MFFFNPEm Resource

From: Yates, Douglas A. [DAYates@moxproject.com]
Sent: Thursday, June 24, 2010 10:26 AM
To: Tiktinsky, David
Cc: Gwyn, Dealis W.
Subject: SER Section 15 Accuracy Feedback
Attachments: Master SER Chapter 15.doc

Dave,

I've attached our feedback (1 comment) for the subject section.

Regards,

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Hearing Identifier: MixedOxideFuelFabricationFacility_NonPublic
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Recipients:
"Gwyn, Dealis W." <DWGwyn@moxproject.com>
Tracking Status: None
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15.0 Management Measures

Management measures are functions that MOX Services performs, generally on a continuing basis, that are applied to items relied on for safety (IROFS), to ensure the items are available and reliable to perform their safety functions when needed. Management measures shall be implemented to ensure compliance with the performance requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance requirements," and the degree to which they will be applied will be a function of the item's importance in terms of meeting performance requirements, as evaluated in the integrated safety analysis (ISA). This chapter addresses each of the management measures included in the definition of management measures in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," including (1) configuration management (CM), (2) maintenance, (3) training and qualifications, (4) procedures, (5) audits and assessments, (6) incident investigations, (7) records management, and (8) other quality assurance (QA) elements.

The purpose of this review is to verify whether the MOX Services license application (MOX, 2010a) provided conclusive information to demonstrate that the management measures applied to IROFS, as documented in the ISA Summary, provide adequate assurance that the IROFS will be available and reliable and will function according to the performance requirements of 10 CFR § 70.61.

Quality level definitions and the requirements for applying graded QA to IROFS are found in the MOX Services Project Quality Assurance Plan (MPQAP), which the staff of the U.S. Nuclear Regulatory Commission (NRC) has reviewed and approved. Revision 8 of the MPQAP was reviewed and accepted by the staff, as documented in letter dated October 19, 2009 (ML092790580).

15.1 Regulatory Requirements

The requirements in 10 CFR Part 70 specify fuel cycle facility management measures, as follows:

- 10 CFR § 70.4, "Definitions," states that management measures include CM, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other QA elements.

- 10 CFR § 70.22(a)(8), Contents of applications," requires that each application for a license contain proposed procedures to protect health and minimize danger to life or property.

- 10 CFR § 70.62(a)(3), "Safety program and integrated safety analysis," states that records must be kept for all IROFS failures, describes required data to be reported, and sets time requirements for updating the records.

- 10 CFR § 70.62(d) requires an applicant to establish management measures for engineered and administrative controls (ACs) and control systems that are identified as IROFS, pursuant to 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

- 10 CFR § 70.64(a)(1), “Requirements for new facilities or new processes at existing facilities,” states that new facilities or new processes at existing facilities shall develop and implement designs in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their safety function when needed.

- 10 CFR § 70.64(a)(1) states that appropriate records of IROFS must be maintained by, or under the control of, the licensee throughout the life of the facility.

- 10 CFR § 70.64(a)(8) states that the design of IROFS must provide for inspection, testing, and maintenance adequate to ensure their availability and reliability to perform their function when needed.

- Facility changes and change processes are required to conform to 10 CFR § 70.72, “Facility Changes and Change Process.”

- 10 CFR § 70.74(a) and (b), “Additional reporting requirements,” require incident investigation and reporting.

- In addition, an applicant to possess and use special nuclear material (SNM) in a plutonium processing and fuel fabrication facility such as the mixed oxide (MOX) fuel fabrication facility (MFFF) is required, pursuant to 10 CFR § 70.22(f), to describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components (SSCs) of the facility.

- 10 CFR Part 21, “Reporting of Defects and Noncompliance,” contains additional pertinent regulatory requirements for identifying, controlling, and reporting defects with a facility, activity, or basic component supplied to a facility licensed under 10 CFR Part 70.

15.2 Regulatory Acceptance Criteria

Section 15, “Management Measures,” of NUREG-1718, “Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility” (NRC, 2000), contains the acceptance criteria for the NRC review of MOX Service’s management measures program.

15.3 Staff Review and Analysis

15.3.0 Management Measures

The applicant established management measures to ensure that facility IROFS would be available and reliable to perform their safety function when needed and to ensure that work is conducted efficiently and in a manner that protects workers, the public, and the environment. The applicant describes its management measures as a framework of administrative and programmatic measures that includes CM, maintenance, training and qualification, procedures, audits and assessments, incident investigations, and records management.

The applicant commits to implementing management measures in accordance with a QA program established in accordance with Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” of 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.”

The applicant commits to applying management measures to IROFS to ensure that they are available and reliable upon demand. The applicant assigns management measures for training based on four types of IROFS classifications and the risk-reduction level attributed to the IROFS. The types of IROFS classifications are as follows:

(1) passive engineered controls (PECs), which are devices that use only fixed physical design features to maintain safe process conditions and require no human action

(2) active engineered controls (AECs), which are physical devices that use active sensors, electrical components, or moving parts to maintain safe process conditions and which require no human action

(3) enhanced ACs (EACs), which are procedurally required or prohibited human actions, combined with a physical device that alerts the operator that the action is needed to maintain safe process conditions, or otherwise adds substantial assurance of the required human performance

(4) ACs, which are procedurally required or prohibited human actions needed to maintain safe process conditions

The applicant identifies the specific elements of the various management measures programs assigned to each IROFS classification in the license application. This illustrates how the various management measures elements apply to the different IROFS classifications (i.e., PECs, EACs, AECs, and ACs). The applicant describes the application of EACs and states that, for the EAC, the specific management measures for the physical device are covered under the AEC classification.

15.3.1 Quality Assurance

In accordance with Option A of NUREG-1718, the applicant elects to implement and maintain a QA program in conformance with the applicable requirements of Parts I and II of ASME-NQA-1-1994, as revised by the ASME NQA-1a-1995 (ASME, 1995) Addenda or equivalent. The MOX Services QA program is described in the MPQAP, which the NRC approved in a safety evaluation report dated October 1, 2001 (NRC, 2001). The MPQAP establishes the QA requirements to control quality-affecting activities related to the design, construction, and operation of the MFFF. By letter dated October 19, 2009 (NRC, 2009), the staff documented its review and approval of the latest revision to the MPQAP, Revision 8.

The applicant commits to submitting any change that would reduce the commitments of the NRC-approved QA program, along with written justification for the change, to the NRC for acceptance before implementing it. The applicant states that it will update the MPQAP, as necessary, during testing, operation, and deactivation of the MFFF. The applicant commits to implementing the requirements of 10 CFR Part 21 for design, construction, procurement, testing, and operations of Quality Level 1 SSCs (i.e., IROFS). Section 4 of the MPQAP, “Procurement Document Control,” requires that 10 CFR Part 21 be invoked for procurements of IROFS for the MFFF, unless the procurement is for a commercial grade item.

15.3.2 Configuration Management

15.3.2.1 Configuration Management Policy

The applicant states that the CM program for MFFF will ensure that IROFS are designed and operated within the design basis. As stated in the application, the MFFF CM program will identify and control the preparation and review of documentation associated with IROFS, control changes to IROFS, and maintain the physical configuration of the facility consistent with the approved design.

The applicant states that it accomplishes configuration control during design through the use of procedures for controlling design activities. These design control procedures will encompass activities related to the preparation, review, verification (where appropriate), approval, release, and distribution of the design for use. The applicant states that changes to the approved design are subject to a review to ensure consistency with the design bases of the IROFS.

The applicant has established quality level classifications for MFFF SSCs and associated documents, as documented in Section 2.2 of the MPQAP. As described in the MPQAP, quality levels are assigned to SSCs commensurate with their safety significance and a combination of the likelihood and consequences of design basis events. Quality Level 1 (QL-1) SSCs are IROFS credited in the Integrated Safety Analysis with a required function to prevent or mitigate design basis events such that high-consequence events are made highly unlikely; intermediate-consequence events are made unlikely; or to prevent criticality. Quality Level 2 (QL-2) SSCs are not relied on to satisfy the performance requirements of 10 CFR 70.61; they perform functions such as maintaining public and worker radiological exposure within normal operating limits; monitoring and alerting personnel of changes to facility conditions, such as criticality; managing radioactive waste; and protecting IROFS from potentially harmful physical interactions. Quality Level 3 (QL-3) SSCs have no safety function but their performance may be important to ensuring operational or mission-critical goals are achieved. Finally, Quality Level 4 (QL-4) SSCs are those SSCs that are not designated as QL-1, QL-2, or QL-3, and controls on those SSCs do not impact the regulatory basis of the MFFF.

The applicant states that it will accomplish CM through design review and verification, which ensure that design documents are consistent and that design requirements for IROFS are met. The applicant states that changes identified during construction or testing must be approved by the Engineering Department through a documented engineering change process or an approved nonconformance report before implementation to ensure that testing is successfully accomplished and that configuration is maintained.

The applicant commits to conducting initial and periodic assessments of the CM system to determine its effectiveness and to correct deficiencies. The applicant states that it will conduct audits and assessments of the CM program to ensure that the program meets its goals and that the design is consistent with the design bases. The applicant also states that it will perform the corrective action process in accordance with the MPQAP and associated procedures, in the event that any problems are identified. The applicant will develop prompt corrective actions in response to audit or assessment findings or as a result of incident investigations.

The applicant states that it will maintain CM as the project progresses from design and construction to operations and will establish procedures to define the turnover responsibilities and processes.

The applicant demonstrates that it has established design requirements and associated design bases and that the appropriate organizational unit maintains them. The applicant states that the Functional Area Manager will approve procedures and revisions thereto for facility modifications

made during the operations phase. Change procedures will ensure quality in the facility modification program and will include technical and quality requirements necessary to implement a modification, as well as the requirements for initiating, approving, monitoring, designing, verifying, and documenting modifications. The applicant also states that it will write the facility modification procedure to ensure that policies are formulated and maintained to satisfy the MPQAP, as applicable.

The applicant describes its compliance with the provisions of 10 CFR § 70.72 and commits to ensuring that each change to the MFFF or to activities of personnel during operations will have an evaluation performed in accordance with the requirements of 10 CFR § 70.72, as applicable. The applicant also states that it will evaluate each modification for any required changes or additions to the facility's procedures, personnel training, testing program, or regulatory documents, as applicable.

The applicant demonstrates that the CM system will ensure that the appropriate technical, management, and safety reviews are performed in support of changes to the MFFF and its IROFS. In describing its change control process, the applicant states that it will require that the impacts of any change (i.e., new design or operation) or modification to the facility or to activities of personnel (e.g., site SSCs, computer programs, processes, operating procedures, management measures) that involve or could affect the ISA, be evaluated and documented. The change control process also requires that, before implementing any change, the applicant shall demonstrate that it does not affect the safety basis, in accordance with 10 CFR § 70.72. Changes that affect the safety basis require NRC approval before implementation.

In the application, the applicant states that it will evaluate and document each modification to the facility or to activities of personnel for radiation exposure to minimize worker exposures as part of the facility's as-low-as-reasonably-achievable program (ALARA), criticality and worker safety requirements, or restrictions. The applicant states that it may also evaluate modifications in terms of cost; lessons learned from similar completed modifications; QA requirements; potential operability, maintainability, or constructability concerns; postmodification testing requirements; environmental considerations; human factors; and the ISA, as applicable.

