate the item to an applicable design or to other pertinent specifying documents.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes provided a more thorough description of MOX Services controls that will be applied to the identification and control of material, parts, and components and provides examples of those items that will be applicable to this section. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion VIII of Appendix B to 10 CFR Part 50.

3.9 CONTROL OF SPECIAL PROCESSES

Section 9.2.3, "Qualification of Nondestructive Examination Personnel," of the MPQAP was revised in Revision 9 of the MPQAP to remove one of the examples for nondestructive examination. Specifically, the applicant removed the neutron radiography from the list of nondestructive examination examples because the method will not be employed at the MFFF.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant and reflect current practices at the facility. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion VIX of Appendix B to 10 CFR Part 50.

3.10 INSPECTION

In Revision 9 of the MPQAP, the applicant added a statement to Section 10.1, "General," of the MPQAP to clearly state that the inspection program will establish the inspections to be performed, including source, in-process, final, receipt, maintenance, modification, in-service, and operations inspections. It also added a statement clarifying that the inspection program may be implemented by or for MOX Services.

In Section 10.2, "Requirements" of the MPQAP, MOX Services describes the requirements for inspection activities, including the documentation and control. In Revision 9 of the MPQAP, MOX Services clarified that the inspection activities associated with QL-1 and QL-2 items will be (1) documented, (2) controlled by instructions, procedures, drawings, checklists, and other appropriate means, and (3) require qualified inspection personnel.

In Section 10.2.1, "Inspection Planning," of the MPQAP, the applicant added a requirement to include the organization responsible for performing the inspection as part of the inspection planning documentation.

Section 10.2.7, "Accepting Items," of the MPQAP, requires the acceptance of items to be approved and documented. In Revision 9 of the MPQAP, the requirement for accepting items was clarified to state that the acceptance of items shall be documented, reviewed, and approved by qualified personnel to evaluate the technical adequacy of the inspection results.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes provided a more thorough description of controls that will be applied to inspection activities performed by or for MOX Services. Specifically, the applicant added requirements related to inspection planning and acceptance of items. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion X of Appendix B to 10 CFR Part 50.

3.11 TEST CONTROL

In Section 11.1, “General,” of the MPQAP, the applicant added a statement to clarify that the test control program includes various types of testing such as proof tests before installation, preoperational tests, post maintenance tests, post modification tests, and operational tests.

The NRC staff evaluated these changes and found that they were acceptable as they were minor in nature, did not reduce any commitments made by the applicant, and added clarification with respect to the scope and conduct of test control activities. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XI of Appendix B to 10 CFR Part 50.

3.12 CONTROL OF MEASURING AND TEST EQUIPMENT

In Section 12.1, “General,” of the MPQAP, the applicant establishes the applicability of the section. In Revision 9 of the MPQAP, the applicant expanded the listing of equipment controlled in accordance with Section 12 of the MPQAP to include reference standards and nondestructive examination equipment. Other equipment that was identified in Revision 8 and maintained in Revision 9 included tools, gages, instruments, and other measuring and test equipment (M&TE) equipment used for quality affecting activities.

Section 12.2.1, “Calibration,” of the MPQAP was revised to clarify that the reference calibration standard that will be used to calibrate, maintain, and adjust M&TE will be certified.

In Section 12.2.7, “M&TE Documentation,” of the MPQAP, the applicant describes the requirements for M&TE documentation. In Revision 9, the applicant added a statement to identify its commitment to maintain records of (1) M&TE calibration status and (2) the capability of M&TE to perform its intended function.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant in Revision 8 to the MPQAP. The revision provided clarification on (1) the scope of M&TE subject to the controls of this section of the MPQAP, (2) the references standards that will be used for calibration, and (3) documentation requirements for M&TE. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XII of Appendix B to 10 CFR Part 50.

