MFFFPEm Resource

From: Tiktinsky, David
Sent: Tuesday, March 23, 2010 3:48 PM
To: Cleavenger, Sabrina; Arroyo, Damaris
Cc: Oesterle, Eric; Morrissey, Kevin; MFFFHearingFile Resource
Subject: FW: Files and Responses to MPQAP Rev 9 Review Questions
Attachments: Ch.04 Org and Admin.doc; Ch.15 Management Measures .doc; MOX Questions of Draft MPQAP Rev 9 REVISED SET and Responses.doc

Follow Up Flag: Follow up
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Info on MM and QA.

From: Gwyn, Dealis W. [mailto:DWGwyn@moxproject.com]
Sent: Tuesday, March 23, 2010 3:41 PM
To: Tiktinsky, David
Subject: Files and Responses to MPQAP Rev 9 Review Questions

Dave,

Attached are draft responses to the clarification questions on draft MPQAP Rev 9. Also, attached are associated draft LA change pages.

Please let me know if you have any questions.

Thanks

Dealis

Hearing Identifier: MixedOxideFuelFabricationFacility_Public
Email Number: 129

Mail Envelope Properties (0A64B42AAA8FD4418CE1EB5240A6FED11164BDE27A)

Subject: FW: Files and Responses to MPQAP Rev 9 Review Questions
Sent Date: 3/23/2010 3:47:34 PM
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From: Tiktinsky, David

Created By: David.Tiktinsky@nrc.gov

Recipients:
"Oesterle, Eric" <Eric.Oesterle@nrc.gov>
Tracking Status: None
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"Arroyo, Damaris" <Damaris.Arroyo@nrc.gov>
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Files	**Size**	**Date & Time**
MESSAGE	1170	3/23/2010 3:47:36 PM
Ch.04 Org and Admin.doc	103490	
Ch.15 Management Measures .doc	411202	
MOX Questions of Draft MPQAP Rev 9 REVISED SET and Responses.doc	175682	

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4.0 ORGANIZATION AND ADMINISTRATION

The Shaw AREVA MOX Services, LLC (MOX Services) functional organizational structure for the operational phase of the Mixed Oxide Fuel Fabrication Facility (MFFF) is shown in Figure 4-1~~Figure 4-1Figure 4-1~~.

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4.1 FACILITY ORGANIZATIONAL STRUCTURE

Functional responsibilities and authority are described below for key management functions. The authority to make commitments to the U.S. Nuclear Regulatory Commission (NRC) is only held by the explicitly stated positions. The key management functions are responsible for items relied on for safety (IROFS) and related activities.

The key MOX Services management functions with health, safety and environmental (HS&E) responsibilities are the MOX Services President, Plant Manager, Operations Manager, Engineering Manager, and Environmental Safety & Health (ES&H) Licensing Manager. Operations, Engineering and ES&H Licensing are independent functions allowing each organization to provide objective audits, assessments, and reviews. Independence means that none of these organizations report administratively to the other.

Qualification requirements for key management positions are provided below. Relevant work experience of at least five years, in addition to the minimum experience requirements specified below, may be substituted for the Bachelor's degree requirements. Where work experience in more than one field is required for a given position (e.g., four years of engineering experience and two years of management experience), the experience may be concurrent unless otherwise indicated. The MOX Services President may approve exceptions to the qualification requirements for the positions described in this chapter.

Stop work authority is vested in each MOX Services employee. Any employee may stop work when the continuation of such work could jeopardize the health and safety of workers or the public, result in adverse consequences to the environment, or produce results that do not comply with the MOX Services Quality Assurance (QA) program. Following a stop-work, activities related to safety are stopped until the deficiency or unsatisfactory condition has been resolved in accordance with MOX Services procedures.

4.2 KEY MANAGEMENT FUNCTIONS

4.2.1 Facility Management Function

The MOX Services President manages all aspects of the MFFF, including safety and nuclear fuel manufacturing activities at the facility. This individual directs licensed activities and staff functions through designated operations, engineering, safety, and business management personnel. The President provides for the health and safety of the public and workers and protection of the environment by delegating and assigning responsibility to qualified managers and personnel. The President's direct reports are shown on Figure 4-1. The President reports to the MOX Services Board of Governors (not shown on Figure 4-1).

The corporate officer that has the overall responsibility for health, safety, and environmental (HS&E) matters for MFFF is the President of MOX Services.

The minimum qualifications for the MOX Services President are a Bachelor's degree (or equivalent) in engineering or science, five years of experience in operations, and/or engineering of nuclear facilities, and five years of experience in management.

4.2.2 Quality Assurance Function

The manager of the quality assurance QA function is responsible for maintaining the MOX Services Project Quality Assurance Plan (MPQAP) and reports directly to the MOX Services President. This function is independent of the organizations responsible for performing quality-affecting work and is independent of cost and schedule considerations. This function may be assigned other duties; however, these duties are not allowed to compromise the independence of this function or to prevent attention to quality assurance matters. The manager of the QA function has the same access to the MOX Services President as the line managers of other functional areas of the MFFF.

The manager of the QA function is responsible for identifying quality problems, recommending and verifying implementation of solutions, and ensuring further work is controlled until the unsatisfactory conditions has been corrected. The manager of the QA function is responsible for approval of the subcontractor quality assurance programs, oversight, and audit functions. The manager of the QA function also interfaces with NRC, stakeholders and other governmental agencies regarding the QA requirements, compliance with QA requirements, and resolution of QA concerns. These functions are accomplished by delegating and assigning responsibility to qualified personnel.

The QA manager is the only key management position in the QA organization. The minimum qualifications for the QA Manager position are a Bachelor's degree (or equivalent), ~~four years of~~ quality assurance-related experience, ~~two years of~~ nuclear industry experience, and ~~one year of~~ supervisory or management experience.

4.2.3 Production Function Including the Operations Function

The managers of the production function are responsible for the production, operation, technical support activities for the MFFF, including aqueous polishing (AP), fuel fabrication (MP), and maintenance. The production function includes the Plant Manager, Operations Manager, Operations Shift Managers, Maintenance Manager, and Technical Support Manager. This position also is directly responsible for maintenance, analytical laboratory, balance of plant systems, logistics, waste disposal, product quality control, safeguards, security, and material control and accountability (MC&A). Production functions are accomplished by delegating and assigning responsibility to qualified managers, supervisors and other personnel. The plant manager has the authority to make commitments to the NRC

The Plant Manager reports directly to the President. The Operations Manager reports to the Plant Manager, and the Operations Shift Managers reports to the Operations Manager. The Plant

Manager, Operations Manager, and Operations Shift Managers are the only key management personnel in the production function.

The manager of the production functions are responsible for the safety and control of operations, knowledgeable of safety program concepts as they apply to the overall safety of the facility, and compliance with MFFF licensing requirements. These managers are also responsible for ensuring the overall implementation of the configuration management program. The Operations Manager and the Operations Shift Managers are responsible for the day-to-day processing, handling, and storing of licensed materials. These managers ensure configuration control for the integrated safety of facility processes while meeting production objectives. Operations Managers and Shift Operations Managers accomplish these functions by ensuring that operations personnel are adequately trained and that approved written procedures are available and adhered to. They are knowledgeable of, and responsible for, the control of IROFS within their area of supervision.

The minimum qualifications for the Plant Manager are a Bachelor's degree, (or equivalent) in engineering or science, ~~four years of~~ operational or manufacturing production experience in a nuclear facility, and ~~one year of~~ supervisory or management experience.

The minimum qualifications for the Operations Manager are a Bachelor's degree (or equivalent) in engineering or science, ~~four years of~~ operational or manufacturing production experience in a nuclear facility, and ~~one year of~~ supervisory or management experience.

The minimum qualifications for Operations Shift Managers are a Bachelor's degree, (or equivalent) in engineering or science~~high school diploma~~, ~~one year of~~ operations or manufacturing production experience in a nuclear facility, and ~~one year of~~ supervisory or management experience.

Supervisors shall have at least the qualifications required of personnel being supervised and either one additional year experience supervising the technical area at a similar facility or completion of supervisor training.

The minimum qualifications for Technical staff identified in the ISA Summary whose activities are relied on for safety to satisfy the performance requirements identified in 10 CFR Part 70, are a Bachelor's degree (or equivalent) in an appropriate technical field and experience and training appropriate for their activities, authority, and responsibilities.

Facility operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations shall have completed the training process or have equivalent experience or training.

The minimum qualifications for candidates for process operator positions are a high school education (or equivalent).

4.2.4 Engineering Functions

The manager of the engineering function is the MFFF design authority and is directly responsible for system engineering and facility upgrade engineering. The engineering function is independent of other MFFF functions. The engineering function is accomplished by delegating and assigning responsibilities to qualified managers, engineers, and designers.

The Engineering Manager reports directly to the President. Only the Engineering Manager is a key management position in the engineering function.

The minimum qualifications for the Engineering Manager are a Bachelor's degree (or equivalent) in engineering, ~~four years of~~ experience in engineering or operations of nuclear facilities, and ~~one year of~~ supervisory or management experience.

4.2.5 Environmental, Safety & Health Licensing Functions

The manager of the Environmental, Safety & Health (ES&H) Licensing function is independent of the production function and is directly responsible for the health, safety and environmental (HS&E) functions including fire safety, radiation protection, chemical safety, criticality safety, nuclear safety analysis, and environmental protection. The ES&H Licensing Manager is responsible for maintaining the MOX Services special nuclear material possession and use license, planning and executing licensing and regulatory compliance activities, maintaining licensing-related documents, and interfacing with the NRC and other regulatory agencies regarding licensing matters. The manager of ES&H Licensing function has the authority to make commitments to the NRC. These functions are accomplished by delegating and assigning responsibility to qualified personnel. The ES&H Licensing Manager reports directly to the President.

The ES&H Licensing Manager is the only key management position within ES&H Licensing.

The minimum qualifications for ES&H Licensing Manager are a Bachelor's degree (or equivalent), ~~four years of~~ experience in engineering, licensing, safety or operations of nuclear facilities, and ~~one year of~~ supervisory or management experience.

4.2.6 Support Services Functions

The support services function includes business-related functions that are necessary to support the MFFF mission. The support services functions include training for employees, plant engineering, contracts, legal, finance and accounting, human resources, and procurement. The support services function manager reports to the President. The managers of this function are not responsible for the HS&E functions for the facility and are not key management personnel. Therefore, the minimum qualifications for support services managers are not included in the License Application.