The applicant commits to post-modification testing of items in addition to established periodic performance monitoring and maintenance functions. The applicant states that, upon completion of a modification to an SSC, the modification's responsible manager, or designee, will confirm that applicable testing has been completed to ensure correct operation of the system(s) affected by the modification. The applicant adds that the responsible manager will also ensure that documentation regarding the modification is complete. Documents such as the revised process description, checklists for operation, and flowsheets will be made available to operations and maintenance departments before the startup of the modified system to ensure that operators are able to operate the modified system safely. The applicant also states that it will complete the appropriate training on the modification before a system is placed in operation and will distribute a formal notice of the modification completion to appropriate managers. The applicant will complete drawings incorporating the modification, in accordance with MFFF design control procedures, and will retain identifiable records related to the modification, in accordance with the MFFF records management procedures.

15.3.2.2 Implementation of Configuration Management

As stated in the application, during the design phase of the project, the applicant will base CM on the design control provisions and associated procedural controls over design documents to

establish and maintain the technical baseline. The applicant states that it will identify documents that provide design input, analysis, or results specifically for IROFS, including the ISA, with the appropriate quality level. The applicant states that these design documents will undergo interdisciplinary review during the initial issue and during each subsequent revision.

During the construction phase of the project, the applicant states that it systematically reviews and verifies changes to drawings and specifications issued for construction, procurement, or fabrication; evaluates changes for impact to the ISA; and approves the changes before implementing them. The applicant commits to verifying proper implementation of such changes by the QA organization.

The applicant states that it will implement measures to ensure that the quality of MFFF IROFS is not compromised by planned changes (modifications). These measures will include assigning responsibility for the design of and modifications to facility IROFS to the Plant Manager. These measures will also include performing the design and implementation of modifications so as to ensure quality is maintained in a manner commensurate with the remainder of the system that is being modified, or as dictated by applicable regulations.

15.3.2.3 Organization

The applicant describes the organizational structure and staffing interfaces of the CM system. The President of MOX Services is responsible for the overall implementation of the CM program, including development and approval of plans and policies necessary to provide overall program direction. The Vice President—Engineering administers the CM program during design, and the engineering organization includes engineering disciplines. Discipline engineers have primary technical responsibility for the work performed within their disciplines. Responsibility for interdisciplinary reviews lies with the responsible managers. Reviews are also conducted, as appropriate, by construction management, operations, environmental safety and health, QA, and support services personnel.

The applicant commits to an acceptable method of controlling and storing documents within the CM system. The applicant states that the MFFF design control process interfaces with the document control and records management process through procedures. The applicant's document control program includes provisions for the inclusion of documents in the MOX Services electronic document management system (Documentum), maintenance and distribution of documents, document retention, tracking of document change status, and document retrieval.

The Vice President—Construction is responsible for CM during construction and establishes and maintains processes and procedures used during construction of the facility.

The Plant Manager is responsible for ensuring the implementation of CM during operational testing, operation, and deactivation of the MFFF.

The various MOX Services departments and subcontractors perform quality-related activities, and the primary MOX Services subcontractors work to the MPQAP. Some MOX Services subcontractors will develop and implement their respective QA programs in a manner that is consistent with the requirements of the MPQAP for activities determined to be within the scope of the MPQAP. The interfaces between subcontractors and MOX Services or among subcontractors will be documented. MOX Services and subcontracted personnel have the responsibility to identify quality problems. Disagreements that cannot be resolved will be

elevated to the next level of management for resolution and, if necessary, through successive layers of management until resolution is achieved.

15.3.2.4 Scope of Configuration Management Program

The applicant clearly defines the IROFS to be included in the scope of the CM program. The MFFF CM program includes the IROFS identified by the ISA and any items that may affect the safety function of the IROFS. The applicant also shows that the CM system will consistently capture documents that are relevant and important to safety as the project evolves from design and construction through operations. The applicant states that calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, operating procedures, and specifications that establish design and safety requirements for IROFS are also subject to CM. During the design phase, these documents are maintained under CM upon initial approval.

The applicant's design process leading to drawings and other statements of requirements proceeds logically from the MFFF design basis. The applicant states that the number of documents included in the CM program will increase throughout the design process as drawings and specifications related to IROFS are prepared and issued for procurement, fabrication, or construction. The related documents are included in CM.

The applicant states that, during construction, initial startup, and operations, the scope of documents under CM will continue to increase and will include, as appropriate: vendor data; test data; inspection data; initial startup, test, operating, and administrative procedures, as applicable to IROFS; and nonconformance reports. These documents will be generated through functional interfaces with QA, maintenance, and personnel training and qualification. The applicant commits to establishing CM procedures that evaluate, implement, and track changes to IROFS, as well as processes, equipment, computer programs, and activities of personnel that affect IROFS.

The applicant states that CM is implemented through or related to other management measures. The applicant identifies key interfaces and the relationship of CM to other management measures, including QA, records management, maintenance, training and qualifications, audits and assessments, and procedures.

The applicant states that the MFFF QA program establishes the framework for CM and other management measures for IROFS and items that affect the function of the IROFS.

The applicant commits to generating and processing records associated with IROFS, in accordance with the applicable requirements of the QA program. The applicant also commits to providing evidence of the conduct of activities associated with the CM of those IROFS.

The applicant commits to the establishment of maintenance requirements as part of the design basis, which is controlled under CM. The applicant will maintain records sufficient to provide evidence of compliance with preventative and corrective maintenance schedules for IROFS.

The applicant states that it will control personnel training and qualification in accordance with approved project procedures. Personnel qualifications and training to specific processes and procedures are management measures that support the safe design, operation, maintenance, and testing of IROFS. The applicant commits to developing and implementing procedures for work activities that are themselves IROFS (i.e., ACs) and to training and qualifying personnel to

these procedures. The applicant also states that training and qualification requirements and documentation of training may be considered part of the design basis and be controlled under CM.

The applicant describes the interface between CM and audits, assessments, and incident investigations and applies its audit and assessment activities to the CM program, which includes the control of design requirements and the implementation of those requirements. The applicant states that corrective actions identified as a result of the management measures of audits, assessments, and incident investigations may result in changes to design features, ACs, or other management measures (e.g., operating procedures). The applicant commits to using the MFFF QA program and procedures to evaluate changes to maintain CM and to conducting periodic assessments of the CM program, in accordance with the audit and assessment program. The audit and assessment program includes requirements to perform both document assessments and physical assessments (walkdowns) to check the adequacy of the CM system and to document assessment and follow-up activities.

The applicant states that it will use operating, administrative, maintenance, and emergency procedures to conduct various operations associated with IROFS and will review these procedures as part of the CM program to identify potential impacts to the design basis. The applicant also states that work activities that are themselves IROFS (i.e., ACs) will be contained in procedures.

15.3.2.5 Change Control

The applicant fully describes the activities that comprise its CM program. According to the applicant, CM includes those activities conducted under design control provisions to ensure that design and construction documentation is prepared, reviewed, and approved in accordance with a systematic process. This process includes interdisciplinary reviews appropriate to ensure consistency between the design and the design bases of IROFS. During construction, it also includes those activities that ensure that construction is consistent with design documents. Finally, it includes activities that provide for operation of the IROFS in accordance with the limits and constraints established in the ISA and that provide for the control of changes to the facility in accordance with 10 CFR § 70.72.

The applicant states that CM also includes records to demonstrate that personnel conducting activities that are IROFS are appropriately qualified and trained to perform that work.

The applicant commits to applying the MFFF document control system to the control of implementing documents as a means of controlling documents within the CM system. The applicant states that implementing documents include those documents that support CM by ensuring that only reviewed and approved procedures, specifications, and drawings are used for procurement, construction, installation, testing, operation, and maintenance of IROFS, as appropriate.

The applicant demonstrates that the CM system provides for keeping design requirements and the safety assessment of the ISA current and ensures that suitable hazard and accident analysis methods are available to evaluate safety margins of proposed changes. The applicant states that it uses procedures to control changes to the design documents, and the change process includes an appropriate level of technical, management, and safety review and approval before implementation. During the design phase of the project, the method of

controlling changes is the design control process described in the implementing procedures. This process includes conducting interdisciplinary reviews and design reviews and verifications that constitute a primary mechanism for ensuring that the design is consistent with the design bases. During both the construction and operations phases of the facility, the applicant will use appropriate reviews to ensure consistency with the design bases of IROFS and the ISA, respectively, to ensure that the design is constructed and operated or modified within the limits of the design basis.

The applicant commits to performing a systematic review of the design bases when making changes to the design, to ensure consistency. In the event that changes reflect design or operational changes from the established design bases, the applicant commits to properly modifying, reviewing, and approving the ISA before the change is implemented. The applicant states that it will make approved changes available to personnel through the established document control function.

During design, the applicant commits to using the interdisciplinary review process as the method of ensuring consistency between documents, including consistency between design changes and the safety analyses. The applicant asserts that interdisciplinary reviews ensure that design changes: (1) do not affect the ISA, (2) are accounted for in subsequent changes to the ISA, or (3) are not approved or implemented. Before issuance of the license, MOX Services commits to notifying the NRC of potential changes that reduce the level of commitments or margin of safety in the design bases of IROFS.

When the project enters the construction phase, the applicant will document, review, approve, and post changes to documents issued for construction, fabrication, and procurement against each affected design document. Vendor drawings and data will also undergo an interdisciplinary review to ensure compliance with procurement specifications and drawings and to incorporate interface requirements into facility documents.

During construction, the applicant will continue to evaluate design changes against the approved design bases. The applicant expects changes to the design as detailed design and construction activities progress and states that it will use a systematic process, consistent with that described above, to evaluate changes in the design against the design bases of IROFS and the ISA.

Upon issuance of the MFFF Possession and Use License, the applicant states that the configuration change process will fully implement the provisions of 10 CFR § 70.72, including reporting changes made without prior NRC approval, as required by 10 CFR § 70.72(d)(2) and (3). The applicant also states that it will submit any change that requires Commission approval as a license amendment request, as required by 10 CFR § 70.72(d)(1), and that it will not implement the change without prior NRC approval.

During the operations phase, the applicant commits to documenting, reviewing, and approving changes to the design before implementation. The applicant also commits to using a change process that fully implements the provisions of 10 CFR § 70.72. The applicant states that it will make responsible facility personnel aware of design changes and modifications that may affect the performance of their duties.

The applicant assigns specific personnel the responsibility for maintaining the design bases and requirements. The applicant states that, upon acceptance by Operations, the Plant Manager will be responsible for the design of and modifications to IROFS and for designing and

implementing modifications so as to ensure that quality is maintained in the remainder of the system, or as dictated by applicable regulations.

The applicant commits to applying CM controls incorporated into the original design and modifications throughout operations to facilitate deactivation of the facility.