3.13 HANDLING, STORAGE, AND SHIPPING

The applicant added new subsection, Section 13.2.4, to Section 13, “Handling, Storage, and Shipping,” of the MPQAP. This section includes provisions for handling, storage, and shipping activities that take place during operations. The applicant commits to establish controls for (1) packaging, shipping, handling, and storage of items on a case-by-case basis commensurate with the item’s complexity, use, and sensitivity to damage, (2) hoisting, rigging, and transport activities to protect the integrity of the item involved and the affected nearby structures and components, and (3) cleanliness controls for work being performed on IROFS and non-IROFS to minimize introduction of foreign material and maintain system/component cleanliness during maintenance and modification activities.

The NRC staff evaluated these changes and found that they were acceptable. The changes do not reduce the commitments made by the applicant in Revision 8 to the MPQAP and enhance

the guidance provided for the operations phase of the facility. Specifically, the revision commits to establish controls for the packaging, shipping, handling, storage, hoisting, rigging, transport, and cleaning activities that are performed during operations at the MFFF. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XIII of Appendix B to 10 CFR Part 50.

3.14 INSPECTION, TEST AND OPERATING STATUS

Section 14.2.2, "Indicating Status," establishes the requirements for the indication of status of items. As part of Revision 9, the applicant added controls applicable during the operations phase, including a statement that procedures will include the requirement to perform independent verifications, if appropriate, to ensure that necessary measures (i.e., tagging equipment) have been implemented correctly. As revised, the MPQAP also requires that temporary modifications, such as temporary bypass lines, electrical jumpers, lifted leads, and temporary trip point settings, be controlled by approved procedures that include a requirement for independent verification.

The NRC staff evaluated these changes and found that they were acceptable. The changes do not reduce the commitments made by the applicant in Revision 8 to the MPQAP. As revised, the section provides more robust guidance for the performance of independent verifications and the implementation of appropriate procedures during the operations phase of the facility. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XIV of Appendix B to 10 CFR Part 50.

3.15 NONCONFORMING MATERIALS, PARTS, AND COMPONENTS

The applicant modified Section 15.2.1, "Documenting and Evaluating Nonconforming Items," of the MPQAP to clearly state that nonconforming items will be properly controlled to prevent their inadvertent test, installation, or use. In Revision 9 of the MPQAP, the applicant added commitments to use procedures for the following activities associated with nonconforming items: identifying, documenting, segregating, disposing, and notifying affected organizations. The applicant also added a commitment to establish and use procedures for documenting reviews, acceptance, rejection, repair or any rework done on nonconforming items.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant in Revision 8 to the MPQAP. The revision provides clarification on controls implemented for nonconforming material, parts, and components found at the MFFF and the use of procedures for these activities. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XV of Appendix B to 10 CFR Part 50.

3.16 CORRECTIVE ACTION

Section 16.1, "General," of the MPQAP was revised to clarify that the conditions adverse to quality will be not only be promptly identified and corrected, but also documented and classified as soon as practical. Revision 9 of the MPQAP also included a commitment that the applicant will enact provisions to ensure that corrective actions are not inadvertently nullified by subsequent actions. The applicant also replaced the term MOX Services with the term MOX Services Licensing throughout the section.

In Revision 9 of the MPQAP, the applicant added Section 16.2.4, “Incident Investigations,” to describe the incident investigation program for the operations phase and to include commitments for investigating abnormal events other than those that involve Conditions Adverse to Quality. As revised, the applicant states that anyone in the MFFF organization is able to identify the need for incident investigations. Section 16.2.4 also states that these investigations be performed and documented by personnel assigned by the manager of production using a process that is controlled by documented procedures.