4.3 ADMINISTRATION

The managers responsible for the above functions are appropriately available to perform their duties. In times of absence, their duties may be delegated to other qualified personnel, as

determined by the responsible manager. While these managers have the authority to delegate tasks to other individuals, the responsible manager retains the ultimate responsibility and accountability for compliance with applicable requirements.

MOX Services procedures are used to implement HS&E functions associated with the MFFF and management measures that supplement IROFS. See Chapter 15 for a discussion of management measures, which include quality assurance, configuration management, maintenance, training and qualifications, plant procedures, audits and assessments, incident investigations, and records management. Plant procedures are formally approved and controlled. If a procedure cannot be adhered to, work is stopped and not resumed until the procedure has been corrected or changed.

Figure **4-1**. MFFF Functional Organization

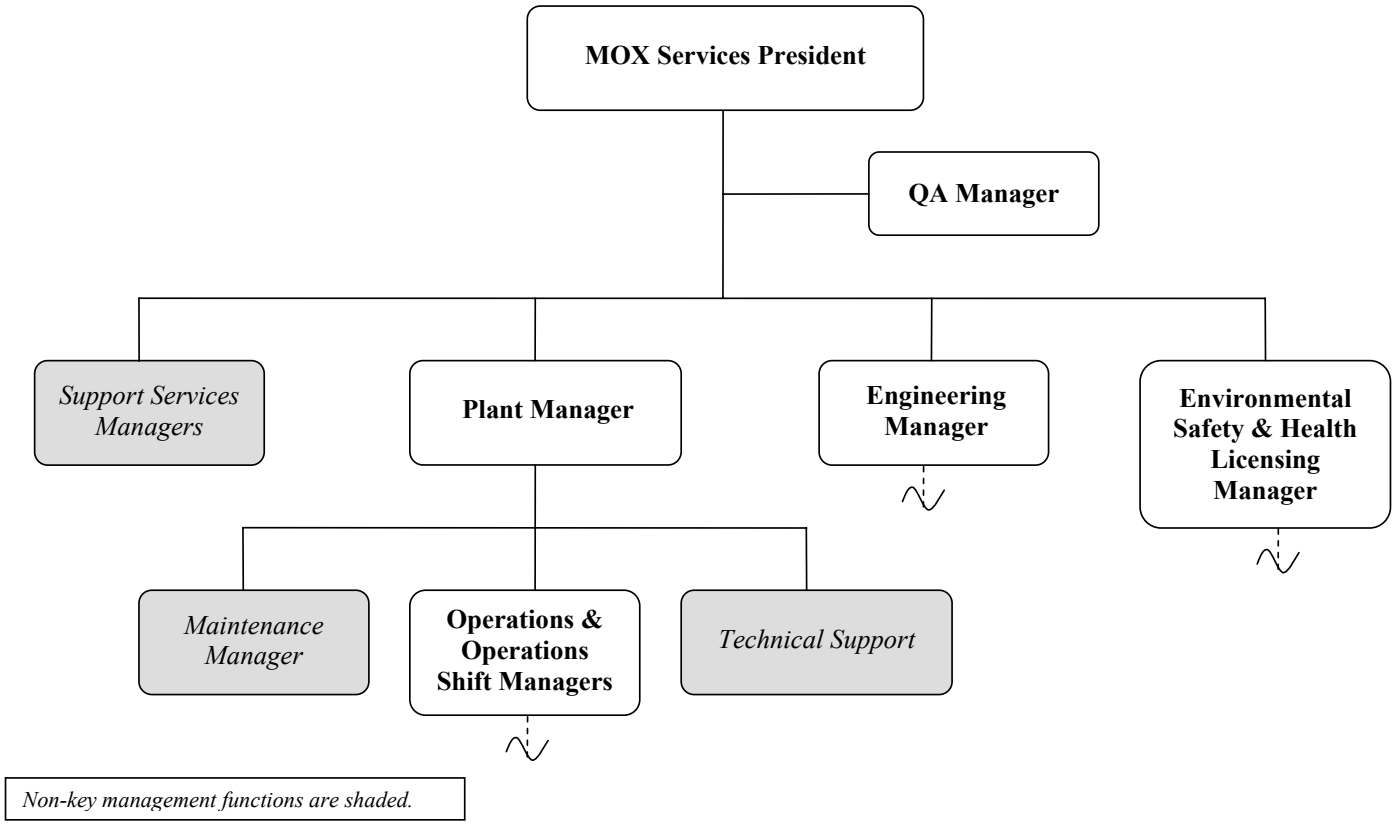
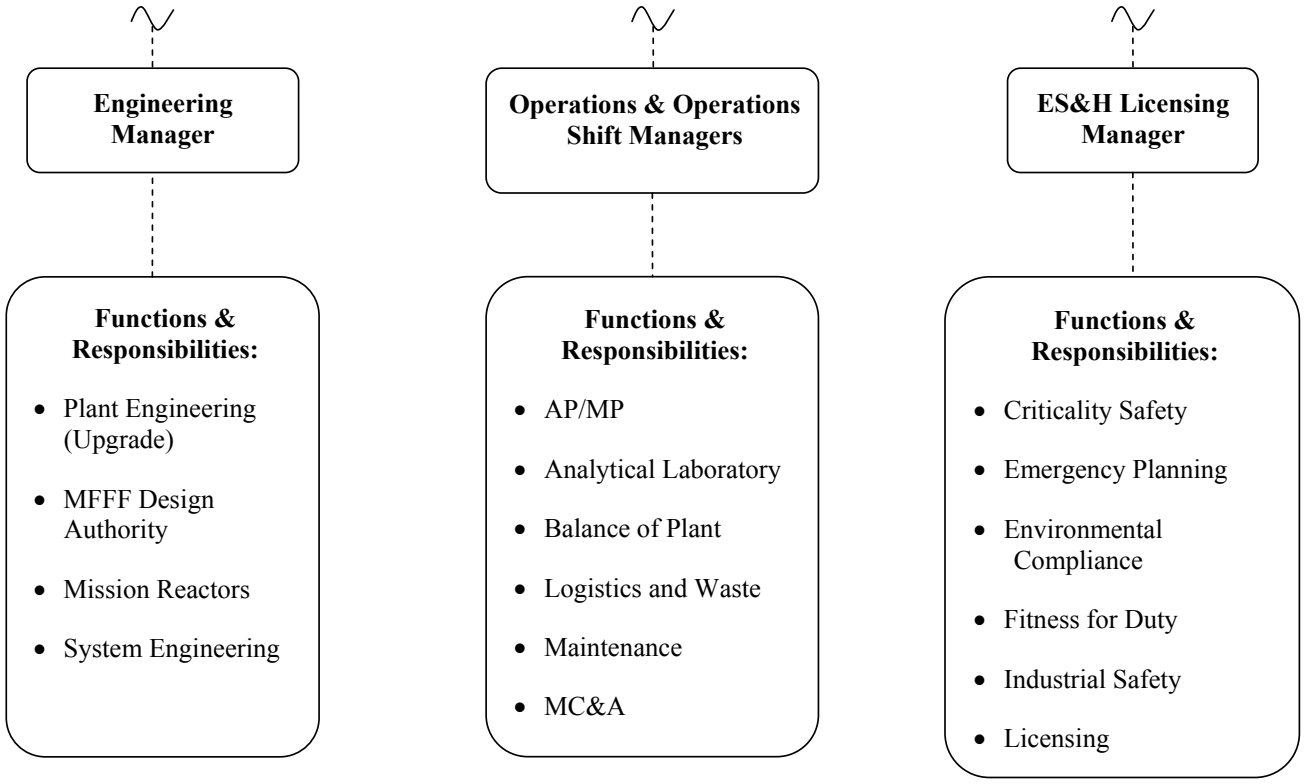


Figure 4-1 MFFF Functional Organization (continued)



15.0 MANAGEMENT MEASURES

Shaw Areva MOX Services, LLC (MOX Services) has established management measures, an administrative and programmatic framework that ensures that facility items relied on for safety (IROFS) are available and reliable to perform their safety function when needed, and that work is conducted efficiently and in a manner that protects workers, the public, and the environment. This framework includes configuration management, maintenance, training and qualification, procedures, audits and assessments, incident investigations, and records management. Within this framework are the administrative and programmatic measures implemented for Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) IROFS to ensure safety. This chapter describes the management measures implemented for MFFF IROFS. These management measures are implemented in accordance with a quality assurance (QA) program established in accordance with Title 10 of the Code of Federal Regulations (CFR) Part 50, Appendix B.

This chapter makes frequent reference to the MOX Services QA program described in the MOX Project Quality Assurance Plan (MPQAP), because management measures are closely related to quality assurance requirements. The MPQAP has previously been approved by the U.S. Nuclear Regulatory Commission (NRC).

Application of Management Measures

Management measures are applied to IROFS to ensure that they are reliable and available upon demand. The set of applied management measures consists of applicable elements of the following management measures programs: quality assurance, configuration management, maintenance, training and qualification of plant personnel, plant procedures, audits and assessments, incident investigations, and records management.

Management measures are assigned based on the following types of IROFS classifications and the risk reduction level attributed to that particular IROFS:

- Passive Engineered Controls (PEC) – A device that uses only fixed physical design features to maintain safe process conditions without any required human action
- Active Engineered Controls (AEC) – A physical device that uses active sensors, electrical components, or moving parts to maintain safe process conditions without any required human action
- Enhanced Administrative Controls (EAC) – A procedurally required or prohibited human action, 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 (i.e., augmented administrative control)
- Administrative Controls (AC) – A procedural human action that is prohibited or required to maintain safe process conditions (i.e., a simple administrative control).

The specific elements of the various management measures programs assigned to each IROFS classification are provided in Table 15-1~~Table 15-1~~. This table illustrates how the various management measures elements apply to the different IROFS classifications. For the enhanced

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EAC, the specific management measures for the physical device are covered under the AEC classification.

The following information provides a brief overview of the MOX management measures programs.

Quality Assurance – The MOX QA program is described in the MPQAP and established in accordance with Title 10 of the CFR Part 50, Appendix B. The MPQAP describes the quality assurance requirements for quality-affecting activities on the project and coincide with the 18 criteria of 10CFR50, Appendix B.

Configuration Management – Configuration management processes and requirements are required to maintain effective control of the MFFF as-designed facility arrangement and operation. This provides reasonable assurance that IROFS safety functions are properly controlled, and that changes to the facility are properly addressed, evaluated, and approved. The configuration management processes and requirements are described in the MFFF Configuration Management Plan. The plan consists of the following five basic plan elements: 1) plan management, 2) technical requirements, 3) change control, 4) document control, and 5) audits and assessments. MOX implements these five elements to maintain consistency among design requirements, design basis, physical configuration, and facility documentation throughout the life cycle of the facility.