The applicant describes its technical management review and approval procedure. The applicant states that the Functional Area Manager approves the administrative instructions for modifications contained in a facility administrative procedure, including revisions. The applicant states that the modification procedure contains (1) the technical and quality requirements that shall be met to implement a modification and (2) requirements for initiating, approving, monitoring, designing, verifying, and documenting modifications. The applicant maintains that the facility modification procedure will be written to ensure that policies are formulated and maintained to satisfy the MPQAPas applicable and that QA is ensured.

The applicant commits to performing an evaluation of each change to the facility or to activities of personnel, in accordance with the requirements of 10 CFR § 70.72, as applicable. The applicant also commits to the evaluation of modifications to identify any required changes or additions to the facility's procedures, personnel training, testing program, or regulatory documents.

The applicant states that it will evaluate and document the impacts of changes (e.g., new design or operation, or modification to the facility or to activities of personnel, IROFS, computer programs, processes, operating procedures, management measures) that involve or could affect the ISA. The applicant also maintains that, before implementing any change, it will demonstrate that the change does not affect the safety basis, in accordance with 10 CFR § 70.72.

15.3.2.5.1 Identification of Changes

The applicant states that design bases and design requirements that are derived from the design bases will be established and maintained by the engineering organization during design and construction and by the Plant Manager during operations. The applicant will document the design bases in licensing bases documents and in design documents such as calculations, safety analysis, engineering drawings, system descriptions, technical documents, and specifications. The applicant commits to controlling design documents under the design control provisions of the CM program.

The applicant describes the quality levels and CM controls assigned to IROFS. The applicant has designated all IROFS as Quality Level 1 and commits to performing interdisciplinary reviews and design review and verification activities for design documents associated with IROFS, as well as for analyses constituting the ISA. The applicant summarizes IROFS in the ISA Summary and commits to evaluating changes to the design to ensure consistency with the design bases.

The applicant demonstrates that suitable design control analysis methods are available to evaluate the safety margins of proposed changes and describes the methods applied to control computer codes used for such evaluations. The applicant states that it will subject computer codes used in safety analyses and the design of IROFS to the same design control measures as IROFS and ISA analyses, with additional requirements, as appropriate, for software control, verification, and validation.

The applicant describes personnel responsibilities for maintaining design bases and requirements. The applicant states that qualified individuals will prepare design documents (e.g., calculations, specifications, procedures, or drawings) and will specify and include the appropriate codes, standards, and license requirements within the design documents. The applicant states that these individuals will note any deviations or changes from such standards within the design documentation package.

The applicant identifies its process for the review and approval of design documents. After the preparation of design documents by qualified individuals, each design document is reviewed by another individual qualified in the same discipline. The applicant states that design inputs will be sufficiently detailed so as to permit verification of the document. The manager having overall responsibility for the specific design function will then approve the document and will record the entire review process in accordance with approved procedures. The applicant's procedures will include provisions to ensure that design documents specify the appropriate quality standards, including quantitative or qualitative acceptance criteria. The QA Manager will conduct audits on the design control process using independent technically qualified individuals to augment the QA audit team.

During the review of design documents, the applicant commits to emphasizing conformance with applicable codes, standards, and license application design commitments. The applicant grants full and independent authority to engineering personnel assigned to perform document reviews such that review personnel may withhold approval of design documents until questions concerning the work have been resolved.

The applicant will accomplish the design verification function through design reviews, alternative calculations, or qualification testing. The applicant requires that (1) the bases for a design, such as analytical models, theories, examples, tables, codes, and computer programs, be referenced in the design document, and (2) the application of such bases be verified during check and review. The applicant states that the responsible qualified individual will review and approve model tests when such tests are required to prove the adequacy of a concept or a design. The applicant commits to applying design verification testing to demonstrate adequate performance under conditions that simulate the most adverse design conditions. The applicant states that tests used for design verification will meet the design requirements.

The applicant will use qualified individuals other than those who prepared the design to verify it. MFFF personnel from the same organization as those who prepared the design may verify it; the supervisor of the individual who prepared the design may verify it, provided that the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs.

The applicant commits to accomplishing independent design verification before use of the design document (or information contained therein) by other organizations for design work or to support other activities, such as procurement, construction, or installation. The applicant states that, when this is not practical because of time constraints, it will identify and control the unverified portion of the document; however, the applicant commits to completing all design verification activities before relying on an item to perform its function. The applicant requires that the review and approval of changes to design and procurement documents be commensurate with the original approval requirements. This requirement applies to all changes, including field changes.

15.3.2.5.2 Review and Approval of Changes

The applicant demonstrates that the CM system will maintain strict consistency among design requirements, physical configuration, and facility documentation. The applicant will accomplish configuration control during design through the use of design control procedures. These procedures include controls for design preparation, review (including interdisciplinary review and preparation of nuclear safety evaluations (NSEs) and nuclear criticality safety (NCS) evaluations (NCSEs), as applicable), verification, approval, and release and distribution for use. The applicant will assess engineering documents for quality level classification and will review changes to the approved design to ensure consistency with the design bases of IROFS.

The applicant will apply design verification in the CM program to ensure that design documents are consistent and that design requirements for IROFS are met. The applicant states that the construction and quality control organizations will conduct in-process verifications during construction, and the startup and quality organizations will verify configuration during testing to demonstrate the performance of IROFS.

The applicant states that the MPQAP will require the use of procedures to ensure that work is accomplished in accordance with the requirements and guidelines imposed by applicable specifications, drawings, codes, standards, regulations, QA criteria, and site characteristics.

The applicant will incorporate acceptance criteria established by the designer into the instructions, procedures, and drawings used to perform work at the MFFF. The applicant commits to maintaining documentation, such as test results and inspection records, to demonstrate the proper performance of work activities. The applicant also states that MFFF procedures will provide for review, audit, approval, and documentation of activities affecting the quality of items to ensure that applicable criteria have been met.

The applicant establishes measures to review procedures to ensure that current maintenance, operations, and other facility procedures reflect any modifications to facility IROFS. The applicant states that qualified personnel knowledgeable in the QA disciplines will review MFFF maintenance, modification, and inspection procedures to determine the need for inspection, identification of inspection personnel, and documentation of inspection results. The review will also verify that applicable procedures have identified the necessary inspection requirements, methods, and acceptance criteria. The applicant commits to reviewing facility procedures on a frequency based on the age and use of the procedure to determine if changes are necessary or desirable and to ensuring that procedures are kept current with the facility configuration. The applicant states that procedure reviews will be conducted by individuals knowledgeable in the area(s) affected by each procedure.

15.3.2.5.3 Implementation of Changes

The applicant describes its process for tracking, implementing, documenting, and distributing changes to design requirements and facility documentation, including the placement of documents into a document control center and plans to disseminate these changes to affected functions within the facility. The applicant states that, after the appropriate parties have properly prepared, reviewed, and approved design documents, the responsible engineer will send them to document control for distribution. After the document is entered into Documentum, it will be electronically routed (distributed) to employees identified on the record submittal form.

The applicant describes its process for identifying, authorizing, and implementing changes to design requirements and facility documentation in the event that it identifies deficiencies that affect the design of IROFS. The applicant states that it documents and resolves such deficiencies in accordance with approved corrective action program (CAP) procedures. In accordance with the CAP, the deficiency report documenting the inadequacy is forwarded for appropriate review to the responsible manager, who coordinates further review of the problem and revises the design documents affected by the deficiency. Where required, the responsible manager will forward the report to engineers in other areas to enable them to coordinate necessary revisions to their affected documents.

The applicant states that design interfaces will be maintained by communication among the Functional Area Managers. The applicant describes the methods used to accomplish effective communication among design interfaces. The responsible engineer or authorized representative will review design documents. Project interface meetings will provide the primary working interface among the MFFF organizations and will be scheduled and held to coordinate design, procurement, construction, and preoperational testing of the facility. In addition to document review activities and project interface meetings, the applicant will maintain design interfaces by using procedures to establish policies for the transmittal and control of nonconformance reports.

The applicant commits to establishing measures for MFFF operations to ensure responsible facility personnel are made aware of design changes and modifications that may affect the performance of their duties.

15.3.2.6 Document Control

15.3.2.6.1 Storage of Documents

The applicant commits to establishing procedures to control the preparation, issuance, and revision of documents, such as manuals, instructions, drawings, procedures, specifications, procurement documents, and supplier-provided documents. The applicant also commits to establishing measures to ensure that documents, including revisions thereto, will be adequately reviewed, approved, and released for use by authorized personnel.

In the MFFF electronic document control and storage system, the applicant states that approved documents included in the CM program will be stored in Documentum, which is a tool capable of reporting the status of documents. The applicant commits to storing records not suitable for storage in Documentum in accordance with the requirements of MPQAP Section 6, “Document Control.”

The applicant states that document control procedures will require documents to be transmitted and received in a timely manner at appropriate locations (including the location where the prescribed activity will be performed) to ensure that controlled copies of documents and their revisions are distributed to and used by the persons performing the activities.

As stated in the application, the MFFF will retain superseded documents within Documentum and control them through document control. The applicant commits to generating indexes of current documents using Documentum.

15.3.2.6.2 Identification of Documents

The applicant describes procedures that it will use to implement the document control program at the MFFF. The applicant states that it will implement approved procedures to track and retrieve current documents, historical records, and other information included in the CM program by attributes such as document number, document subject, component number, component name, and status. The applicant also states that the MFFF document control system will be capable of generating indices of controlled documents, which will be uniquely numbered (including revision numbers).

The applicant commits to maintaining controlled documents until they are cancelled or superseded, after which the applicant commits to maintaining the documents as records for the life of the project or until termination of the license, whichever occurs later. The applicant commits to distributing controlled documents in hard-copy format when needed, in accordance with applicable procedures (e.g., when the electronic document management system (EDMS) is not available).

The applicant defines documents that will be controlled at the MFFF. These documents will include design requirements; the ISA, through the controlled copies of supporting analyses; NSEs and NCSEs; drawings; specifications; calculations; technical reports; project procedures; QA documents; maintenance documents; audit and assessment reports; operating procedures; emergency response plans; and system modification documents.

15.3.2.7 Audits and Assessments

The applicant commits to performing initial assessment(s) of the CM program as part of system turnover upon entering the operations phase. The applicant further commits to performing periodic assessments of the CM and design control program to determine the system's effectiveness and to correct deficiencies. The applicant states that assessments will include a review of the adequacy of documentation and will be scheduled, conducted, and documented in accordance with approved procedures.

As stated in Section 15.2.1, "Configuration Management Policy," of the license application and reiterated in Section 15.2.7, the applicant commits to ensuring that the system meets its goals and that the design is consistent with the design bases through periodic audits and assessments of the CM program and of the design. The applicant states that it will perform incident investigations in accordance with the MPQAP and associated CAP procedures in the event problems are encountered. When needed as a result of incident investigations or in response to adverse audit or assessment results, the applicant commits to developing prompt corrective actions in accordance with CAP procedures.