The NRC staff evaluated these changes and found that they were acceptable as they did not constitute a reduction in commitments made by the applicant in Revision 8 to the MPQAP. Furthermore, the revisions (1) clarified requirements for the documentation and classification of conditions adverse to quality; (2) provided controls for the operations phase of the facility; and (3) described the procedural, personnel, and process requirements for incident investigations. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

3.17 QUALITY ASSURANCE OF RECORDS

Section 17.2.2, “Generation of Records,” of the MPQAP establishes the requirements for the generation of records. In Revision 9 of the MPQAP, the applicant added a commitment to provide training to individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/regeneration, and recovery. In addition, in this section the applicant clarified the requirements for document authentication, which entails verification of records and stamp/initial/signature and date by authorized personnel. As part of Revision 9, the applicant committed to allow the transfer of authentication authority only when it is documented and controlled in accordance with written procedures.

Section 17.2.3, “Receiving Records,” was modified in Revision 9 of the MPQAP to add commitments for electronic records. Specifically, Revision 9 of the MPQAP states that for electronic records, the Records Center will be responsible for organizing and implementing an inventory of system applications, record formats, and programs required to process and retrieve electronic records. In addition, the applicant commits to index records to ensure retrievability. As part of Revision 9, the applicant added indexing controls specific to electronic records; in addition to the minimum indexing information requirements, the applicant commits to identify the software name, version, and equipment (hardware) used to produce and maintain the electronic media in the indexing system.

Section 17.2.4, “Storing and Preserving Records,” of the MPQAP includes the requirements for record storage and preservation at the MFFF. As part of Revision 9, the applicant added a commitment to enhance QA procedure requirements associated with record storage and preservation to include a method to safeguard records against equipment malfunction or human error. The revision also included additional requirements for the storage of electronic media. The applicant states that it will store electronic media in dust-free, temperature-controlled, humidity-controlled environments, away from electronic devices and demagnetizing equipment. In addition, the applicant commits to test magnetic and optical media periodically to ensure that the records are complete, readable, and retrievable.

In Section 17.2.5, “Retrieving Records,” of the MPQAP was modified to add a statement requiring authorized personnel who have access to electronic records and information systems to have a unique user ID and password for access control.

Section 17.2.6, “Retention of Records,” of the MPQAP established the requirements and commitments for the retention of lifetime and nonpermanent records at the MFFF. In Revision 9 of the MPQAP, the applicant added requirements for the retention of electronic records. Specifically, the applicant identified that electronic records will require the same retention requirements as paper records. In addition, the applicant committed to identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces as part of the electronic record requirements. As described in Revision 9 of the MPQAP, MOX Services will implement a migration/regeneration program, in accordance with documented procedures, for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. The migration/regeneration program will provide for appropriate record authentication and verification of the completion and accuracy of the data transferred.

In Section 17.2.7, “Correcting Information in Records,” of the MPQAP, the applicant added a statement clarifying that for records stored in electronic media, a new record will be generated when substantial corrections or changes are made to previously generated electronic records.

Revision 9 of the MPQAP also includes additional content in Figure 17-1, “Examples of Typical Lifetime QA Records.” The figure was modified to add examples for maintenance records as part of the operational records section.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant in Revision 8 to the MPQAP and enhance the guidance provided for electronic records receipt, storage, retrieval, retention and correction. The revision also added requirements related to records personnel training, authentication of records, and maintenance records that meet the definition of typical lifetime QA records. The NRC staff has concluded that the descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XVII of Appendix B to 10 CFR Part 50.

3.18 AUDITS

In Section 18, “Audits,” of the MPQAP, the applicant establishes the requirements for audits performed to evaluate the effectiveness and implementation of QA Program elements and other management measures for IROFS and to address the technical adequacy of the items evaluated. In Revision 9 of the MPQAP, the applicant clarifies Section 18.2, “Requirements,” of the MPQAP to state that audits will provide a comprehensive independent evaluation of MFFF activities and procedures.

Section 18.2.1 of the MPQAP, “Internal Audit Schedules” was revised to include a statement indicating that a grace period of 90 days may be applied for those activities required to be performed on a periodic basis unless otherwise noted. In addition, the applicant stated that the grace period does not allow the clock for a particular activity to be reset forward; however, if an activity was performed earlier, the clock for that activity will be reset backward.