Maintenance – MOX implements a maintenance program that includes provisions for planned, scheduled, and unplanned maintenance to ensure MFFF equipment will be available and reliable to perform their intended safety functions. Maintenance for IROFS is developed and conducted to maximize availability and reliability for assurance that the safety functions and ISA requirements will be achieved. Maintenance activities include surveillances, preventive maintenance, and corrective maintenance. Surveillances are planned and scheduled systematic procedures conducted at required intervals to monitor the performance of IROFS equipment for assurance that they continue to meet their performance specifications, including availability and reliability goals. Surveillances may consist of measurements, inspections, functional tests, and calibration checks. Preventive maintenance activities are planned and scheduled and include actions that detect, preclude, or mitigate degradation and to sustain or extend the useful life of SSCs. Corrective maintenance is performed to repair or replace equipment that has failed or is significantly degraded to the point that failure is imminent and no longer conforms to or is incapable of performing its intended safety function. Post maintenance functional tests are performed to confirm equipment functions have been restored to normal conditions. Maintenance work is performed through a coordinated and structured work control process that integrates with ongoing production activities and requirements. This work control process includes representation from various disciplines, such as radiation protection, safety, operations and others, as necessary, for complete pre-planning of the required work. Coordination of work activities includes items such as work orders, procedures, schedules, radiation work permits, and lockout/tagout requirements.

Training and Qualification – Training and qualification of MOX employees is essential to the safe and successful design, construction, testing, and operation of the MFFF. Training is commensurate with the complexity of assigned tasks. Lesson plans are used for classroom and

on-the-job training as required to assure consistent presentation of subject matter. When design changes or plant modifications are implemented, updates of applicable lesson plans are included in the change control process of the configuration management system. A needs/job analysis is performed and tasks identified to ensure that appropriate training is provided to personnel. Learning objectives identify the training content established by needs/job analyses and position-specific requirements. Lesson plans are developed from learning objectives, which are based on job performance requirements. Trainee mastery of learning objectives is evaluated through observation/demonstration, or oral or written tests. In addition to appropriate classroom training, on-the-job training is used for selected activities when appropriate. Completion of on-the-job training is demonstrated by task performance, where feasible and appropriate. The training program is periodically and systematically evaluated to measure the program's effectiveness in producing competent employees. Trainees provide feedback after completing their classroom training as their evaluation for program improvements. Training records are maintained to support management information needs associated with personnel training, job performance, and employee qualifications.

Procedures – Plant procedures are developed and controlled in accordance with the requirements of the MPQAP. They are broadly categorized as either administrative procedures or operating procedures. Administrative procedures specify controls that apply to specific functions or specific interfaces with other organizational functions. Operating procedures provide specific direction for functional task-based work within an organizational function. Operating procedures include production, maintenance, and emergency procedures. Operating procedures include operating limits and controls, and specific IROFS administrative controls to ensure nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection. Prior to initial use and after major revisions, production and maintenance procedures are verified and validated. The MFFF training program ensures that employees are trained in the use of approved procedures before implementation. To ensure technical accuracy, operating procedures are periodically reviewed by qualified individuals to verify their continued applicability and accuracy.

Audits and Assessment – MOX utilizes two distinct levels of activities (audits and assessments) to evaluate the effectiveness and implementation of QA Program elements and other management measures for IROFS and to address the technical adequacy of the items evaluated. Audits are independently planned and documented evaluations performed by the QA organization. Audits evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of quality-affecting activities. Assessments are management directed evaluations of the scope, status, adequacy, programmatic compliance, and implementation effectiveness of QA and other management measures in their area of responsibility.

Incident Investigations – MOX implements two programs for investigating discrepancies: the corrective action process and incident investigations. The MOX corrective action process is used for identifying, investigating, reporting, tracking, correcting, and preventing recurrence of conditions adverse to quality. Nonconforming materials, parts, or components are identified and controlled in accordance with the MPQAP. Incident investigations are used for investigating unplanned events such as accidents, unexpected transients, operator error, and unacceptable performance deficiencies. An incident investigation is performed by one or more individuals

assigned by the manager of production. The process used for the investigation may be similar to that of the corrective action process. Upon completion, a report on the incident and its investigation is made to the production manager, who initiates appropriate action(s), if determined necessary.

Records Management – MOX records are managed in accordance with the records management program under the requirements of the MPQAP. Records management program procedures have been established to address the receipt, processing, indexing, filing, storage, access control, preservation, retrieval, correction, and retention of QA records developed or received by the MOX project.

15.1 QUALITY ASSURANCE

MOX Services, based on option A of NUREG-1718, implements and maintains the QA program described in the MPQAP in conformance with the applicable requirements of Parts I and II of ASME-NQA-1-1994, as revised by the ASME NQA-1a-1995 Addenda or equivalent. As noted above, the MPQAP has been approved by the NRC. A change that would reduce the commitments of the NRC approved QA program is submitted with written justification to the NRC for acceptance, prior to implementation by MOX Services. The MPQAP will be updated as necessary during testing, operation, and deactivation of the MFFF. MOX Services implements the requirements of 10 CFR Part 21, *Reporting of Defects and Noncompliance,* for design, construction, procurement, testing, and operations of Quality Level 1 structures, systems, and components (SSCs) (i.e., IROFS). MPQAP Section 4, *Procurement Document Control*, requires that 10 CFR Part 21 be invoked for procurements of IROFS, unless the procurement is for a Commercial Grade Item.

15.2 CONFIGURATION MANAGEMENT

15.2.1 Configuration Management Policy

MOX Services implements configuration management (CM) processes to ensure design and operation within the design basis of IROFS by: identifying and controlling preparation and review of documentation associated with IROFS; controlling changes to IROFS; and maintaining the physical configuration of the facility consistent with the approved design.

The Integrated Safety Analysis (ISA) of the design determines the IROFS and establishes the safety function(s) associated with each IROFS. Configuration control is accomplished during design through the use of procedures for controlling design, including preparation, review (including interdisciplinary review), design verification where appropriate, approval, release and distribution for use. Quality level classifications are established for the MFFF structures, systems, components, and associated documents. Changes to the approved design are subject to a review to ensure consistency with the design bases of IROFS. Configuration management is also accomplished through design review and design verification, which ensures that design documents are consistent and that design requirements for IROFS are met. Changes identified during construction or testing must be approved by Engineering via a documented engineering change process or an approved non-conformance report prior to change implementation to ensure configuration is maintained and that testing that is specified to demonstrate performance of

IROFS is accomplished successfully. Periodic audits and assessments of the configuration management program and of the design confirm that the system meets its goals and that the design is consistent with the design bases. The corrective action process occurs in accordance with the MPQAP and associated procedures in the event problems are identified. Prompt corrective actions are developed as a result of incident investigations or in response to audit or assessment results.

Configuration management provides the means to establish and maintain the essential features of the design basis of IROFS, including the ISA. As the project progresses from design and construction to operation, configuration management is maintained. Procedures will define the turnover process and responsibilities.

The administrative instructions for modifications during the operations phase are contained in procedures that are approved, including revisions, by the Functional Area Manager. The change procedure contains the following items necessary to ensure quality in the modification program:

- The technical and quality requirements which shall be met to implement a modification
- The requirements for initiating, approving, monitoring, designing, verifying, and documenting modifications. The facility modification procedure shall be written to ensure that policies are formulated and maintained to satisfy the MPQAP, as applicable.

Each change to the facility or to activities of personnel during operations shall have an evaluation performed in accordance with the requirements of 10 CFR 70.72, as applicable. Each modification shall also be evaluated for any required changes or additions to the facility's procedures, personnel training, testing program, or regulatory documents, as applicable.

For any change (i.e., new design or operation, or modification to the facility or to activities of personnel, e.g., site structures, systems, components, computer programs, processes, operating procedures, management measures), that involves or could affect the integrated safety analysis, the impacts shall be evaluated and documented. Prior to implementing the change, it shall be demonstrated that the change does not affect the safety basis in accordance with 10 CFR 70.72. Changes that impact the safety basis require NRC approval prior to implementation.

Each modification is also evaluated and documented for radiation exposure to minimize worker exposures in keeping with the facility as low as reasonably achievable (ALARA) program, criticality and worker safety requirements and/or restrictions. Other areas of consideration in evaluating modifications may include, but are not limited to the review of:

- Modification cost
- Lessons learned from similar completed modifications
- QA requirements
- Potential operability or maintainability concerns
- Constructability concerns
- Post-modification testing requirements

- Environmental considerations
- Human factors
- Integrated safety analysis

After completion of a modification to a structure, system, or component, the modification Responsible Manager, or designee, shall ensure that applicable testing has been completed to ensure correct operation of the system(s) affected by the modification and documentation regarding the modification is complete. In order to ensure operators are able to operate a modified system safely, when a modification is complete, documents necessary (e.g., the revised process description, checklists for operation and flowsheets) are made available to operations and maintenance departments prior to the start-up of the modified system. Appropriate training on the modification is completed before a system is placed in operation. A formal notice of a modification being completed is distributed to the appropriate managers. Drawings incorporating the modification are completed in accordance with the design control procedures. These records shall be identifiable and shall be retained in accordance with the records management procedures.

15.2.2 Implementation of Configuration Management

During the design phase of the project, configuration management is based on the design control provisions and associated procedural controls over design documents to establish and maintain the technical baseline. Design documents, including the ISA, that provide design input, design analysis, or design results specifically for IROFS are identified with the appropriate Quality level. These design documents undergo interdisciplinary review during the initial issue and during each subsequent revision. During the construction phase of the project, changes to drawings and specifications issued for construction, procurement, or fabrication are systematically reviewed and verified, evaluated for impact, including impact to the ISA, and approved prior to implementation. Proper implementation is verified by the Quality Assurance organization.

In order to provide for the continued safe and reliable operation of the MFFF IROFS, measures are implemented to ensure that the quality of these IROFS is not compromised by planned changes (modifications). Upon acceptance by Operations, the Plant Manager is responsible for the design of, and modifications to, facility items relied on for safety. The design and implementation of modifications are performed in a manner so as to assure quality is maintained in a manner commensurate with the remainder of the system which is being modified, or as dictated by applicable regulations.

15.2.3 Organization

The MOX Services President is responsible for the overall implementation of the configuration management program. This includes development and approval of plans and policies necessary to provide overall program direction.