15.3.3 Maintenance

The applicant describes the maintenance and functional testing programs that will be implemented for the operations phase of the facility in Section 15.3 of the application. The applicant states that it will develop the maintenance program using information from sources such as equipment suppliers, reference plants, and lessons learned from other appropriate facilities. The preventive and corrective maintenance activities, surveillance activities, and performance trending, as discussed in this section, will provide 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 providing and implementing measures that ensure that: (1) the safe and reliable operation of IROFS is continued, (2) the quality of the IROFS is not compromised by planned changes (modifications) or maintenance activities, and (3) quality will be maintained, in accordance with the quality requirements of the system under modification or as required by applicable regulations. As stated in the application, the Plant Manager will be responsible for the design of, and any modifications to, IROFS, as well as for maintenance activities performed during operations. The Plant Manager will also be responsible for ensuring the operational readiness of IROFS during maintenance.

The applicant will develop and maintain IROFS so as to maximize their availability and reliability. The applicant commits to performing planned and scheduled maintenance of IROFS to ensure that they remain in a condition of readiness to perform their planned and designed functions when required. As stated in the application, the applicant will perform maintenance activities in accordance with approved procedures that meet the applicable requirements of the MPQAP. However, 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 that will be compiled by the applicant. The work management group will also be responsible for the assessments of any recommendations or corrective actions identified by the Incident Investigations Program.

15.3.3.1 Maintenance Categories

The applicant's maintenance activities are categorized into four general areas or programs: (1) surveillance and monitoring, (2) preventive maintenance (PM), (3) corrective maintenance, and (4) functional testing. The applicant commits to performing audits and assessments of the maintenance activities to ensure the effectiveness of the maintenance function.

15.3.3.1.1 Surveillance and Monitoring

The applicant states the general purpose of the surveillance and monitoring program is to measure the degree to which IROFS meet performance specifications and detect degradation and adverse trends of IROFS. The applicant states that it will use data sources such as surveillances, periodic and diagnostic test results, plant computer information, operator rounds, walkdowns, as-found conditions, failure trending, and predictive maintenance to select parameters to be monitored. As stated by the applicant, these parameters will be selected based upon their ability to detect the predominant failure modes of the critical components.

Surveillances, as stated by the applicant, may consist of measurements, inspections, functional tests, and calibration checks. The applicant will conduct surveillances at specified intervals and will trend results. The applicant states that PM frequencies will be adjusted and appropriate corrective actions implemented when trending identifies the degradation of IROFS. Incident investigations may be used, as stated in the application, to identify the root causes of failures that are related to the type or frequency of maintenance performed. The lessons learned from such investigations will be factored into the surveillance and monitoring and PM programs, as appropriate.

The applicant states that it will establish criteria to monitor plant performance, IROFS functions, and component parameters. The applicant commits to establishing maintenance procedures that include appropriate compensatory measures for surveillance tests of IROFS that can be performed only while equipment is out of service.

The applicant commits to maintaining records identifying the current surveillance schedule, performance criteria, and test results for IROFS, in accordance with the record management system.

15.3.3.1.2 Preventive Maintenance

The applicant provides a description of the PM program, including the commitment to conduct preplanned and scheduled periodic refurbishment, partial or complete overhauls, or replacement of IROFS, as necessary, to ensure the continued safety function of IROFS, even with unplanned outages. The applicant states that it will consider the results of surveillance and monitoring activities, in addition to any failure history, during PM planning.

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 further states that it will provide compensatory measures during testing performed on IROFS that are not redundant to ensure that the IROFS function until they are returned to service.

The applicant states that it will determine initial PM frequencies and procedures through the use of applicable industry experience, vendor-recommended intervals, and data derived from the reference facilities. Should it choose to deviate from those industry standards or vendor recommendations, the applicant commits to documenting the rationale for the deviation. In addition, the applicant states that 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, in determining the PM frequencies, it will consider the need to appropriately balance the objective of preventing failures through maintenance against the objective of minimizing the unavailability of IROFS because of PM.

After conducting PM on IROFS, and before returning IROFS to operational status, the applicant commits to performing necessary functional testing as described in Section 15.3.1.4 of the application, “Functional Tests,” to ensure IROFS will perform their intended safety function.

The applicant commits to maintaining records pertaining to PM in accordance with the records management system. As stated by the applicant, it will evaluate the results of PM activities related to IROFS through the CM system by safety disciplines to determine any impact on the ISA and the need for updates.

15.3.3.1.3 Corrective Maintenance

The applicant describes the corrective maintenance program as the repair or replacement of equipment that has unexpectedly degraded or failed. The applicant’s corrective maintenance program provides a planned, systematic, controlled, and documented approach for repair and replacement activities associated with IROFS.

After conducting corrective maintenance on IROFS, and before returning them to operational status, the applicant commits to performing necessary functional testing, as described in Section 15.3.1.4 of the application, to ensure IROFS will perform their intended safety function.

As stated by the applicant, it will evaluate the results of corrective maintenance activities related to IROFS through the CM system by safety disciplines to determine any impact on the ISA and the need for updates.

15.3.3.1.4 Functional Tests

The applicant states that it will implement a test control program incorporating plant procedures for test control and will provide for applicable compensatory measures during testing, in accordance with the limiting conditions for operations.

The applicant divided the operational testing program structure into two major testing programs—the preoperational testing program (defined below) and the operational testing program (defined below), each of which contains two testing categories. The preoperational testing program contains functional and initial startup testing, while the operational testing program includes periodic and special testing.

The applicant defines the objectives of the preoperational and operational testing program as ensuring that IROFS: (1) have been adequately designed and constructed, (2) meet licensing requirements, (3) do not adversely affect the health and safety of workers or the public, and (4) can be operated in a dependable manner so as to perform their intended function. In addition, the applicant states that the programs will ensure that operating, emergency, and surveillance procedures are correct.

The applicant states that the facility operating, emergency, and surveillance procedures will be progressively use-tested throughout the testing program and will also be used in the development of preoperational and startup testing procedures, to the extent practicable. In addition, the preoperational use of procedures will serve to familiarize personnel with plant operations during the testing phases and also will ensure the adequacy of the procedures under actual or simulated operating conditions.

Preoperational Testing Program

The applicant defines preoperational testing as testing performed following construction turnover to determine facility parameters and to verify the ability of IROFS to meet performance requirements. As stated in the application, the applicant will complete MFFF preoperational functional tests related to IROFS before the introduction of SNM to the facility to verify that those IROFS that are essential to the safe operation of the plant are capable of performing as intended. The applicant states that any tests or portions thereof that are not required to be completed before the introduction of the SNM will be specified in the test plans.

Functional Testing

As stated in the application, the applicant will perform functional testing, as appropriate, (1) following initial installation, (2) as part of periodic surveillance testing, and (3) after PM or corrective maintenance or calibration, to ensure that the item is capable of performing its safety function when required.

Initial Startup Testing

The applicant defines the period during which it will perform initial startup testing. The applicant states that initial startup testing will begin during the introduction of SNM to the facility and will end with the start of operations. The applicant states that the purpose of initial startup testing is to ensure the safe processing of SNM and the verification of parameters assumed in the ISA.

Operational Testing Program

The operational testing program, as described by the applicant, consists of periodic testing and special testing. Periodic testing will be conducted at the facility to monitor facility parameters and verify the continuing integrity and capability of IROFS. Special testing is defined by the applicant as any testing that does not fall under any of the other testing programs and is conducted on a nonrecurring basis.

The applicant states that the Maintenance Manager will have overall responsibility for the development and conduct of the operational testing program. The Operations Manager and Licensing Manager, in conjunction with the Maintenance Manager, will ensure that testing commitments and applicable regulatory requirements are met.

Periodic Testing

Periodic testing, as described by the applicant, will verify that the facility (1) complies with regulatory and licensing requirements, (2) does not endanger health and minimizes danger to life or property, and (3) is capable of operating so as to perform its intended function. The applicant states that the periodic testing program will apply during preoperational and operational stages of the facility, and the applicant commits to performing periodic testing and surveillances associated with the Quality Level 1 and Quality Level 2 SSCs in accordance with written procedures.

The applicant states that it will establish a periodic testing schedule to ensure that required testing is performed properly, in a timely manner, and consistent with the limiting conditions for operations, as identified in the Operating Limits Manual. The applicant further states that it will schedule periodic testing, such that the plant's safety will not be dependent on IROFS that are not tested. In cases where the testing is not performed within the specified timeframe, the applicant commits to providing appropriate compensatory measures.

Special Testing

The applicant describes special testing as testing that is not a facility preoperational test, periodic test, postmodification test, or postmaintenance test. The applicant states that it will conduct special testing to determine facility parameters or to verify the capability of IROFS to meet performance requirements. The applicant states that, at the discretion of the plant manager, any test may be conducted as a special test.

The applicant identifies some of the purposes of special testing as acquisition of particular data for special analysis; determination of information relating to facility incidents; verification that required corrective actions reasonably produce expected results and do not adversely affect the safety of operations; and confirmation that facility modifications reasonably produce expected results and do not adversely affect systems, equipment, or personnel by causing them to function outside established design conditions.

15.3.3.2 Measuring and Test Equipment

The Measuring and Test Equipment/Calibration Program, as described by the applicant, will be used to calibrate and maintain active engineered components used as IROFS. The applicant states that this program will identify the processes and plans to maintain and control calibration

instruments and calibrations used at the MFFF. The applicant states that the program will also describe how instrument maintenance activities will take place.

15.3.3.3 Work Control

The applicant describes the maintenance work control process as a coordinated and structured process that integrates production activities and requirements. The work control process, as structured, seeks to minimize challenges to safety and production requirements, maximize work efficiency, and maintain consistency when making modifications. As stated by the applicant, it will include representation from other organizations, as needed to complete work activities. Some of the coordinated work support functions identified by the applicant include work requests, procedures, schedules, radiation work permits, and lockout or tagout requirements.

15.3.3.4 Relationship of Maintenance to Other Management Measures

The applicant states that it will perform maintenance activities in accordance with the QA program, as described in the MPQAP. The applicant also states that approved and controlled documents needed to support maintenance activities will be obtained through the CM program. Furthermore, the applicant states that the training and qualification program will ensure that maintenance personnel are trained to perform their tasks.

The applicant commits to performing audits and assessments of the maintenance program to ensure that the program implementation is effective. The applicant states that it will establish procedures to support the maintenance activities and that records management will provide the framework for review, maintenance, approval, handling, identification, retention, and retrieval of QA records related to maintenance activities. As stated by the applicant, incident investigations will identify the root cause(s) of any failures of the maintenance program.

15.3.4 Training and Qualification

The applicant's QA plan provides training and qualification requirements applicable during the operations phase of the facility, including preoperational functional testing and startup testing. The applicant states that the training program requirements apply to plant personnel who perform activities related to IROFS to ensure competent and safe job performance. The applicant commits to establishing requirements for the training of personnel performing QA Level 1 and Level 2 work activities; personnel performing nondestructive examination, inspections, and tests; and QA auditors.

The applicant states that the principal objective of the training program system is to ensure job proficiency of all facility personnel through effective training and qualification. The applicant commits to providing employees with (1) training to establish the knowledge foundation, (2) on-the-job training (OJT) to develop work performance skills, and (3) continuing training, as required, to maintain proficiency in these knowledge and skill components, and to provide further employee development.

The applicant identifies the requirements for personnel qualification and states that qualification will be indicated by the successful completion of prescribed training, a demonstration of the ability to perform assigned tasks, and the maintenance of requirements established by regulation. The applicant states that training will be designed, developed, and implemented according to a systematic approach that includes a variety of methods to accomplish the analysis, design, development, implementation, and evaluation of training.