The applicant also included requirements for requirements for nuclear criticality safety audits and internal audits requirements for operations as part of this revision. Section 18.2.1.D states that the applicant ‘s internal audit program will allow that internal audit frequencies during operations be extended one year at a time beyond the two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the applicant clarifies that the

audit frequency intervals should not exceed four years and, if adverse trends are identified, then the extension of the internal audit frequency interval will be rescinded and an audit will be scheduled as soon as practicable.

In Revision 9 of Section 18.2.1.F of the MPQAP, the applicant discussed the MOX Services audit organization and stated that, as a minimum, the organization's functions will include verification of compliance and effectiveness of implementation of internal rules and procedures. As defined by the applicant, the functional areas of the MOX Services organization that will undergo audits include:

(1) Engineering, Configuration and Modification Control
(2) Operations(
(3) Maintenance
(4) Radiation Protection/Radwaste Management
(5) Chemical/Radiochemical Control
(6) Nuclear Safety
(7) Environmental Control
(8) Operating Limits Manual Compliance
(9) Performance, Training & Qualification
(10) Corrective Action.

In Section 18.2.1.G, as revised, the applicant commits to audit any work performed under a QA program, even if delegated to others.

The applicant added Section 18.2.2, "External Audit Schedules," in Revision 9 of the MPQAP to describe the audit process for procurement of items. As described by the applicant, the supplier's QA program will be audited on a triennial basis – starting the triennial period with the first audit performed prior to the supplier starting work. The applicant states that it may apply a grace period of 90 days for activities required to be performed on a periodic basis unless otherwise noted. However, the applicant clarifies that the grace period does not allow the clock for a particular activity to be reset forward; alternately, the clock will be reset backward if the activity is performed early.

In addition, should the scope of supply or methods or controls implemented by an approved supplier be changed or significantly enlarged by a new contract or a contract modification, the applicant commits in Section 18.2.2 to conduct an audit of modified requirements and initiate a new triennial period. In addition, the applicant states that a pre-award survey may serve as the first triennial audit if the supplier is implementing the same QA program for other customers that is proposed for use on the auditing party's contract. Therefore, when such pre-award surveys are employed as the first triennial audits, the applicant requires that they satisfy the same audit elements and criteria as those used on other triennial audits.

The applicant states that if more than one purchaser (i.e., MOX Services, sub-suppliers, & other Licensees) buys from a single supplier, MOX Services may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. As described in the MPQAP, the applicant commits to verify that the scope of the audit satisfies the requirements of the MOX MPQAP. Additionally, the applicant commits to maintain any audit reports for such audits as QA records and to maintain responsibility for the adequacy of the audit, even when it is performed by another entity.

Section 18.2.10, "Audit Team Qualification Requirements," of the MPQAP was modified to clarify that the MOX Services QA indoctrination provides a working knowledge in nuclear-related

codes, standards, regulations, and regulatory guides in addition to the working knowledge of the general structure of the QA Program, procedures, and appropriate documents used in the audit process.

In Subsection C of Section 18.2.10, “Lead Auditors Qualifications,” the applicant describes the requirements for lead auditors. In Revision 9 of the MPQAP, the applicant added requirements for lead auditor qualifications. Revision 9 requires that the lead auditor be capable in closing audit findings in addition to being capable of organizing and directing audits, reporting audit findings, and evaluating corrective actions. In addition, the applicant added requirements for lead auditors to demonstrated knowledge and understanding of audit planning in IROFS functions for designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, operating, maintaining, repairing, refueling, modifying, and safety of the facility.