The configuration management program is administered by the Vice President - Engineering during design. Engineering includes engineering disciplines. The discipline engineers have

primary technical responsibility for the work performed by their disciplines. The Responsible Managers are responsible for the conduct of interdisciplinary reviews as discussed previously in this section. Reviews are also conducted, as appropriate, by construction management, operations, ES&H, QA, and support services personnel. The design control process also interfaces with the document control and records management process via procedures.

During construction, the Vice President - Construction has responsibility for configuration management through establishment and maintenance of processes and procedures used during construction of the facility.

During operational testing, operation, and deactivation, the Plant Manager is responsible for ensuring the implementation of configuration management.

The various MOX Services departments and subcontractors perform quality-related activities. The primary MOX Services subcontractors work to the MPQAP. Some MOX Services subcontractors are responsible for development of their respective QA Programs, which shall be consistent with the requirements of the MPQAP for those activities determined to be within the scope of the MPQAP. The interfaces between subcontractors and MOX Services or among subcontractors shall be documented. MOX Services and subcontracted personnel have the responsibility to identify quality problems. Disagreements that cannot be resolved are elevated to the next level of management for resolution. If this level of management cannot resolve the issue, then the issue is elevated through successive layers of management until resolution is achieved.

15.2.4 Scope of CM Program

The scope of configuration management includes IROFS identified by the integrated safety analysis and any items which may affect the safety function of the IROFS. Documents subject to configuration management include calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, operating procedures and specifications that establish design and safety requirements for IROFS. During the design phase, these documents are maintained under configuration management when initially approved.

The number of documents included in the configuration management program increases throughout the design process. As drawings and specifications related to IROFS are prepared and issued for procurement, fabrication, or construction, these documents are included in configuration management.

During construction, initial startup, and operations, the scope of documents under configuration management similarly increase to 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 include documentation related to IROFS that is generated through functional interfaces with QA, maintenance, and training and qualifications of personnel. Configuration management procedures will provide for evaluation, implementation, and tracking of changes to IROFS, and processes, equipment, computer programs, and activities of personnel that impact IROFS.

Configuration management is implemented through or otherwise related to other management measures. Key interfaces and relationships to other management measures are described below:

Quality Assurance - The QA program establishes the framework for configuration management and other management measures for IROFS and items that affect the function of the IROFS.

Records Management - Records associated with IROFS are generated and processed in accordance with the applicable requirements of the QA Program and provide evidence of the conduct of activities associated with the configuration management of those IROFS.

Maintenance - Maintenance requirements are established as part of the design basis, which is controlled under configuration management. Maintenance records for IROFS provide evidence of compliance with preventative and corrective maintenance schedules.

Training and Qualifications - Training and qualification are controlled in accordance with approved project procedures. Personnel qualifications and/or training to specific processes and procedures are management measures that support the safe design, operation, maintenance, and testing of IROFS. Also, work activities that are themselves IROFS, (i.e., administrative controls) are proceduralized, and personnel are trained and qualified to these procedures. Training and qualification requirements and documentation of training may be considered part of the design basis controlled under configuration management. Training and Qualification of plant personnel is described in Section 15.4.

Audits and Assessments / Incident Investigation - Audits, assessments, and incident investigations are described in Sections 15.6, Audits and Assessments, and 15.7, Incident Investigations and Corrective Action Process. Corrective actions identified as a result of these management measures may result in changes to design features, administrative controls, or other management measures (e.g., operating procedures). The Corrective Action Program (CAP) is described in Section 15.7. Changes are evaluated under the provisions of configuration management through the QA Program and procedures. Periodic assessments of the configuration management program are also conducted in accordance with the audit and assessment program described in Section 15.6.

Procedures - Operating, administrative, maintenance, and emergency procedures are used to conduct various operations associated with IROFS and will be reviewed for potential impacts to the design basis. Also, work activities that are themselves IROFS, (i.e., administrative controls) are contained in procedures.

15.2.5 Change Control

Configuration management includes those activities conducted under design control provisions for ensuring 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 control of changes to the facility in accordance with 10 CFR 70.72.

Configuration management also includes records to demonstrate that personnel conducting activities that are IROFS are appropriately qualified and trained to conduct that work.

Implementing documents are controlled within the document control system. These documents support configuration management 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.

Procedures control changes to the design documents. The process includes an appropriate level of technical, management, and safety review and approval prior to 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 the conduct of interdisciplinary reviews, design reviews and design verification that constitute a primary mechanism for ensuring consistency of the design with the design bases. During both construction and operation, appropriate reviews to ensure consistency with the design bases of IROFS and the ISA, respectively, will similarly ensure that the design is constructed and operated/modified within the limits of the design basis. Additional details are provided below.

Changes to the design include a systematic review of the design bases for consistency. In the event of changes to reflect design or operational changes from the established design bases, the integrated safety analysis are properly modified, reviewed, and approved prior to implementation. Approved changes are made available to personnel through the document control function discussed previously in this section.

During design, the method of ensuring consistency between documents, including consistency between design changes and the safety analyses, is the interdisciplinary review process. The interdisciplinary reviews ensure design changes either (1) do not impact the ISA, (2) are accounted for in subsequent changes to the ISA, or (3) are not approved or implemented. Prior to issuance of the License, MOX will notify 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, changes to documents issued for construction, fabrication, and procurement will be documented, reviewed, approved, and posted against each affected design document. Vendor drawings and data also undergo an interdisciplinary review to ensure compliance with procurement specifications and drawings, and to incorporate interface requirements into facility documents.

During construction, design changes will continue to be evaluated against the approved design bases. Changes are expected to the design as detailed design progresses and construction begins. A systematic process consistent with the process described above will be used 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 configuration change process will fully implement the provisions of 10 CFR 70.72, including reporting of changes made without prior NRC approval as required by 10 CFR 70.72(d)(2) and (3). Any change that requires Commission approval, will be

submitted as a license amendment request as required by 10 CFR 70.72(d)(1) and the change will not be implemented without prior NRC approval.

During the operations phase, changes to design will also be documented, reviewed, and approved prior to implementation. MOX will implement a change process that fully implements the provisions of 10 CFR 70.72. Measures are provided to ensure responsible facility personnel are made aware of design changes and modifications that may affect the performance of their duties.

In order to provide for the continued safe and reliable operation of MFFF IROFS, measures are implemented to ensure the quality of these IROFS are not compromised by planned changes (modifications). Upon acceptance by Operations, the Plant Manager is responsible for the design of and modifications to IROFS. The design and implementation of modifications are performed in a manner so as to assure quality is maintained in the remainder of the system that is being modified, or as dictated by applicable regulations.

During deactivation, configuration management incorporated into the original design and modifications throughout operation facilitate deactivation of the facility.

The administrative instructions for modifications are contained in a facility administrative procedure that is approved, including revisions, by the Functional Area Manager. The modification procedure contains the following items necessary to ensure quality in the modification program:

- The technical and quality requirements which shall be met to implement a modification
- The requirements for initiating, approving, monitoring, designing, verifying, and documenting modifications. The facility modification procedure shall be written to ensure that policies are formulated and maintained to satisfy the MPQAP, as applicable.

Each change to the facility or to activities of personnel shall have an evaluation performed in accordance with the requirements of 10 CFR 70.72, as applicable. Each modification shall also be evaluated for any required changes or additions to the facility's procedures, personnel training, testing program, or regulatory documents.

For 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 involves or could affect the integrated safety analysis, the impacts shall be evaluated and documented. Prior to implementing the change, it shall be demonstrated that the change does not affect the safety basis in accordance with 10 CFR 70.72.

15.2.5.1 Identification of Changes

Design requirements and associated design bases are established and maintained by the Engineering organization during design and construction and by the Plant Manager during operations. The configuration management controls on design requirements and the integrated safety analysis of the design bases are described previously in this section.

The design bases are documented in the design documents (e.g., calculations, safety analysis, engineering drawings, system descriptions, technical documents, and specifications) and Licensing Bases Documents. Design requirements are derived from the design bases identified above. The design documents are controlled under the design control provisions of the configuration management program.

IROFS are designated as Quality Level 1. The associated design documents are subject to interdisciplinary reviews, design review and verification. Analyses constituting the integrated safety analysis are subject to the same requirements. Changes to the design are evaluated to ensure consistency with the design bases. Computer codes used in safety analyses and design of IROFS are also subject to these design control measures, with additional requirements as appropriate for software control, verification, and validation. IROFS are summarized in the Integrated Safety Analysis Summary.

A qualified individual who specifies and includes the appropriate codes, standards, and licensing commitments within the design documents prepares each design document, such as a calculation, specification, procedure, or drawing. This individual also notes any deviations or changes from such standards within the design documentation package. Each design document is then reviewed by another individual qualified in the same discipline. These design inputs are in sufficient detail to permit verification of the document. The manager having overall responsibility for the design function approves the document. The Responsible Manager documents the entire review process in accordance with approved procedures. These procedures include provisions to assure that appropriate quality standards are specified in design documents, including quantitative or qualitative acceptance criteria. The QA Manager conducts audits on the design control process using independent technically qualified individuals to augment the QA audit team.

During the review, emphasis is placed on assuring conformance with applicable codes, standards and license application design commitments. The individuals in engineering assigned to perform the review of a document have full and independent authority to withhold approval until questions concerning the work have been resolved. Design reviews, alternative calculations, or qualification testing accomplish verification of design. The bases for a design, such as analytical models, theories, examples, tables, codes and computer programs must be referenced in the design document and their application verified during check and review. Model tests, when required to prove the adequacy of a concept or a design, are reviewed and approved by the responsible qualified individual. Testing used for design verification shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The tests used for design verification must meet the design requirements.

Qualified individuals other than those who performed the design but may be from the same organization perform design verification. Verification may be performed by the supervisor of the individual performing the design, provided the supervisor did not specify a singular design approach or rule out certain design considerations, and did not establish the design inputs used in the design.

Independent design verification shall be accomplished before the design document (or information contained therein) is used by other organizations for design work or to support other

activities such as procurement, construction, or installation. When this is not practical due to time constraints, the unverified portion of the document is identified and controlled. Design verification shall be completed before relying on the item to perform its function. Changes to the design and procurement documents, including field changes, must be reviewed and approved commensurate with the original approval requirements.

15.2.5.2 Review and Approval of Changes

Configuration control is accomplished during design through the use of procedures for controlling design, including preparation, review (including interdisciplinary review and preparation of NSEs and NCSEs as applicable), and design verification where appropriate, approval, and release and distribution for use. Engineering documents are assessed for Quality level classification. Changes to the approved design also are subject to a review to ensure consistency with the design bases of IROFS.

Configuration verification is also accomplished through design verification, which ensures that design documents are consistent and that design requirements for IROFS are met. During construction, in-process verification is conducted by the construction and quality control organizations. During testing to demonstrate performance of IROFS, configuration is verified by the startup and quality organizations.