15.3.4.1 Organization and Management of Training

The applicant states that line management is responsible and accountable for the development and effective conduct of training. The position description for line managers includes their training responsibilities; they are given the authority to manage, supervise, and implement training for their personnel and are supported by the training organization. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training is clearly defined. The applicant identifies the accountability of line managers on the organizational chart included in the license application. The training manager is responsible for the facility training programs. The applicant will use performance-based training to analyze, design, develop, conduct, and evaluate training.

The applicant will develop and implement administrative procedures to establish requirements for the training of personnel performing activities related to IROFS. The procedures will also provide reasonable assurance that all phases of training are conducted reliably and consistently. The applicant will grant exceptions from training requirements when justified, properly documented, and approved by appropriate management. The applicant will incorporate the results of human factor engineering analysis into the training process and will incorporate the human factors task analysis of the IROFS identified in the ISA into plant procedures.

The applicant will use lesson plans or other approved process-controlling documents, as required, for training to ensure consistent presentation of the subject matter and will include updates to affected lesson plans in the change control process of the CM system when making design changes or plant modifications.

The applicant will maintain accurate and retrievable training records to support management information needs associated with personnel training, job performance, and qualifications. It will maintain individual records on each employee's qualifications, experience, and training. Specifically, training files will include records of general employee training, technical training, and employee development training conducted at the facility. The training manager is responsible for training records, which are retained in accordance with records management procedures. The applicant will use a learning management system to maintain training and qualification records. As stated in the application, all data entries will be peer reviewed within the training organization to ensure accuracy of the data, and data will be backed up nightly by the MOX information technology organization, with backup copies of the tapes stored remotely.

15.3.4.2 Analysis and Identification of Functional Areas Requiring Training or Qualification

The applicant will perform a needs and job analysis and will identify tasks to ensure that it provides appropriate training to personnel engaged in managing, supervising, performing, and verifying activities related to IROFS. The applicant states that it will identify job hazards as precautions and limitations in the procedure related to that task and will include them in the task's needs and job analysis.

The applicant will consult relevant subject matter experts, as necessary, to identify tasks for which training is appropriate. The applicant states that the training organization will identify, document, and address areas requiring training for competent and safe job performance and will consult with relevant subject matter experts, as necessary, to develop a list of tasks for which personnel training for specific jobs is appropriate. The applicant commits to comparing

and reviewing the tasks selected for training with training materials as part of a training effectiveness evaluation. As stated in the application, the applicant will update the list of tasks selected for training as necessitated by changes in procedures, processes, plant systems, equipment, or job scope and will create a matrix of the task list and the supporting procedures and training materials.

15.3.4.3 Position Training Requirements

The applicant states that it will develop minimum training requirements for positions where activities are relied on for safety. The initial identification of job-specific training requirements will be based on experience from the MFFF reference facilities of MELOX and La Hague, and other U.S. fuel cycle facilities. The applicant will determine the level at which an employee will initially enter the training program by an evaluation of the employee's past experience, level of ability, and qualifications. The applicant will describe, in position descriptions, the entry-level criteria for positions where activities are relied on for safety and will grant exceptions from training requirements when justified and documented in accordance with the approved MFFF procedure. The applicant will conduct radiation safety training commensurate with each employee's duties.

The applicant also states that facility personnel may be trained through participation in general employee training or technical training. The applicant states that it will design the training program to prepare initial and replacement personnel for the safe, reliable, and efficient operation of the facility. The applicant commits to providing appropriate training for personnel of various abilities and experience backgrounds. As stated in the application, training requirements will be applicable, but not necessarily restricted, to personnel within the plant organization who have a direct relationship to the operation, maintenance, testing, or other technical aspects of the facility IROFS. The applicant will update training courses before use to reflect plant modifications and changes to procedures, when applicable.

15.3.4.3.1 General Employee Training

The applicant describes the general employee training that is required for access to the Savannah River Site and the MOX facility. The applicant states that general employee training will include QA, radiation protection, safety, emergency, and administrative procedures that are established by facility management and applicable regulations. The applicant states that persons that are under the supervision of facility management, including subcontractors, must participate in general employee training; however, certain temporary service and maintenance personnel will receive training to the extent necessary to ensure the safe execution of their duties.

15.3.4.3.2 Technical Training

The applicant states that it will design, develop, and implement technical training to assist employees in understanding applicable fundamentals, procedures, and practices related to IROFS. In addition, the applicant will use the technical training to develop the manipulative skills necessary to perform work related to IROFS. The applicant states that technical training will consist of initial training, OJT, and continuing training.

<u>Initial Training</u>

The applicant described the initial training as that used to provide employees with an understanding of the fundamentals, basic principles, and procedures involved in work related to IROFS. The applicant states that initial training will consist of, but will not be limited to, live lectures, taped and filmed lectures, required reading, self-guided study, demonstrations, laboratories, workshops, and OJT.

The applicant states that certain new employees or employees transferred from other sections of the facility may be partially qualified by reason of previous training or experience, and thus it will determine the extent of training for these employees by applicable regulations, performance in review sessions, comprehensive examinations, or other techniques that can identify the employee's level of ability.

The applicant will develop initial job training and qualification programs for operations, maintenance, and technical services classifications and will group training for each program into logical blocks or modules. It will present training in a manner that ensures that specific behavioral objectives are accomplished, and it will evaluate trainee progress by written examinations and oral or practical tests.

On-the-Job Training

The applicant will conduct OJT to provide the required job-related skills and knowledge for positions. It will conduct OJT in an environment as close to the work environment as feasible and will supplement and complement classroom training. The OJT and qualifications program will comprise applicable tasks and related procedures for each technical area. The applicant states that it will derive technical areas for OJT based on the activities identified in the ISA Summary, job and task analyses, and associated procedures.

Continuing Training

The applicant defines continuing training as any training not provided as initial qualification or basic training that maintains and improves job-related knowledge and skills. The applicant will establish continuing training courses on a frequency needed to ensure that facility personnel remain proficient and will use periodic exercises, computer or classroom instruction, and any other type of training that is appropriate. The applicant states that, once it has established the objectives for continuing training, the methods for conducting it may vary; however, the method selected will provide clear evidence of objective accomplishment and consistency in delivery.

15.3.4.4 Basis and Objectives for Training

The applicant states that the objective of the training program shall be to ensure the safe and efficient operation of the facility and compliance with applicable established regulations and requirements. The applicant also states that its training requirements shall be applicable, but not necessarily restricted, to those personnel within the plant organization who have a direct relationship to the operation, maintenance, testing, or other technical aspects of the facility IROFS.

The applicant's learning objectives will identify the training content based on needs, and job analyses, and position-specific requirements. The applicant will use the task list from the needs and job analysis to develop action statements describing desired post-training performance. The training program's learning objectives will include: the knowledge, skills, and abilities to be

demonstrated by the trainee; the conditions under which required actions will take place; and the standards of trainee performance expected by the applicant.

15.3.4.5 Organization of Instruction

The applicant will develop lesson plans from training learning objectives, which are based on job performance requirements. The lesson plans and other training guides are developed under guidance from the training organization. These plans are reviewed by the training organization and, generally, by the organization responsible for the subject matter before approval and or use. The applicant will use lesson plans as required for classroom training and OJT and will include standards for evaluating acceptable trainee performance in the plans.

15.3.4.6 Evaluation of Trainee Learning

The applicant will use observation, demonstration, or oral or written tests to evaluate a trainee's mastery of learning objectives. The evaluations will measure the trainee's skills and knowledge of job performance requirements.

15.3.4.7 Conduct of On-the-Job Training

The applicant will use OJT in combination with classroom training for selected activities. The applicant states that it will use lesson plans for classroom and OJT as required. The applicant also commits to using well-organized and current performance-based training materials and to including standards for evaluating acceptable trainee performance in training materials. As stated in the application, OJT will be conducted by personnel who are competent in the program standards of the job being performed and the methods of conducting the training. The applicant states that the completion of OJT will be demonstrated through actual task performance, where feasible and appropriate, or through performance of a simulation of the task, with the trainee explaining task actions based on the conditions that would be encountered during actual performance of the task and using references, tools, and equipment appropriate for the actual task, to the extent practical.

15.3.4.8 Systematic Evaluation of Training Effectiveness

The applicant will evaluate the training program periodically to measure its effectiveness in producing competent employees. The evaluation will consider feedback provided from trainees after completion of classroom training sessions and will evaluate program strengths and weaknesses, determine whether the program content matches current job needs, and identify any corrective actions needed to improve the program's effectiveness.

The applicant may address the following elements of training as they apply to the evaluation objectives of the training program or topical area being reviewed:

- management and administration of training and qualification programs
- development and qualification of the training staff
- position training requirements

- determination of training program content, including its facility change control interface with the CM system
- design and development of training programs, including lesson plans
- conduct of training
- trainee examinations and evaluations
- training program assessments and evaluations

The applicant will document the evaluation results and will highlight the program's noteworthy practices and weaknesses. The applicant will review identified deficiencies, recommend improvements, and make any changes to the affected procedures, practices, or training materials. In the event of plant modifications and procedure changes, the applicant will update affected training materials before their use.

Designated facility or contracted training personnel will periodically monitor training and qualification activities. The applicant states that the QA organization will audit the facility training and qualification program. Trainees and vendors can also provide input related to training program effectiveness. Methods used to obtain training program feedback include surveys, questionnaires, performance appraisals, and staff evaluations, as well as instruments to evaluate the overall effectiveness of the training program. The applicant states that it does not evaluate frequently conducted training classes every time they are held but evaluates them routinely at a frequency sufficient to determine program effectiveness.

15.3.4.9 Personnel Qualification

The applicant will determine qualification requirements for technical personnel in accordance with Chapter 15 of the MOX license application and will identify training and qualification requirements associated with quality-affecting activities in the MPQAP. These requirements will include QA training for project personnel and qualification of nondestructive examination personnel, inspection and test personnel, personnel performing special processes, and auditors. The applicant provides the requirements for key management positions in Chapter 4, "Organization and Administration," of the MOX license application.

15.3.4.10 Provisions for Continuing Assurance

The applicant states that it will evaluate personnel who perform activities relied on for safety at least biennially to verify that they continue to understand, recognize the importance of, and have the qualifications to perform such activities. The applicant will evaluate personnel using written or oral tests or on-the-job performance evaluations and will document the results of the evaluation. The applicant will provide retraining or other appropriate action when results of the evaluations dictate a need. The applicant will retrain personnel in the event of plant modifications, procedure changes, or QA program changes that result in new or revised information.

15.3.5 Plant Procedures

The applicant commits to conducting all activities involving SNM in accordance with approved procedures. The applicant describes the procedures it will use for control of overall facility operations, including the conduct of all operations involving controls identified in the ISA as IROFS and all management control systems supporting IROFS. The applicant states that MFFF management policies will require strict adherence to procedures when performing work. The applicant states that it will require personnel to notify their supervisor in the event that a procedure cannot be executed as written. The applicant also state that each MOX Services employee will have the authority to stop work that is being conducted within his or her scope of responsibility whenever it involves the health and safety of workers or the public, or protection of the environment, or when continued work will produce results that are not in compliance with the MOX Services QA program.