Section 18.2.12, “Lead Auditor Certification,” of the MPQAP was modified in Revision 9 to clarify some of the requirements for lead auditor certifications. The applicant clarified that the documentation of lead auditor certification will include the basis for the qualification, which considers the education, experience, communication skills, training, and examination, as applicable. The applicant also identified that documentation of lead auditor certification will include the signature approval of the designated representative who is responsible for such certification. Revision 8 of the MPQAP stated that the certification will include the approval of the Quality Verification Manager; as written, Revision 9 of the MPQAP, requires signature by the responsible individual but does not specify a particular position to perform the action. This revision is acceptable as it still provides verification that lead auditors have met their certification requirements but allows flexibility to the applicant in designation of the certifying party.

The NRC staff evaluated these changes and found that they were acceptable. The changes do not reduce the commitments made by the applicant in Revision 8 to the MPQAP and enhance the guidance provided for the operations phase of the facility. Specifically, the revision (1) includes additional commitments for internal audits performed during operations, (2) includes a new section to describe the requirements for external audits, (3) clarified the scope of the MOX Services indoctrination and training program for auditors, (4) enhanced the description of personnel requirements necessary in order to become qualified as a lead auditor, and (5) added requirements related to documentation that will be maintained in relation to lead auditor certifications. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

3.19 MAINTENANCE

The applicant added Section 19, “Maintenance,” in Revision 9 of the MPQAP to address maintenance requirements applicable to Operations. In this section, the applicant describes the maintenance and functional testing programs that will be implemented for the operations phase of the facility. The maintenance program, as described in Revision 9 of the MPQAP, will be developed using information from sources as equipment suppliers, reference plants and, lessons learned from other appropriate facilities.

As described by the applicant, equipment used at the MFFF is classified into one of two categories: IROFS and non-IROFS. The MPQAP states that non-IROFS equipment will be maintained commensurate with designed functions, and in general, non-IROFS maintenance will be performed to standard industrial practices. The preventive and corrective maintenance activities, surveillance activities, and performance trending, as discussed in this section, will

provide for reasonable and continuing assurance that IROFS will be available and reliable to perform their safety functions commensurate with the risk levels identified in the ISA.

The applicant commits to implement measures to ensure that the quality of the IROFS is not compromised by planned changes (modifications) or maintenance activities. As described in the MPQAP, the Plant Manager will be responsible for the design of and modifications to IROFS and maintenance activities during operations, which will be performed in a manner so as to assure that quality is maintained in a manner commensurate with the remainder of the system which is being modified, or as dictated by applicable regulations.

The applicant commits to develop and conduct the maintenance of IROFS in such way to maximize their availability and reliability and to assure that any necessary safety functions and/or ISA requirements are satisfied. The applicant further commits to (1) perform maintenance activities in accordance with approved procedures that meet the applicable requirements of the MPQAP and (2) document maintenance and maintain the records as proof of compliance with safety requirements. As described in the MPQAP, planning, scheduling, coordinating, and tracking work activities to completion; maintaining data analysis records; and trending equipment performance will be the responsibility of a work management group. The work management group will also be responsible for the assessments of any recommendations or corrective actions identified by the Incident Investigation Program.

The applicant's maintenance activities are categorized into four major general areas or programs: (a) surveillance/monitoring, (b) preventive maintenance, (c) corrective maintenance and (d) functional testing. The applicant will perform audits and assessments of the maintenance activities to ensure the effectiveness of the maintenance function.

In Section 19.2.1, "Maintenance Categories," of the MPQAP, the applicant identifies that maintenance activities generally fall into one of three categories: (1) Surveillance/Monitoring; (2) Preventive Maintenance; or (3) Corrective Maintenance. The applicant commits to perform audits and assessments to ensure the effectiveness of the activities and to verify procedural compliance.

In Section 19.2.2, "Surveillance/Monitoring," of the MPQAP, the applicant states the general purpose of the surveillance/monitoring program is to measure the degree to which IROFS meet performance specifications and detect degradation and adverse trends of IROFS to prevent component failure and ensure that IROFS remain capable of performing their safety functions. The applicant will use data sources such as surveillances, periodic and diagnostic test results, plant computer information, operator rounds, walk downs, as-found conditions, failure trending, and predictive maintenance to select the parameters to be monitored. The selection of parameters will be based on each parameter's ability to detect the dominant failure modes of critical components.