The MPQAP requires procedures that ensure that work performed shall be accomplished in accordance with the requirements and guidelines imposed by applicable specifications, drawings, codes, standards, regulations, quality assurance criteria and site characteristics.

Acceptance criteria established by the designer are incorporated in the instructions, procedures and drawings used to perform the work. Documentation is maintained, including test results, and inspection records, demonstrating that the work has been properly performed. Procedures also provide for review, audit, approval and documentation of activities affecting the quality of items to ensure that applicable criteria have been met.

Maintenance, modification, and inspection procedures are reviewed by qualified personnel knowledgeable in the quality assurance disciplines to determine:

- The need for inspection, identification of inspection personnel, and documentation of inspection result
- That the necessary inspection requirements, methods, and acceptance criteria have been identified.

Facility procedures shall be reviewed by an individual knowledgeable in the area affected by the procedure on a frequency determined by the age and use of the procedure to determine if changes are necessary or desirable. Procedures are also reviewed to ensure procedures are maintained up-to-date with facility configuration. These reviews are intended to ensure that any modifications to facility items relied on for safety are reflected in current maintenance, operations and other facility procedures.

15.2.5.3 Implementation of Changes

After design documents have been properly prepared, reviewed, and approved by the appropriate parties, the responsible engineer sends the document to document control for distribution. After input into Documentum, documents are electronically routed (distributed) to employees identified on the record submittal form.

When deficiencies are identified which affect the design of IROFS, such deficiencies are documented and resolved in accordance with approved CAP procedures. In accordance with the CAP, the report 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 as necessary. Where required, the responsible manager forwards the report to the engineers in other areas, who coordinate necessary revisions to their affected documents

Design interfaces are maintained by communication among the Functional Area Managers. Methods by which this is accomplished include the following:

- Design documents are reviewed by the responsible engineer or authorized representative.
- Project interface meetings are scheduled and held to coordinate design, procurement, construction and pre-operational testing of the facility. These meetings provide a primary working interface among the organizations.
- Reports of nonconformances are transmitted and controlled by procedures.

During the operational phase, measures are provided to ensure responsible facility personnel are made aware of design changes and modifications that may affect the performance of their duties.

15.2.6 Document Control

15.2.6.1 Storage of Documents

Procedures are established which control the preparation and issuance of documents such as manuals, instructions, drawings, procedures, specifications, procurement documents and supplier-supplied documents, including any changes thereto. Measures are established to ensure documents, including revisions, are adequately reviewed, approved, and released for use by authorized personnel.

Approved documents included in the CM program are stored in the MOX Services electronic document management system (Documentum). Documentum is a tool capable of reporting the status of documents. Records not suitable for storage in this system are stored in accordance with the requirements of MPQAP Section 6, *Document Control*.

Document control procedures require documents to be transmitted and received in a timely manner at appropriate locations including the location where the prescribed activity is to be performed. Controlled copies of these documents and their revisions are distributed to and used by the persons performing the activity.

Superseded documents are retained within Documentum and are controlled by Document Control utilizing a versioning process and by updating the status attribute. Indexes of current documents are generated using Documentum functionality.

15.2.6.2 Identification of Documents

Capabilities to track and retrieve current documents included in the CM program, historical records, and other information by multiple attributes (e.g., document number, document subject, component number, component name, status) are accomplished in accordance with approved procedures.

The system is capable of generating indices of controlled documents, which are uniquely numbered (including revision number). Controlled documents are maintained until cancelled or superseded, and cancelled or superseded documents are maintained as a record, currently for the life of the project or termination of the license, whichever occurs later. Hardcopy distribution of controlled documents is provided when needed in accordance with applicable procedures (e.g., when the electronic document management system is not available).

A part of the configuration management program, the document control and records management procedures, as appropriate, capture various documents. For example:

- Design requirements
- The integrated safety analysis, through the controlled copies of supporting analyses
- Nuclear Safety Evaluations
- Nuclear Criticality Safety Evaluations
- Drawings
- Specifications
- Calculations
- Technical Reports
- Project procedures
- QA Documents
- Maintenance Documents
- Audit and assessment reports
- Operating procedures
- Emergency response plans
- System modification documents

15.2.7 Audits and Assessments

Initial assessment(s) of the configuration management program is performed as part of system turnover upon entering the operations phase. Periodic assessments of the configuration management and design control program are conducted to determine the system's effectiveness and to correct deficiencies. These assessments include review of the adequacy of documentation. Such audits and assessments are scheduled, conducted and documented in accordance with approved procedures.

Periodic audits and assessments of the configuration management program and of the design confirm that the system meets its goals and that the design is consistent with the design bases. Incident investigations occur in accordance with the MPQAP and associated CAP procedures in the event problems are encountered. Prompt corrective actions are developed as a result of incident investigations or in response to adverse audit/assessment results, in accordance with CAP procedures.

15.3 MAINTENANCE

This section outlines the maintenance and functional testing programs to be implemented for the operations phase of the facility. Preventive maintenance activities, surveillance, and performance trending provide reasonable and continuing assurance that IROFS will be available and reliable to perform their safety functions in accordance with the integrated safety analysis (ISA).

The purpose of planned and scheduled maintenance for IROFS is to ensure that the equipment and controls are kept in a condition of readiness to perform the planned and designed functions when required. Appropriate plant management is responsible for ensuring the operational readiness of IROFS under this control. For this reason, the maintenance organization is administratively closely coupled to operations. Maintenance is developed using information from such sources as equipment suppliers, reference plants and, lessons learned from other appropriate facilities. A work management group is assigned to plan, schedule, coordinate, track work activities through completion, and maintain the associated records for analysis and trending of equipment performance and conditions. This information is assessed for indicators of areas for adjustments and improvements to methods and frequencies. Should an incident investigation be initiated in accordance with the MFFF Incident Investigation Program, recommendations and corrective actions identified are assessed by the work management group and applied to the respective portions of the Maintenance Program.

In order to provide for the continued safe and reliable operation of the IROFS, measures are implemented to ensure that the quality of the IROFS is not compromised by planned changes (modifications) or maintenance activities. Upon acceptance by Operations, the Plant Manager is responsible for the design of and modifications to IROFS and maintenance activities. The design and implementation of modifications are performed in a manner so as to assure quality is maintained in a manner commensurate with the remainder of the system which is being modified, or as dictated by applicable regulations. The two categories of MFFF equipment are IROFS and non-IROFS.

Maintenance for IROFS is developed and conducted to maximize availability and reliability for assurance that the designed safety functions and ISA requirements will be achieved, when needed. This maintenance is performed under strict procedural controls and the resultant records are maintained as proof of compliance to safety requirements.

Non-IROFS equipment will be maintained commensurate with designed functions. In general, non-IROFS maintenance will be performed to standard industrial practices.

Procedures used to perform maintenance use the applicable requirements of the design and safety analysis documents and meet the requirements of MPQAP Section 5, *Instructions, Procedures, and Drawings*. Where applicable, grading of QA controls is performed in accordance with requirements of MPQAP Section 2.1.2, *Graded Quality Assurance*. Spare and replacement parts are procured, received, accepted, stored, and issued according to the requirements of MPQAP Section 4, *Procurement Document Control*, Section 7, *Control of Purchased Material Equipment, and Services*, Section 8, *Identification and Control of Materials, Parts, and Components*, and Section 13, *Handling, Storage, and Shipping*. Required special processes are performed to meet the requirements of MPQAP Section 9, *Control of Special Processes*. Equipment used to measure and record maintenance and inspection parameters is calibrated in accordance with the requirements of MPQAP Section 12, *Control of Measuring and Test Equipment*. Nondestructive examination, inspection, and test personnel are qualified and certified in accordance with MPQAP Section 2.2.6, *Personnel Indoctrination, Training, and Qualification*. Inspections are performed to meet the requirements of MPQAP Section 10, *Inspection*, and testing required after maintenance conforms to the requirements of MPQAP Section 11, *Test Control*. Maintenance activities meet the requirements of MPQAP Section 14, *Inspection, Test, and Operating Status*. Completed records of maintenance are maintained in the records management system, which meets the requirements of MPQAP Section 17, *Quality Assurance Records.*

15.3.1 Maintenance Categories

Maintenance activities generally fall into the following categories:

- Surveillance/monitoring
- Preventive maintenance
- Corrective maintenance
- Functional tests.

Audits and assessments are performed to assure that these maintenance activities are conducted in accordance with the written procedures and that the processes reviewed are effective. These maintenance categories are discussed in the following sections.

15.3.1.1 Surveillance / Monitoring

Surveillance/monitoring is utilized to detect degradation and adverse trends of IROFS so that action may be taken prior to component failure. The monitored parameters are selected based upon their ability to detect the predominate failure modes of the critical components. Data

sources include; surveillance, periodic and diagnostic test results, plant computer information, operator rounds, walk downs, as-found conditions, failure trending, and predictive maintenance. Surveillance/monitoring and reporting is required for IROFS and any administrative controls that could impact the functions of an IROFS.

Plant performance criteria are established to monitor plant performance and to monitor IROFS functions and component parameters. These criteria are established using industry experience, operating data, surveillance data, and plant equipment operating experience. These criteria ensure the reliability and availability of IROFS. The performance criteria are also used to demonstrate that the performance or condition of an IROFS is being effectively controlled through appropriate predictive and repetitive maintenance strategies so that IROFS remain capable of performing their intended function.

Surveillance of IROFS is performed at specified intervals. The purpose of the surveillance program is to measure the degree to which IROFS meet performance specifications. The results of surveillances are trended, and when the trend indicates potential IROFS performance degradation, preventive maintenance frequencies are adjusted or other appropriate corrective action is taken.

Surveillances may consist of measurements, inspections, functional tests, and calibration checks. Incident investigations may identify root causes of failures that are related to the type or frequency of maintenance. The lessons learned from such investigations are factored into the surveillance/monitoring and preventive maintenance programs as appropriate.

Maintenance procedures prescribe compensatory measures, if appropriate, for surveillance tests of IROFS that can be performed only while equipment is out of service.

Records showing the current surveillance schedule, performance criteria, and test results for IROFS will be maintained in accordance with the Record Management System.

Results of surveillance/monitoring activities related to IROFS via the configuration management program will be evaluated by the safety disciplines to determine any impact on the ISA and any updates needed.

15.3.1.2 Preventive Maintenance

Preventive maintenance (PM) includes preplanned and scheduled periodic refurbishment, partial or complete overhaul, or replacement of IROFS, if necessary, to ensure their continued safety function even with unplanned outages. Planning for preventive maintenance includes consideration of results of surveillance and monitoring, including failure history. PM also includes instrument calibration and testing.