The applicant commits to implementing the requirements of the MPQAP for the development and control of plant procedures. The applicant states that activities associated with the development and control of plant procedures will be performed by personnel who have undergone training in accordance with the requirements of MPQAP Section 2, "Quality Assurance Program." The applicant states that all MFFF maintenance, testing, and operating procedures will meet the requirements of MPQAP Section 5, "Instructions, Procedures, and Drawing," and that plant procedures will be distributed and controlled in accordance with the requirements of MPQAP Section 6, "Document Control." The applicant also states that it will maintain documents that contain the results of procedure implementation (e.g., sign-offs, checklists, data sheets) in the records management system in accordance with the requirements of MPQAP Section 17, "Quality Assurance Records."

15.3.5.1 Types of Procedures

The applicant states that it will categorize MFFF procedures as either administrative procedures (which apply to functions or specific interfaces with other organizational functions) or operating procedures (which provide specific direction for functional task-based work). The applicant states that operating procedures can apply to all MOX Services organizations or only to a specific organization within MOX Services.

15.3.5.1.1 Administrative Procedures

The applicant states that administrative procedures will specify controls that apply to specific MFFF functions or to specific interfaces with other MFFF organizational functions. The applicant commits to implementing administrative procedures to address the administration and conduct of the following process activities: (1) training and qualification, (2) audits and assessments, (3) incident investigation, (4) records management, (5) CM, (6) human systems interface, (7) reporting, (8) QA, (9) equipment control (lockout or tagout), (10) shift turnover, (11) work control, (12) management control, (13) procedure management, (14) NCS, (15) fire protection, (16) radiation protection, (17) radioactive waste management, (18) maintenance, (19) environmental protection, (20) chemical process safety, (21) operations, (22) calibration control, (23) PM, (24) design control, and (25) test control.

15.3.5.1.2 Operating Procedures

The applicant states that operating procedures at MFFF will provide specific direction for functional task-based work within an organizational function and will include production, maintenance, and emergency procedures that address startup, operation, shutdown, control of process operations, and recovery after a process upset. The applicant identifies the specific

areas addressed by these procedures as follows: ventilation; criticality alarms; shift routines, shift turnover, and operating practices; decontamination operations; plant utilities (air, other gases, cooling water, firewater, steam); temporary changes in operating procedures; and abnormal operation or alarm responses, including loss of cooling water, loss of instrument air, loss of electrical power, loss of the criticality alarm system, loss of containment, fires, and chemical process releases. The applicant commits to using the results of the ISA to identify the need for, and to support the development of, specific ACs for IROFS contained in operating procedures.

The applicant states that its operating procedures will include operating limits and controls and specific IROFS ACs necessary to ensure nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection. The applicant commits to identifying safety checkpoints (e.g., hold points for radiological or criticality safety checks, QA verifications, independent operator verification) at appropriate steps in operating procedures, if needed, to ensure the proper accomplishment of work.

The applicant states that it will organize all of the documents that comprise operating procedures with a consistent structure. The applicant commits to applying a consistent structure to general rules for production, maintenance, operational safety, and security; abnormal operating procedures; emergency planning procedures; emergency operating procedures; and the environmental protection program. The applicant will also apply a consistent structure to unit operating instructions and maintenance instructions, which provide instructions for operating and maintaining process units, systems, and equipment.

The applicant describes three categories of operating procedures that it will maintain at the MFFF: production, maintenance, and emergency procedures. Production procedures will control the startup, operation, and shutdown functions at the facility, as well as provide instructions for dealing with abnormal conditions, responding to alarms, controlling process and laboratory operations, and recovering after a process upset. Maintenance procedures will control preventive and corrective maintenance, calibration, surveillance, functional testing, and work control activities. Emergency procedures will describe the applicant's response to a criticality event, a hazardous chemical release, or an emergency external to the MFFF that may affect the MFFF.

15.3.5.1.2.1 Production Procedures

The applicant states that production procedures will control MFFF process operations and will apply to utility, workstation, and control room operations. The applicant commits to including the following elements, as applicable, in all production procedures: (1) purpose of the activity, (2) regulations, policies and guidelines governing the procedure, (3) type of procedure, (4) steps for each operating process phase, (5) initial startup and periodic startup and shutdown, (6) normal operations, (7) offnormal operations, (8) temporary operations, (9) emergency shutdown, (10) emergency operations, (11) normal shutdown, (11) startup following an emergency or extended downtime, (12) hazards and safety considerations (13) operating limits, (14) precautions necessary to prevent exposure to hazardous chemicals or SNM, (15) measures to be taken if contact or exposure occurs, (16) safety controls and the functions associated with the process, and (17) specified time period or other limitations on the validity of the procedure.

15.3.5.1.2.2 Maintenance Procedures

The applicant states that MFFF maintenance procedures will include requirements for premaintenance activities, as necessary, and that these activities may include reviews of the work to be performed, work controls, and reviews of procedures. The applicant commits to requiring clearance from, or notification of, the operations organization as appropriate, when maintenance work and associated postmaintenance functional testing are complete. The applicant commits to monitoring and assessing maintenance activities in accordance with the MPQAP.

The applicant states that it will maintain facility SSCs in accordance with written procedures, documented instructions, checklists, or drawings appropriate to the circumstances. The applicant further states that maintenance activities will address repair, calibration, surveillance, and functional testing and will specifically include repairs and preventive repairs of IROFS, testing of criticality alarm units, calibration of IROFS, maintenance of high-efficiency particulate air filters, functional testing of IROFS, relief valve replacement and testing, surveillance and monitoring, pressure vessel testing, piping integrity testing, and containment device testing. The applicant identifies the organizational responsibilities for the preparation of maintenance procedures; specifically, the applicant states that the MFFF maintenance department, which is led by the Maintenance Manager, will be responsible for the preparation and implementation of maintenance procedures.

The applicant will use approved, written procedures for periodic tests performed to determine various facility parameters and verify the continuing capability of IROFS to meet performance requirements. The applicant states that periodic test procedures will be sufficiently detailed so as to enable qualified personnel to perform the required functions without direct supervision. The applicant commits to implementing compensatory measures when testing is performed on IROFS that are not redundant, to ensure that they are able to perform their safety functions until they are returned to service.

15.3.5.1.2.3 Emergency Procedures

The applicant commits to implementing emergency procedures to address the preplanned actions of operators and other plant personnel in response to an incident, criticality event, hazardous chemical release, or external emergency that may affect the MFFF. The applicant also commits to reviewing applicable procedures after unusual incidents (e.g., accidents, unexpected transients, significant operator errors, equipment malfunctions, system modifications) and to making revisions, as needed.

15.3.5.2 Preparation of Procedures

The applicant states that its facility procedures will be consistent in format, well organized, clear, concise, and comprehensive. The applicant also states that its procedures may include (approved) checklists or data sheets as documented records of completion. The applicant describes its approval process for plant procedures; other members of the MFFF staff and vendors, as appropriate, will review procedure drafts for inclusion and correctness of technical information, including formulas, set points, and acceptance criteria. The applicant will require a peer review of all procedures that are written for the operation of equipment related to IROFS. The Functional Area Manager will be responsible for (1) determining whether procedures require any additional, cross-disciplinary review, and (2) approving procedures. The applicant commits to clearly identifying safety limits associated with IROFS in the applicable procedures.

15.3.5.2.1 Identification and Preparation

The applicant commits to using the results of the ISA and other processes to identify specific operating and administrative procedures that are developed for MFFF. The applicant also states that plant procedures will be prepared by qualified individuals who are assigned by the organization's management to be responsible and accountable for the operation associated with the procedure.

The applicant commits to including consideration of ISA results or changes in ISA results in the process of identifying procedures needed for facility operation. The applicant further commits to incorporating a methodology for identifying, developing, approving, implementing, and controlling operating procedures. The applicant states that the methodology it is committed to implementing will ensure that, as a minimum, (1) the procedure will specify operating and safety limits related to IROFS, (2) procedures will include required actions for normal and abnormal conditions of operation. (3) safety checkpoints will be identified at appropriate steps in the procedure, if necessary, (4) procedures will be validated through field tests, (5) Functional Area Managers who are responsible and accountable for the operation will approved procedures, (6) a mechanism will be specified for revising and reissuing procedures in a controlled manner, (7) the QA elements and CM program at the facility will provide reasonable assurance that current procedures are available and in use at work locations, and (8) the facility training program will train the required persons in the use of the latest procedures available.

15.3.5.2.2 Review and Approval

The applicant states that managers who are responsible and accountable for an operation will review and approve the associated operating and administrative procedures. The applicant further states that the functional management may specify a review to be performed by another functional group. The applicant commits to verifying and validating production and maintenance procedures before initial use or after major revisions.

15.3.5.2.3 Revisions

The applicant commits to preparing and approving procedure revisions, including temporary changes, in the same manner as the original. The applicant also commits to defining the procedure change process in an MFFF procedure.

15.3.5.3 Use of Procedures

The applicant states that it will require compliance with operating and maintenance procedures and will train operators and technicians to report inadequate procedures or the inability to follow procedures. The applicant states that procedures will either be available at work stations or readily accessible where needed to perform work.

15.3.5.4 Control of Procedures

The applicant describes its process for document control of plant procedures and states that, after approval, plant procedures will be processed for entry into the EDMS and issued for use. The applicant commits to implementing the MFFF training program, which is addressed in Section 15.4 of the MPQAP, to ensure that necessary personnel are trained in the use of approved procedures before implementation.

The applicant commits to applying the same change control measures to operating and administrative procedures that are applied to other items in the document management system. The applicant states that document management procedures will ensure that changes to the facility, including procedures, are entered into the EDMS. The applicant also states that document management procedures will address control and distribution of changes, including changes implemented for emergency conditions, temporary procedure changes, and temporary modifications. The applicant states that the MPQAP will provide requirements for QA procedures, which will detail the controls for design input, design output, processes, verification, interfaces, changes, approval, and records.

The applicant commits to reviewing radiation protection, respiratory protection, operating, maintenance, and administrative procedures every five years to ensure technical adequacy and to verify their continued applicability and accuracy. The applicant also commits to reviewing respiratory protection procedures, as appropriate, whenever the MFFF undergoes a modification, change in process, or replacement of equipment. The applicant commits to reviewing emergency procedures annually for the first two years of MFFF operation and at least every two years thereafter. The applicant states that periodic reviews will be performed by qualified individuals who are assigned to be responsible and accountable for the associated operation by functional management. The applicant states that any reissue or approval of a procedure will meet the requirements for periodic review, and if a procedural inadequacy is identified as a root cause from an incident investigation, it will review and modify the applicable procedures as necessary.