Surveillances, as stated by the applicant, may consist of measurements, inspections, functional tests, and calibration checks. Surveillances will be conducted at specified intervals, and the results will be trended. Identified degradations of IROFS will be used to adjust the preventive maintenance frequencies or to implement the appropriate corrective actions. Incident investigations may identify root causes of failures that are related to the type or frequency of maintenance performed. The applicant commits to factor the lessons learned from such investigations into the surveillance/monitoring and preventive maintenance programs, as appropriate.

The applicant states that it will establish criteria to monitor plant performance, IROFS functions, and component parameters. As described in the MPQAP, the applicant will have maintenance procedures in place to prescribe proper compensatory measures for surveillance tests of IROFS that can be performed only while equipment is out of service.

The applicant commits to maintain records showing the current surveillance schedule, performance criteria, and test results for IROFS in accordance with the Record Management System.

In Section 19.2.3, "Preventive maintenance," the applicant provides a description of the preventive maintenance (PM) program, including the commitment to conduct preplanned and scheduled periodic refurbishment, partial or complete overhauls, or replacement of IROFS, if necessary, to ensure IROFS continued safety function even with unplanned changes. The applicant will consider the results of surveillance and monitoring activities, in addition to any failure history during the PM planning activities.

As part of PM activities, the applicant states that it will address instrumentation calibration and testing through procedures and calibration standards traceable to the national standards system. The applicant commits to provide compensatory measures during testing performed on IROFS that are not redundant to ensure that the IROFS function will be performed until it is put back into service.

As described in the MPQAP, initial PM frequencies and procedures will be determined by using applicable industry experience, vendor recommended intervals, and data derived from the reference facilities. If the applicant will deviate from those industry standards or vendor recommendations, the rationale for the deviation will be documented. In addition, feedback from PM and corrective maintenance, the results of incident investigations and identified root causes, as appropriate, will be used to modify the frequency or scope of PM. The applicant states that consideration will be given to appropriately balancing the objective of preventing equipment failures through routine maintenance against the objective of minimizing unavailability of IROFS because of PM during the determination of the PM frequencies.

After conducting preventive maintenance on IROFS, and prior to returning IROFS to operational status, the applicant commits to perform necessary functional testing, as necessary, to ensure IROFS will perform its intended safety function.

As described in the MPQAP, the applicant will maintain records pertaining to PM in accordance with the Records Management System. In addition, the results of PM activities related to IROFS via the configuration management system will be evaluated by safety disciplines to determine any impact on the ISA and whether updates are needed.

In Section 19.2.4, "Corrective maintenance," the applicant describes the corrective maintenance as the repair or replacement of equipment that has unexpectedly degraded or failed. The applicant states that the corrective maintenance program will restore equipment to acceptable performance through a planned, systematic, controlled, and documented approach for repair and replacement activities associated with IROFS. As described by the applicant, the corrective action program requires facility personnel to determine the cause of conditions adverse to quality and promptly act to correct these conditions.

As described in the MPQAP, after conducting corrective maintenance on IROFS, and prior to returning IROFS to operational status, the applicant will perform necessary functional testing of

the IROFS, if necessary, to ensure the capability of the IROFS to performs its intended safety function.

As stated by the applicant, results of corrective maintenance activities related to IROFS via the configuration management system will be evaluated by safety disciplines to determine any impact on the ISA and whether updates are needed.

The NRC staff evaluated these changes and found that they were acceptable as they did not reduce any commitments made by the applicant, and the changes provided a description of MOX Services maintenance program. Specifically, the applicant described the four major general areas or programs of the maintenance program: (a) surveillance/monitoring, (b) preventive maintenance, (c) corrective maintenance, and (d) functional testing. The descriptions provided for the MFFF QA Program, as revised, are consistent with the requirements of Criterion X of Appendix B to 10 CFR Part 50.