The PM program procedures and calibration standards (traceable to the national standards system) enable the facility personnel to calibrate equipment and monitoring devices important to plant safety and safeguards. Testing performed on IROFS that are not redundant will provide for compensatory measures to be put into place to ensure that the IROFS function is performed until it is put back into service.

Industry experience, vendor recommended intervals and data derived from the reference facilities, as applicable, is used to determine initial PM frequencies and procedures. In determining the frequency of PM, consideration is given to appropriately balancing the objective of preventing failures through maintenance against the objective of minimizing unavailability of IROFS because of PM. In addition, feedback from PM and corrective maintenance and the results of incident investigations and identified root causes are used, as appropriate, to modify the frequency or scope of PM. The rationale for deviations from industry standards or vendor recommendations for PM shall be documented.

After conducting preventive maintenance on IROFS, and before returning an IROFS to operational status, functional testing of the IROFS, if necessary, is performed to ensure the IROFS performs its intended safety function. Functional testing is described in detail in Section 15.3.1.4, Functional Tests.

Records pertaining to preventive maintenance will be maintained in accordance with the Records Management System.

Results of preventive maintenance activities related to IROFS via the configuration management system will be evaluated by safety disciplines to determine any impact on the ISA and whether updates are needed.

15.3.1.3 Corrective Maintenance

Corrective maintenance involves repair or replacement of equipment that has unexpectedly degraded or failed. Corrective maintenance of IROFS restores the equipment to acceptable performance through a planned, systematic, controlled, and documented approach for the repair and replacement activities.

Following any corrective maintenance on IROFS, and before returning an IROFS to operational status, functional testing of the IROFS, if necessary, is performed to ensure the IROFS performs its intended safety function.

The CAP requires facility personnel to determine the cause of conditions adverse to quality and promptly act to correct these conditions.

Results of corrective maintenance activities related to IROFS via the configuration management program will be evaluated by the safety disciplines to determine any impact on the ISA and whether updates are needed.

15.3.1.4 Functional Tests

A test control program will be implemented that incorporates plant procedures for test control that delineates the criteria for determining when, why, and how tests are required along with other elements of the test control program. Compensatory measures will be applied in accordance with the limiting conditions for operation as provided in the Operating Limits Manual (OLM). See Chapter 5 for a description of the OLM.

The overall testing program is broken into the two major testing programs and within each testing program are two testing categories:

Preoperational Testing Program

- Functional Testing
- Initial Startup Testing

Operational Testing Program

- Periodic Testing
- Special Testing

Results of surveillance/monitoring activities related to IROFS via the configuration management program will be evaluated by the safety disciplines to determine any impact on the ISA and any updates needed.

The objectives of the overall facility preoperational and operational testing programs are to ensure that items relied on for safety:

- Have been adequately designed and constructed
- Meet licensing requirements
- Do not adversely affect worker or the public health and safety, and
- Can be operated in a dependable manner so as to perform their intended function.

Additionally, the preoperational and operational testing programs ensure that operating, ~~and~~ emergency and surveillance procedures are correct and that personnel have acquired the correct level of technical expertise.

Preoperational Testing Program

Preoperational functional tests (cold startup) are completed prior to introduction of special nuclear material (SNM). Other preoperational tests, not required prior to SNM introduction and not related to IROFS, such as office building ventilation tests, may be completed following SNM introduction. Tests (or portions of tests), which are not required to be completed before SNM introduction are identified in the test plan. Preoperational functional testing at the facility consists of that testing conducted to initially determine various facility parameters and to initially verify the capability of items relied on for safety to meet performance requirements. The tests conducted are primarily associated with IROFS (Quality Level 1) and certain Quality Level 2 structures, systems and components. Preoperational functional tests are performed following constructor turnover. The major objective of preoperational functional testing is to verify that IROFS essential to the safe operation of the plant are capable of performing their intended function.

Functional Testing

Functional testing of IROFS is performed as appropriate following initial installation, as part of periodic surveillance testing, and after corrective or preventive maintenance or calibration to ensure that the item is capable of performing its safety function when required.

Initial Startup Testing

Initial startup testing (hot startup) is performed beginning with the introduction of SNM and ending with the start of operation. The purpose of initial startup testing is to ensure safe and orderly SNM processing and to verify parameters assumed in the ISA.

Records of the preoperational and startup tests required prior to operation are maintained. These records include testing schedules and the testing results for IROFS.

The use of properly reviewed and approved test procedures is required for preoperational and startup tests. The results of each preoperational test are reviewed and approved by the responsible Functional Area Manager or designee before they are used as the basis of continuing the test program. In addition, the results of each individual startup test will receive the same review as that described for preoperational functional tests. Modifications to IROFS that are found to be necessary are subjected to an evaluation per 10 CFR 70.72 prior to making the change.

The impact of modifications on future and completed testing is evaluated during the 10 CFR 70.72 evaluation process and retesting is conducted as required.

The overall preoperational functional testing program is reviewed, prior to initial SNM introduction, by the Plant Manager and Functional Area Managers to ensure that prerequisite testing is complete.

The facility operating, emergency and surveillance procedures are use-tested throughout the testing program phases and are also used in the development of preoperation functional testing and initial startup testing procedures to the extent practicable. The trial use of operating procedures serves to familiarize operating personnel with systems and plant operation during the testing phases and also serves to ensure the adequacy of the procedures under actual or simulated operating conditions before plant operation begins.

Procedures which cannot be use-tested during the testing program phase are revised based on initial use-testing, operating experience and comparison with the systems. This ensures that these procedures are as accurate and comprehensive as practicable.

Operational Testing Program

The operational testing program consists of periodic testing and special testing. Periodic testing is conducted at the facility to monitor various facility parameters and to verify the continuing integrity and capability of facility IROFS. Special testing which may be conducted at the facility is testing which does not fall under any other testing program and is of a non-recurring nature.

The Maintenance Manager has overall responsibility for the development and conduct of the operational testing program and in conjunction with the Operations Manager and the Licensing Manager ensures that testing commitments and applicable regulatory requirements are met.

Surveillance commitments, procedures identified to satisfy these commitments and surveillance procedure responsibility assignments for the facility are identified in a computer database. The database is also used to ensure surveillance testing is completed in the required time interval.

Periodic Testing

The periodic testing program at the facility consists of testing conducted on a periodic basis to verify the continuing capability of IROFS to meet performance requirements.

The facility periodic test program verifies that the facility:

- Complies with regulatory and licensing requirements
- Does not endanger health and minimizes danger to life or property
- Is capable of operation in a dependable manner so as to perform its intended function.

The facility periodic testing program begins during the preoperational testing stage and continues throughout the facility's life.

A periodic testing schedule is established to ensure that required testing is performed and properly evaluated on a timely basis. The schedule is revised periodically, as necessary, to reflect changes in the periodic testing requirements and experience gained during plant operation. Testing is scheduled such that the safety of the plant is not dependent on the performance of an IROFS that has not been tested within its specified testing interval. Testing is scheduled consistent with the limiting conditions for operation as identified in the Operating Limits Manual such that the performance requirements of 70.61 continue to be met. Periodic test scheduling is handled through the Maintenance department.

In the event that a test cannot be performed within its required interval due to system or plant conditions, appropriate actions will be taken.

Periodic testing and surveillance associated with Quality Level 1 and 2 structures, systems and components are performed in accordance with written procedures.

Special Testing

Special testing is testing conducted at the facility that is not a facility preoperational test, periodic test, post-modification test, or post-maintenance test. Special testing is of a non-recurring nature and is conducted to determine facility parameters and/or to verify the capability of IROFS to meet performance requirements. Purposes of special testing include, but are not necessarily limited to, the following:

- 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
- Confirmation that facility modifications reasonably produce expected results and do not adversely affect systems, equipment and/or personnel by causing them to function outside established design conditions; applicable to testing performed outside of a post-modification test.

The determination that a certain plant activity is a Special Test is intended to exclude those plant activities which are routine surveillances, normal operational evolutions, and activities for which there is previous experience in the conduct and performance of the activity. At the discretion of the Plant Manager, any test may be conducted as a special test.

15.3.2 Measuring and Test Equipment

The MFFF Measuring and Test Equipment / Calibration (M&TE) program is responsible for the calibration and maintenance of active engineered components used as IROFS, including storage of test equipment, control of calibration standards, collection and storage of performance data used in the development of calibration procedures, and repair of active engineered IROFS that fail in service. This program identifies the processes and plans for maintenance and control of calibration instruments and calibrations standards for the facility and provides a description of how instrument maintenance activities will take place. This program identifies the method by which calibration standards are maintained within the environmental conditions needed to assure their accuracy sufficient to appropriately calibrate and maintain components used as IROFS.

15.3.3 Work Control

Maintenance work, as described above, is performed through a coordinated and structured work control process that integrates with ongoing production activities and requirements and is managed by the Maintenance Work Management Group. The purpose of this structure is to minimize challenges to safety requirements, minimize challenges to production requirements, and maximize work efficiency. This work control process includes representation from various organizations, such as radiation protection, safety, operations and others, as necessary, for complete pre-planning of the required work. Coordinated work support functions include such items as work requests, procedures, schedules, radiation work permits, and lockout/tagout requirements.

Should modifications be identified to plant structures, systems, or components, the change will be prepared in accordance with the Configuration Management process. A modification package will be prepared that will contain the description and rationale for the change and the applicable instructions for implementation. Implementation of the modification is done through the work control process for consistency in implementing work activities in the MFFF.

15.3.4 Relationship of Maintenance Elements to Other Management Measures

The maintenance elements, as described above, interface with other management measures, for example:

- Maintenance activities are implemented in accordance with the quality assurance (QA) program described in the MOX Project Quality Assurance Plan (MPQAP).
- Configuration Management, for obtaining the current approved and controlled documents necessary to support the maintenance activity, such as drawings, specifications, and procedures. Training and Qualification to ensure maintenance personnel are trained to perform their assigned tasks.

Audits and assessments are performed to assure that Maintenance activities are conducted in accordance with the written procedures and that the processes reviewed are effective.

Plant Procedures for the applicable operating and maintenance procedures pertinent to support the maintenance activity.

Records Management provides the framework for reviewing, maintenance, approving, handling, identification, retention, and retrieval of Maintenance related quality assurance records

- Incident investigations may identify root causes of failures that are related to the type or frequency of maintenance. The lessons learned from such investigations are factored into the surveillance/monitoring and preventive maintenance programs as appropriate.