15.3.6 Audits and Assessments

As described in Section 16 of the application, the applicant will maintain the audits and assessment program in accordance with Section 18, “Audits” of the MPQAP. The applicant states that it will review any changes to the MPQAP to ensure that the audit and assessment program will be current and will reflect the program description. As described by the applicant, audits will focus on verifying compliance with regulatory and procedural requirements, licensing commitments, and selected operating limits, and assessments will focus on evaluating the effectiveness of activities and ensuring that IROFS and items that affect the function of IROFS are available and reliable to perform their intended safety functions. In addition, the applicant states that it will perform audits and assessments to ensure that facility activities are conducted in accordance with the written procedures and that the processes reviewed are effective. As a minimum, the applicant commits to performing audits and assessments for activities related to radiation protection; criticality safety control; hazardous chemical safety; industrial safety, including fire protection; results of the ISA; environmental protection; and other areas identified through trends.

As stated in the application, the applicant will perform audits in accordance with a written plan that identifies the audits to be performed and their schedules. The applicant confirms that qualified staff personnel who are not directly responsible for production activities will perform audits and assessments on an annual basis. The applicant states that audit team members will not have direct responsibility for the function and area being audited, will have technical expertise or experience in the area being audited, and will be trained in audit techniques.

The applicant commits to performing technical and programmatic audits and assessments internally and externally to provide a comprehensive independent verification and evaluation of procedures and activities for IROFS. As described by the applicant, the QA Department will be responsible for audits related to Quality Level 1 work activities and items required to satisfy

regulatory requirements for which Quality Level 1 requirements are applied. The applicant states that it will provide audits results to the Plant Manager and the managers responsible for the activities audited.

The applicant states that any deficiencies identified during audits or assessments that require corrective action will be forwarded to the responsible manager in accordance with the CAP procedure. The manager will then be responsible for promptly responding to any deficiencies noted in the audits. The applicant states that it will enter deficiencies into the CAP, track them to completion, and re-examine them during future audits to ensure that associated corrective actions have been completed. As described by the applicant, the audit and assessment program will provide for on-the-spot corrective actions with appropriate documentation, in accordance with the CAP procedure, and will include the evaluation of corrective actions to determine their effectiveness.

In the application, the applicant describes two assessments categories: (1) management assessments conducted by the line organizations responsible for the work activity and (2) independent assessments conducted by individuals not involved in the area being assessed.

The applicant states that it will maintain records of the instructions and procedures, persons conducting the audits or assessments, identified violations of license conditions, and any corrective actions taken.

15.3.6.1 Areas to be Audited or Assessed

The applicant identifies a list of areas that it will audit or assess at the MFFF, including radiation safety; nuclear criticality safety; chemical safety; industrial safety, including fire protection; environmental protection; emergency management; QA; CM; maintenance; training and qualifications; procedures; CAP and incident investigations; records management; and other ISA safety areas. The applicant commits to performing assessments of nuclear criticality safety in accordance with ANSI/ANS-8.19 to ensure that operations conform to criticality requirements.

15.3.6.2 Scheduling of Audits and Assessments

The applicant states that it will establish a schedule identifying audits and assessments to be performed and the responsible organization assigned to conduct the activity. As described by the applicant, the frequency of audits and assessments will be reviewed periodically and revised as necessary to ensure coverage commensurate with current and planned activities. The applicant states that major activities will be audited or assessed on an annual basis.

The applicant also states that it will conduct and document nuclear criticality safety audits such that ~~all~~ aspects of the Nuclear Criticality Safety Program will be audited every two years and assessed annually.

Comment [d1]: Delete "all" to be consistent with LA text

15.3.6.3 Procedures for Audits and Assessments

The applicant commits to conducting internal and external audits and assessments in accordance with approved procedures. Among the audit and assessment activities that will be controlled by procedures are scheduling, planning, certifying personnel, developing audit plans, and reporting, tracking, and closure of findings. The applicant states that it will emphasize, through the applicable procedures, the importance of reporting and correcting findings to prevent recurrence.

As described in the application, the applicant will conduct audits and assessments by using checklists (where applicable); interviewing personnel; performing plant area walkdowns, including accessible out-of-the-way and limited-access areas; reviewing plans and procedures; observing work in progress; and reviewing completed QA documentation. The applicant commits to tracking the results of audits and assessments in the CAP. The applicant states that it will evaluate audit and assessment results for trends and needed improvements, which will be reported to the appropriate levels of management when identified. As described in the application, deficiencies will require corrective action in accordance with the applicable CAP procedure, and the QA organization will be responsible for performing followup reviews on significant deficiencies reported as a result of the trend analysis and for verifying completion of corrective actions.

The applicant states that the audit or assessment team leader will develop a report documenting the findings, observations, and recommendations for program improvement and provide it to management. As described by the applicant, the report will include documented verification of performance against established performance criteria for IROFS and will be developed, reviewed, approved, and issued in accordance with applicable procedures. The applicant states that audit reports will contain an effectiveness evaluation and statement for each of the applicable QA program elements that were reviewed during the audit. The applicant commits to closing the audit or assessment with the proper documentation, in accordance with the applicable audit and assessment procedure.

As described in the application, the QA organization will conduct followup audits or assessments to verify that corrective actions were taken in a timely manner and to assess their effectiveness.

15.3.6.4 Qualifications and Responsibilities for Audits and Assessments

The applicant states that the QA Manager will initiate audits and will determine the scope of each audit in coordination with the lead auditor. The QA Manager will also be responsible for the initiation of any special audits or the expansion of the scope of audits, when necessary. As described by the applicant, the lead auditor will direct the audit team in conducting the audit as well as in developing the applicable checklists, instructions, or plans for performing the audit. The applicant states that audit teams will consist of one or more auditors, and, should the team deem it necessary, it may expand the scope of the audit during the audit activity. The applicant commits to ensuring that audits will be performed in accordance with applicable checklists.

The applicant states that auditors and lead auditors will hold the appropriate certifications, as required by the MPQAP. As stated in the application, to be certified under the MOX Services QA program, MFFF auditors will be required to complete training in areas such as the MFFF QA program, audit fundamentals, objectives and techniques of performing audits, and OJT.

As described in the license application, to form the basis of each auditor's certification, the QA Manager will evaluate the auditors' and lead auditors' education, experience, professional qualifications, leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and success in completion of QA training courses. The applicant states that lead auditors must meet additional requirements for qualification, such as a minimum of five QA audits or audit equivalents within a period of time not to exceed three years before the date of certification, at least one of which must be a nuclear-related QA audit or audit equivalent within the year before certification.

The applicant states that it will require personnel performing assessments to complete QA orientation training, as well as training on the assessment process. The applicant states that personnel performing assessments will not report to the production organization and will have no direct responsibility for the function or area being assessed, enabling them to maintain independence and objectivity.

15.3.7 Incident Investigations

Section 15.7 of the application describes the two MFFF programs for investigating discrepancies during operations: the corrective action process and incident investigations.

15.3.7.1 Corrective Action Process

The applicant states that it will use the corrective action process, which is described in Section 16 of the MPQAP, "Corrective Action," to identify, investigate, report, track, correct, and prevent recurrence of conditions that are adverse to quality or that may affect radiation protection, safety, quality, regulatory compliance, reliability, human performance, or project performance. The applicant states that MOX Services employees have the authority and responsibility to initiate the corrective action process if they discover deficiencies. The applicant further states that it will analyze reports of conditions adverse to quality to identify trends in quality performance, and these will be reported to senior management in accordance with corrective action process procedures.

15.3.7.2 Incident Investigation

The applicant commits to using the incident investigation program for investigating abnormal events other than those that involve a condition adverse to quality. As described in the application, the process that will be used for incident investigations may be similar to that of the CAP; the applicant states that it will consider events in terms of their regulatory reporting requirements and the level of investigation required. The applicant commits to providing guidance in written procedures for classifying occurrences (including examples of the threshold for offnormal events), incident identification, investigation, root-cause analysis, environmental protection analysis, recording, reporting, and followup.

The applicant states that the depth of incident investigations will depend upon the severity of the classified incident in terms of the levels of SNM released or the degree of potential for exposure of workers, the public, or the environment. The applicant commits to addressing radiological, criticality, hazardous chemical, and other ISA-related safety requirements in incident investigations and states that anyone in the MFFF organization may identify the need for an incident investigation, which will be performed by one or more individuals assigned by the manager of production. As described in the application, MOX Services will maintain a record of corrective actions, including lessons learned and worker training, to be implemented as a result of investigations of offnormal occurrences and will track the corrective actions to completion.

The applicant states that it will establish an incident investigation program to investigate abnormal events that may occur during operation of the facility to determine their specific or generic root cause(s) and generic implications, to recommend corrective actions, and to make reports to the NRC as required by 10 CFR § 70.50, "Reporting Requirements," and 10 CFR § 70.74, "Additional Reporting Requirements." As described by the applicant, the investigation teams will include at least one process expert and one team member trained in root-cause

analysis. The applicant commits to monitoring and documenting corrective actions taken through to completion.

The applicant states that it will maintain auditable records and documentation related to abnormal events, investigations, and root-cause analyses so that it may apply the lessons learned to future operations of the facility. The applicant will compare details of the event sequence with accident sequences already considered in the ISA and, as appropriate, will modify the ISA and ISA Summary to include an evaluation of the risk associated with accidents of the type actually experienced.

The investigation process, as described by the applicant, will include a prompt risk-based evaluation that, depending on the complexity and severity of the event, may be conducted by one individual. The applicant states that incident investigator(s) will be (1) qualified individuals appointed from internal or external staff, (2) independent from the line function(s) involved with the incident under investigation, and (3) assured of no retaliation for participating in investigations. The applicant commits to initiating investigations within forty-eight hours of the abnormal event, or sooner, depending on the safety significance of the event. As described in the application, the applicant will review the record of IROFS failures required to be maintained by 10 CFR § 70.62(a)(3), "Safety program and integrated safety analysis," as part of the investigation. and, following completion of the investigation, the applicant will record revisions necessitated by post-failure investigation conclusions.

The applicant states that it will develop CAP procedures for conducting incident investigations that will contain elements such as the following:

- a documented plan for investigating an abnormal event;
- a description of the functions, qualifications, and responsibilities of the manager who will lead the investigative team and those of the other team members, the scope of the team's authority and responsibilities, and the assurance of management cooperation;
- assurance of the team's authority to obtain the information considered necessary and its independence from responsibility for or to the functional area involved in the incident under investigation;
- requirements for retention of documentation related to abnormal events for two years or for the life of the activity, whichever is greater;
- guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the problem;
- requirements to make original investigation reports available to the NRC on request; and
- a system for monitoring the completion of appropriate corrective actions and for ensuring that those actions are completed in a timely manner.

15.3.8 Records Management

The applicant describes the records management requirements in Section 15.8 of the application and states that Section 17 of the MPQAP contains additional details related to the records management program. The applicant identifies QA records as documents that include the results of tests and inspections required by applicable codes and standards; construction, procurement, and receiving records; personnel certification records; design calculations; purchase orders; specifications; procedures; corrective action records; source surveillance and audit reports; and any other QA documentation required by specifications or procedures. As described in the application, the applicant will use a controlled and systematic approach to records management to provide identifiable and retrievable documentation during design, construction, and operation of the MFFF. The applicant commits to controlling QA records in accordance with approved procedures and will not consider these records valid until they are authenticated by authorized personnel. The applicant further commits to developing and implementing records management procedures that establish the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition. In addition, the applicant states that it will establish procedures to promptly detect and correct deficiencies in the records management system or in the system's implementation.