15.4 TRAINING AND QUALIFICATION

Training and qualification of plant personnel is essential to the safe and successful design, construction, testing, and operation of the MFFF. This section describes the training program for the operations phase of the facility, including preoperational functional testing and initial startup testing. The training program requirements apply to those plant personnel who perform activities related to IROFS to ensure competent and safe job performance.

The MPQAP provides training and qualification requirements during the design, construction, and operations phases, for QA training of personnel performing Quality levels 1 and 2 work activities; for nondestructive examination, inspection, and test personnel; and for QA auditors.

The principle objective of the MOX training program system is to ensure job proficiency of facility personnel through effective training and qualification. The training program system is designed to accommodate future growth and meet commitments to comply with applicable established regulations and standards. Employees are provided with training to establish the knowledge foundation and on-the-job training to develop work performance skills. Continuing training is provided, as required, to maintain proficiency in these knowledge and skill components, and to provide further employee development.

Qualification is indicated by successful completion of prescribed training, demonstration of the ability to perform assigned tasks and the maintenance of requirements established by regulation. Training is designed, developed and implemented according to a systematic approach. A

systematic approach includes a variety of methods to accomplish the analysis, design, development, implementation, and evaluation of training.

15.4.1 Organization and Management of Training

Line managers have the responsibility, accountability ~~for~~ and authority to develop and effectively conduct training for their personnel. Training responsibilities for line managers are included in position descriptions. The training organization provides support to line managers by facilitating the planning, direction, development, conduct, evaluation, and control of a systematic performance-based training process that fulfills job-related training needs.

Performance-based training is a function of analyzing, designing, developing, conducting, and evaluating training. Plant procedures establish the requirements for the training of personnel performing activities related to IROFS. Additionally they ensure the training program is conducted in a reliable and consistent manner. Procedures also allow for exceptions from training when justified and properly documented and approved by appropriate management.. The training process incorporates human factor engineering analysis results. The human factors task analysis of the IROFS identified in the Integrated Safety Analysis (ISA) will be incorporated into plant procedures. Personnel training will be developed based on the plant procedures.

Lesson plans or other approved process controlling documents are used for classroom and on-the-job training as required to assure consistent presentation of subject matter. When design changes or plant modifications are implemented, updates of applicable lesson plans are included in the change control process of the configuration management system.

Training programs and training records at the facility are the responsibility of the Training Manager. Training records are maintained to support management information needs associated with personnel training, and qualification. Records are maintained on each employee's qualifications, experience, and training. The employee training file shall include records of general employee training, technical training, and employee development training conducted at the facility. The employee training file shall also contain records of special company sponsored training conducted by others. The training records for each individual, relative to the employee's performance in completing training and qualification activities, are maintained so that they are accurate and retrievable. Training records are retained in accordance with the records management procedures. Training and qualification records are maintained in a learning management system. The data is backed up nightly by the MOX Information Technology organization and copies of the backup tapes are stored in a remote location. Data entry activities are peer reviewed within the Training organization to ensure data is entered accurately.

15.4.2 Analysis and Identification of Functional Areas Requiring Training or Qualification

A needs/job analysis is performed and tasks identified to ensure that appropriate training is provided to those responsible for managing, supervising, performing, and verifying activities~~personnel working on tasks~~ related to IROFS. Identification of job hazards are referred to as precautions and limitations in the procedure related to that task. These limits and precautions will be part of the needs/job analysis performed for that task.

The training organization consults with relevant subject matter experts, as necessary, to develop a list of tasks for which personnel training for specific jobs is appropriate. The list of tasks selected for training is reviewed and compared to the training materials as part of the systematic assessment of training effectiveness. The task list is also updated periodically as necessitated by changes in procedures, processes, plant systems, equipment, or job scope. The task list is matrixed to supporting procedures and training materials.

15.4.3 Position Training Requirements

Minimum training requirements are developed for those positions whose activities are relied on for safety. Initial identification of job-specific training requirements is based on experience from the MFFF reference facilities of MELOX and La Hague, and other United States fuel cycle facilities. Entry-level criteria (e.g., education, technical background, experience, and/or physical fitness requirements) for these positions are contained in position descriptions. Exceptions from training requirements may be granted when justified and documented in accordance with the approved MFFF procedure.

Radiation safety training is commensurate with the employee's duties. Standardized courses are used to the extent practical and are supplemented by facility-specific information. MFFF personnel will receive training commensurate with the requirements of 10 CFR 19.12. MOX Services commits to ALARA principles as outlined in Chapter 9.2.1.

The training program is designed to prepare initial and replacement personnel for safe, reliable and efficient operation of the facility. Appropriate training for personnel of various abilities and experience backgrounds is provided. The level at which an employee initially enters the training program is determined by the employee's past experience, level of ability, and qualifications.

Facility personnel may be trained through participation in prescribed parts of the training program that consists of the following:

- General Employee Training
- Technical Training

Training is made available to facility personnel to initially develop and maintain minimum qualifications outlined in Chapter 4, Organization and Administration. The objective of the training shall be to ensure safe and efficient operation of the facility and compliance with applicable established regulations and requirements. Training requirements shall be applicable to, but not necessarily restricted to, those personnel within the plant organization who have a direct relationship to the operation, maintenance, testing or other technical aspect of the facility IROFS. Training courses are updated prior to use to reflect plant modifications and changes to procedures when applicable.

15.4.3.1 General Employee Training

Site General Employee Training is required prior to gaining access to the Savannah River Site and the MOX facility. General Employee Training/new hire training encompasses those Quality Assurance, radiation protection, safety, emergency and administrative procedures established by

facility management and applicable regulations. People under the supervision of facility management (including subcontractors) must participate in General Employee Training. Temporary maintenance and service personnel receive General Employee Training to the extent necessary to assure safe execution of their duties.

15.4.3.2 Technical Training

Technical training is designed, developed and implemented to assist facility employees in gaining an understanding of applicable fundamentals, procedures, and practices related to IROFS. Also, technical training is used to develop manipulative skills necessary to perform assigned work related to IROFS . Technical training consists of three segments:

- Initial Training
- On-the-Job Training
- Continuing Training

Initial job training is designed to provide an understanding of the fundamentals, basic principles, and procedures involved in work related to IROFS that an employee is assigned. This training may consist of, but is not limited to, live lectures, taped and filmed lectures, required reading, self-guided study, demonstrations, laboratories and workshops and on-the-job training.

Certain new employees or employees transferred from other sections within the facility may be partially or wholly qualified by reason of previous applicable training or experience. The extent of further training for these employees is determined by applicable regulations, performance in review sessions, comprehensive examinations, or other techniques designed to identify the employee's present level of ability.

Initial job training and qualification programs are developed for operations, maintenance and technical services classifications. Training for each program is grouped into logical blocks or modules and presented in such a manner that specific behavioral objectives are accomplished. Trainee progress is evaluated using written examinations, oral or practical tests.

On-the-job training (OJT) is a systematic method of providing the required job related skills and knowledge for a position. This training is conducted in an environment as close to the work environment as feasible. Applicable tasks and related procedures make up the OJT/qualifications program for each technical area. Technical areas will be derived based on the activities identified in the ISA Summary, job/task analyses and associated procedures. Training is designed to supplement and complement training received through classroom training.

Continuing training courses shall be established when applicable to ensure that personnel remain proficient. Continuing training is any training not provided as initial qualification or basic training that maintains and improves job-related knowledge and skills. ~~The~~ Continuing training may consist of periodic exercises, computer or classroom instruction~~,~~ or any other type of training identified appropriate and performed on a frequency needed to maintain proficiency on the job~~and review of subjects as appropriate to maintain proficiency of personnel assigned to the facility~~. ~~Continuing Training is any training not provided as initial qualification or basic training~~

~~that maintains and improves job-related knowledge and skills. Continuing Training consists of computer-based or classroom and components performed on a frequency needed to maintain proficiency on the job.~~ Once the objectives for Continuing Training have been established, the methods for conducting the training may vary. The method selected must provide clear evidence of objective accomplishment and consistency in delivery.

15.4.4 Basis for and Objectives of Training

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

Learning objectives identify the training content established by needs/job analyses and position-specific requirements. The task list from the needs/job analysis is used to develop action statements that describe the desired post-training performance. Objectives include the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity.

15.4.5 Organization of Instruction

Lesson plans are developed from learning objectives, which are based on job performance requirements. Lesson plans and other training guides are developed under guidance by the training organization. Lesson plans are reviewed by the training organization and, generally, by the organization responsible for the subject matter. Lesson plans are approved prior to issue or use. Lesson plans are used for classroom training and on-the-job training as required and include standards for evaluating acceptable trainee performance.

15.4.6 Evaluation of Trainee Learning

Trainee mastery of learning objectives is evaluated through observation/demonstration, or oral or written tests. Such evaluations measure the trainee's skills and knowledge of job performance requirements.

15.4.7 Conduct of On-the-Job Training

On-the-job training is used in combination with classroom training for selected activities when appropriate. Lesson plans are used for classroom training and on-the-job training as required using well-organized and current performance-based training materials and include standards for evaluating acceptable trainee performance. On-the-job training is conducted by personnel who are competent in the program standards and methods of conducting the training~~technical aspects of the job being performed~~. Completion of on-the-job training is demonstrated by task performance, where feasible and appropriate. When the actual task cannot be performed in the work environment (e.g., conflicting plant operations), a simulation of the task is conducted, with the trainee explaining task actions in consideration of the conditions that would be encountered

during actual performance of the task. This simulation ("walk-through") would use references, tools, and equipment appropriate for the actual task, to the extent practical.

15.4.8 Systematic Evaluation of Training Effectiveness

Periodically the training program is systematically evaluated to measure the program's effectiveness in producing competent employees. The trainees are encouraged to provide feedback after completion of classroom training sessions to provide data for this evaluation for program improvements. These evaluations identify program strengths and weaknesses, determine whether the program content matches current job needs, and determine if corrective actions are needed to improve the program's effectiveness. The training organization is responsible for leading the training program evaluations and for implementing any corrective actions. Program evaluations may consist of an overall periodic evaluation, or a series of topical evaluations over a given period.

Evaluation objectives that are applicable to the training program or topical area being reviewed may address the following elements of training:

- 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 configuration management system
- Design and development of training programs, including lesson plans
- Conduct of training
- Trainee examinations and evaluations
- Training program assessments and evaluations.

Evaluation results are documented, and noteworthy practices and weaknesses are highlighted in the training program. Identified deficiencies are reviewed, improvements are recommended, and changes are made to procedures, practices, or training materials, as necessary. Training materials are updated prior to use to reflect plant modifications and changes to procedures when applicable.