The applicant states that the MPQAP requires procedures for the review, approval, identification, handling, retention, retrieval, and maintenance of QA records. The applicant commits to maintaining records at locations where they can be reviewed and audited to ensure that the required quality of the records is maintained. The applicant further states that applicable design specifications, procurement documents, and other documents will specify applicable QA record requirements.

The applicant states that it will manage classified records in accordance with approved project procedures that will identify the required physical protection and access control measures. As stated in the application, the applicant will establish a satellite records retention facility in accordance with the records management procedure.

The applicant commits to establishing procedures to control and manage computer codes and electronic data used for IROFS over the life cycle of the MFFF. The applicant states that the MFFF Records Center will maintain control over access and use of records, either originals or reproductions, that are entered into the EDMS and will ensure that documents in the EDMS are legible and can be identified with the subject to which they pertain. The applicant states that documents will only be considered valid if stamped, initialed, signed, or otherwise authenticated by authorized personnel.

The applicant will establish requirements to preclude deterioration of records in the EDMS, specifically, requirements pertaining to the records storage arrangement, to prevent damage from moisture, temperature, and pressure. For hardcopy records, the applicant will require records to be: (1) firmly attached in binders, placed in folders, or placed in envelopes for storage in steel file cabinets, or (2) stored on shelving in containers appropriate for the record medium. The applicant further states that the storage arrangement will provide adequate protection of special processed records (e.g., radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored.

The applicant identifies measures to ensure the accurate retrieval of information without undue delay. The applicant states that it will store and preserve the records in the Records Center in accordance with an approved QA procedure that contains the following:

- a description of the storage facility;
- a description of the filing system to be used;
- a method for verifying that the records received are in agreement with the transmittal document;
- a method for verifying that the records are those designated and the records are legible and complete;
- a description of rules governing control of the records, including access, retrieval, and removal;
- a method for maintaining control of, and accountability for, records removed from the storage facility;
- a method for filing supplemental information and disposition of superseded records;
- a method for precluding entry of unauthorized personnel into the storage area, to guard against larceny and vandalism; and
- a method for providing for replacement, restoration, or substitution of lost or damaged records.

The applicant lists examples of the records that it will retain, including operating logs, procedures, non-conforming item reports, drawings and specifications, procurement documents, audit reports, and dosimetry records. As stated in the application, retention times will be specified in records management procedures and will ensure that records are retained in accordance with regulatory requirements. The applicant commits to storing one-of-a-kind records in two hour fire-rated cabinets, to ensure records are adequately protected from damage.

15.4 Evaluation Findings

15.4.1 Quality Assurance

The staff reviewed the QA program for a license for the MFFF to possess and use SNM according to Chapter 15.1 of NUREG-1718. Based on its review of the MOX Services QA Plan, the NRC staff concluded that the applicant has adequately described its QA program, and the applicant's QA program meets the regulatory requirements of 10 CFR Part 70, as applied to SSCs, and will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The staff's review and approval of the MFFF QA program is documented in the safety evaluation report dated October 1, 2001, as updated by the letter dated October 19, 2009.

15.4.2 Configuration Management

The staff reviewed the CM system for MFFF according to Section 15.2 of NUREG-1718. Based on its review of the material submitted in the license application, the NRC staff concluded that

the applicant suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for IROFS identified in the safety assessment for the design bases.

The applicant described management-level policies and procedures, including an analysis and independent safety review of proposed activities involving IROFS, that will ensure that the relationship among design requirements, construction, and facility documentation is maintained as part of a new design or change to an existing design. The MFFF ACs, as described in the application, will ensure that the organizational structure, procedures, and responsibilities necessary to implement CM are in place; that the design requirements and bases are documented and supported by analyses and the documentation is maintained current; that documents, including drawings, are appropriately stored and accessible; that drawings and related documents adequately describe IROFS; that procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, facility construction, and facility documentation; and that methods are in place for suitable analysis, review, approval, and implementation of identified changes to IROFS.

The staff concludes that the applicant's CM function meets the requirements of 10 CFR Part 70 and provides reasonable assurance that the environment and the health and safety of the public are protected.

15.4.3 Maintenance

The staff reviewed the maintenance program for MFFF according to Section 15.3 of NUREG-1718. Based on the review of the license application, the staff concluded that the applicant committed to performing maintenance of IROFS, with the exception of personnel activities (safety controls). The staff reviewed and evaluated the maintenance commitments, which contain measures to ensure availability and reliability of IROFS through surveillance and monitoring, corrective maintenance, PM, and functional testing activities. The functional testing activities comprise a detailed test control program that covers preoperational and operational activities, including initial startup testing and periodic testing. The applicant's maintenance function is proactive, using both surveillance and monitoring and maintenance records to analyze equipment performance and identify the root causes of repetitive failures.

In addition, the surveillance and monitoring activities described in this section of the application provide assurance of the validity of the ISA by examination, calibration, and testing of equipment that monitors process safety parameters and acts to prevent or mitigate accident consequences.

The maintenance function (1) is based on approved procedures, (2) employs work control methods that properly consider personnel safety, awareness of facility operating groups, QA, and the rules of CM, (3) links IROFS requiring maintenance to the ISA, (4) justifies the PM intervals in terms of equipment reliability goals, and (5) creates documentation that includes detailed records of all surveillances, inspections, equipment failures, repairs, and replacements.

The staff concludes that the applicant's maintenance program meets the requirements of 10 CFR Part 70 and provides reasonable assurance that the environment and the health and safety of the public are protected.

15.4.4 Training and Qualifications

The staff reviewed the application for the MFFF according to Section 15.4 of NUREG-1718. The applicant described the structure of the MFFF training and qualification program and committed to providing plant personnel with a combination of general and technical training that includes initial training, OJT, and continuing education, as required, to establish and maintain the proficiency of personnel in their work duties. The applicant commits to performing a needs and job analysis to identify tasks that require training, to ensure that appropriate training is provided to personnel managing, supervising, performing, and verifying activities related to IROFS. The applicant further commits to systematically evaluating the effectiveness of the training program at periodic intervals. Based on its review of the application, the NRC staff concludes that the applicant adequately described its training and qualification of plant personnel and that the applicant's training and qualification of plant personnel will, based on commitments, meet the requirements of 10 CFR Part 70 and provide reasonable assurance of the protection of public health and safety and of the environment.

15.4.5 Procedures

The staff reviewed procedural controls described in the license application for the MFFF according to Section 15.5 of NUREG-1718. The applicant described the administrative and operating procedures for control of overall facility operations, including the conduct of all operations involving controls identified in the ISA as IROFS and all management control systems supporting IROFS. The applicant committed to conducting all activities involving SNM in accordance with approved procedures and to reviewing all radiation protection, respiratory protection, operating, maintenance, and administrative procedures every five years to ensure technical adequacy and to verify the continued applicability and accuracy of the procedures. The applicant has suitably described the processes for development, review, approval, control, and implementation of procedures. As described in the application, MOX Services has established or made commitments to establish sufficient procedural guidance to ensure the proper control and protection of IROFS, as well as systems important to the health of workers and the public and the protection of the environment during testing, startup, and operation of the facility. Based on its review of the application, the NRC staff concludes that the applicant has adequately described its controls for the establishment, maintenance, use, and revision of MFFF procedures, and those controls meet the requirements of 10 CFR Part 70 and provide reasonable assurance of the protection of public health and safety and of the environment.

15.4.6 Audits and Assessments

The staff reviewed the MFFF audit and assessment program description, as described in the license application, according to Section 15.6 of NUREG-1718. The staff reviewed the applicant's description of its policy directives, plans, and procedural requirements with respect to (1) the general structure of the audits and assessments program, (2) the activities to be audited or assessed, (3) the scheduling of audits and assessments, (4) the procedures for audits and assessments, and (5) the qualifications and responsibilities for audits and assessments.

Based on its review of the application, the NRC staff concludes that the applicant has adequately described its system of audits and assessments, and this system meets the requirements of 10 CFR Part 70 and provides reasonable assurance of the protection of public health and safety and of the environment.

15.4.7 Incident Investigations

The staff reviewed the license application for MFFF as it pertains to incident investigations according to Section 15.7 of NUREG-1718. As described, the MFFF incident investigation program specifies the process for investigating abnormal events, the qualification requirements for investigation personnel, the size and composition of investigation teams, corrective action commitments, and records requirements for investigation-related documents. The applicant commits to performing incident investigations in accordance with approved procedures.

Based on its review, the NRC staff concluded that the applicant has established an organization for (1) investigating incidents that occur during operation of the facility, (2) determining the root cause(s) and any generic implications of each incident, and (3) taking corrective actions for ensuring the safety of the MFFF and its operations. Furthermore, the applicant has committed to reviewing the results of the investigation against the ISA, to monitoring and documenting corrective actions through to completion, to maintaining investigation-related documentation, and to applying lessons learned to future operations of the facility. Based on its review of the application, the NRC staff concludes that the applicant has adequately described its program for incident investigations, and the applicant's controls for investigating incidents meet the requirements of 10 CFR Part 70 and provide reasonable assurance of the protection of public health and safety and of the environment.

15.4.8 Records Management

The staff reviewed the MFFF records management controls, as described in the license application, according to Section 15.8 of NUREG-1718. The staff reviewed the applicant's records management requirements for the control and handling of the records and concluded that there is reasonable assurance that the system will (1) be effective in collecting, verifying, protecting, and storing information about the health and safety aspects of the facility and its operations and will be able to retrieve the information in readable form for the designated lifetimes of the records, (2) provide record storage facilities capable of protecting and preserving records that are stored there during the mandated periods, including protecting the stored records against loss, theft, tampering, or damage during and after emergencies, and (3) ensure that any deficiencies in the records management system or its implementation will be detected and corrected in a timely manner. The staff concludes that the applicant's facility records management system meets the requirements of 10 CFR Part 70 and is acceptable.

REFERENCES

(MOX, 2010a) Shaw AREVA MOX Services, "MFFF—License Application," Aiken, SC, March 2010.

(MOX, 2010b) Shaw AREVA MOX Services, "MFFF—Integrated Safety Analysis Summary," Aiken, SC, March 2010.

(NRC, 2009), U.S. Nuclear Regulatory Commission, Letter from Marissa Bailey to David Stinson, "Approval of Changes to the Mixed Oxide Project Quality Assurance Program, Revision 8", Washington, D.C., October 19, 2009

(NRC, 2001), U.S. Nuclear Regulatory Commission, Letter from Andrew Persinko to Peter Hastings, "Duke Cogema Stone & Webster Quality Assurance Program for Construction of the MOX Fuel Fabrication Facility," Washington, D.C., October 1, 2001

(NRC, 2000) U.S. Nuclear Regulatory Commission, NUREG-1718, “Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility,” August 2000.

(ASME, 1995), American Society of Mechanical Engineers, ASME NQA-1a-1995, “Quality Assurance Requirements for Nuclear Facility Applications”, 1995

10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”

10 CFR Part 21, “Reporting of Defects and Noncompliance”

10 CFR 70, “Domestic Licensing of Special Nuclear Material”