Periodically, training and qualifications activities are monitored by designated facility and/or contracted training personnel. The QA organization audits the facility training and qualification system. In addition, trainees and vendors may provide input concerning training program effectiveness. Methods utilized to obtain this information include, among other things surveys, questionnaires, performance appraisals, staff evaluation, and overall training program effectiveness evaluation instruments. Frequently conducted classes are not evaluated each time. However, they are routinely evaluated at a frequency sufficient to determine program effectiveness.

15.4.9 Personnel Qualification

The qualification requirements for technical personnel are determined as discussed in Sections 15.4.2 and 15.4.3. Training and qualification requirements associated with quality-affecting activities are provided in the MPQAP. Such requirements include QA training for project personnel, and qualification of nondestructive examination personnel, inspection and test personnel, personnel performing special processes, and auditors. Qualification requirements for key management positions are provided in Chapter 4.

15.4.10 Provisions for Continuing Assurance

Personnel performing activities relied on for safety are evaluated at least every two years to verify that they continue to understand, recognize the importance of, and have the qualifications to perform their activities that are relied on for safety. The evaluation may be by written test, oral test, or on-the-job performance evaluation. The results of the evaluation are documented. When the results of the evaluation dictate, retraining or other appropriate action is provided. Retraining is also required due to plant modifications, procedure changes, and QA program changes that result in new or changed information.

15.5 PLANT PROCEDURES

This section describes the procedures used for control of overall facility operations, including IROFS. Activities involving special nuclear material (SNM) will be conducted in accordance with approved procedures. This includes procedures for the conduct of all operations involving controls identified in the Integrated Safety Analysis (ISA) as activities relied on for safety and for all management control systems supporting those controls. Management policies require strict adherence to procedures when performing work. In the event that a procedure cannot be executed as written, personnel are required to notify their supervisor. Time-out authority within MOX Services is vested in each MOX Services employee, with respect to work within their scope of responsibility, whenever the health and safety of workers, the public, or the environment is involved, or when continued work will produce results that are not in compliance with the MOX Services QA Program.

Plant procedures are developed and controlled under the requirements of the MPQAP. Specifically, the associated activities are implemented by personnel who are trained in accordance with the requirements of MPQAP Section 2, *Quality Assurance Program*. Plant maintenance, testing, and operating procedures meet the requirements of MPQAP Section 5, *Instructions, Procedures, and Drawings*. Plant procedures are distributed and otherwise controlled in accordance with the requirements of MPQAP Section 6, *Document Control*. When completed, procedure results (e.g., sign-offs, checklists, data sheets) are maintained in the records management system in accordance with the requirements of MPQAP Section 17, *Quality Assurance Records*.

15.5.1 Types of Procedures

Plant procedures are broadly categorized as either administrative procedures or operating procedures. Administrative procedures apply to functions or specific interfaces with other

organizational functions. Operating procedures provide specific direction for functional task-based work. Operating procedures can apply MOX Services-wide or to a specific organization.

15.5.1.1 Administrative Procedures

Administrative procedures specify controls that apply to specific functions or specific interfaces with other organizational functions. They address administration and conduct of process activities in the following areas:

- Training and qualification
- Audits and assessments
- Incident investigation
- Records management
- Configuration management
- ~~Reporting~~ Human systems interface
- Quality Assurance
- Equipment control (lockout/tagout)
- Shift turnover
- Work control
- Management control
- Procedure management
- Nuclear criticality safety
- Fire ~~safety~~ protection
- Radiation protection
- Radioactive waste management
- Maintenance
- Environmental protection
- Chemical process safety
- Operations
- Calibration control
- Preventive maintenance
- Design control
- Test control

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15.5.1.2 Operating Procedures

Operating procedures provide specific direction for functional task-based work within an organizational function. Operating procedures include production, maintenance, and emergency procedures that address startup, operation, shutdown, control of process operations, and recovery after a process upset. These procedures address: 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/alarm response including: Loss of cooling water; Loss of instrument air; Loss of electrical power; Loss of criticality alarm system; Loss of containment; Fires; and Chemical process releases. The results of the ISA are used to identify specific IROFS Administrative Controls that are developed.

Operating procedures include operating limits and controls, and specific IROFS Administrative Controls to ensure: nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection. If needed, safety checkpoints (e.g., hold points for radiological or criticality safety checks, QA verifications, independent operator verification) are identified at appropriate steps.

Operating procedures, with different types of documents, are organized to a consistent architecture, which include:

- General rules for production, maintenance, operational safety, security, abnormal operating procedures, emergency planning and emergency operating procedures, and environmental protection program
- Unit Operating Instructions or Maintenance Instructions – Provide instructions for operating and maintaining process units, systems, and/or equipment

The scope of these procedures is as follows:

- Production procedures – startup, operation, shutdown, off-normal, alarm response, control of process and laboratory operations, and recovery after a process upset condition
- Maintenance procedures – preventive and corrective maintenance, calibration, surveillance, functional testing, and work control
- Emergency procedures – response to a criticality event, a hazardous chemical release, or an emergency external to the MFFF that may affect the MFFF

15.5.1.2.1 Production Procedures

Production procedures control process operations and apply to utility, workstation, and control room operations.

Production procedures contain the following elements, as applicable:

- Purpose of the activity

- Regulations, pPolicies and guidelines governing the procedure
- Type of procedure
- Steps for each operating process phase
- Initial startup, Periodical startup / shutdown
- Normal operations
- Off-normal operations
- Temporary operations
- Emergency shutdown
- Emergency operations
- Normal shutdown
- Startup following an emergency or extended downtime
- Hazards and safety considerations
- Operating limits
- Precautions necessary to prevent exposure to hazardous chemicals or SNM
- Measures to be taken if contact or exposure occurs
- Safety controls and their functions that are associated with the process
- Specified time period or other limitations on the validity of the procedure

15.5.1.2.2 Maintenance Procedures

Where appropriate, maintenance procedures include requirements for pre-maintenance activities involving reviews of the work to be performed, work controls, and reviews of procedures. When appropriate, maintenance work may require clearance from the operations organization to begin work, as well as notification when the work and associated post-maintenance functional testing are complete. Maintenance activities will be monitored/assessed in accordance with the MPQAP.

Maintenance of facility structures, systems and components is performed in accordance with written procedures, documented instructions, checklists, or drawings appropriate to the circumstances. Maintenance activities that address repair, calibration, surveillance, and functional testing include: Repairs and preventive repairs of items relied on for safety (IROFS); Testing of criticality alarm units; Calibration of IROFS; High efficiency air particulate (HEPA) filter maintenance; Functional testing of IROFS; Relief valve replacement/testing; Surveillance/monitoring; Pressure vessel testing; Piping integrity testing; and Containment device testing.

The facility's maintenance department under the Maintenance Manager has responsibility for preparation and implementation of maintenance procedures. The maintenance, testing and calibration of facility IROFS is performed in accordance with approved written procedures.

Testing conducted on a periodic basis to determine various facility parameters and to verify the continuing capability of IROFS to meet performance requirements is conducted in accordance with approved, written procedures. Periodic test procedures are utilized to perform such testing and are sufficiently detailed that qualified personnel can perform the required functions without direct supervision. Testing performed on IROFS that are not redundant will provide for compensatory measures to be put into place to ensure that the IROFS performs until it is put back into service.

15.5.1.2.3 Emergency Procedures

Emergency procedures 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 MFFF. In addition, applicable procedures will be reviewed after unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or after any modification to a system, and procedures will be revised as needed.

15.5.2 Preparation of Procedures

MFFF procedures are prepared using a consistent format, and are clear, concise and comprehensive in addressing the procedure subject. MFFF procedures are well organized, and may include (approved) checklists or data sheets as documented records of completion. Initial procedure drafts are reviewed by other members of the facility staff and vendors as appropriate for inclusion and correctness of technical information, including formulas, set points, and acceptance criteria. Procedures that are written for the operation of equipment related to IROFS shall be subjected to a peer review. The Functional Area Manager shall determine whether or not any additional, cross-disciplinary review is required and shall approve procedures. Applicable safety limits associated with IROFS are clearly identified in the procedures.

15.5.2.1 Identification and Preparation

The results of the ISA and other processes are used to identify specific operating and administrative procedures that are developed. Plant procedures are prepared by qualified individuals assigned by the organization's management responsible and accountable for the associated operation.

MOX Services will incorporate methodology for identifying, developing, approving, implementing, and controlling operating procedures. Identifying needed procedures will include consideration of ISA results or changes in ISA results. The method will ensure that, as a minimum:

- Operating and safety limits related to IROFS are specified in the procedure
- Procedures include required actions for off-normal conditions of operation, as well as normal operations
- If needed safety checkpoints are identified at appropriate steps in the procedure
- Procedures are validated through field tests

- Procedures are approved by Functional Area Managers responsible and accountable for the operation
- A mechanism is specified for revising and reissuing procedures in a controlled manner
- The QA elements and CM Program at the facility provide reasonable assurance that current procedures are available and used at work locations
- The facility training program trains the required persons in the use of the latest procedures available.

15.5.2.2 Review/Approval

Operating and administrative procedures are reviewed and approved by management responsible and accountable for the associated operation. The functional management may specify a review to be performed by another functional group. Prior to initial use or after major revisions, production and maintenance procedures are verified and validated.

15.5.2.3 Revisions

Procedure revisions, including temporary changes, are prepared and approved in the same manner as the original. The procedure change process shall be defined in a MFFF procedure.

15.5.3 Use of Procedures

Compliance with operating and maintenance procedures is required, and operators and technicians are trained to report inadequate procedures or the inability to follow procedures. Dependent on the nature of the procedure and work location, procedures are either available at work stations, or are readily accessible where needed to perform work.

15.5.4 Control of Procedures

Following approval, plant procedures are processed for entry into the Electronic Data Management System (EDMS) and issued for use. The MFFF training program, addressed in Section 15.4, ensures that necessary personnel are trained in the use of approved procedures before implementation.

Change control for operating and administrative procedures is the same as for other items in the document management system. Document management procedures ensure that changes to the facility, including procedures, are entered into the EDMS and address control and distribution of changes (including those for emergency conditions, temporary procedure changes, temporary modifications, etc.). The MPQAP provides requirements for QA procedures, which detail the controls for design input, design output, processes, verification, interfaces, changes, ~~and~~ approval, and records.

To ensure technical accuracy, radiation protection procedures, respiratory protection procedures, operating, ~~and~~ maintenance, and administrative procedures are reviewed every five years to verify their continued applicability and accuracy. Respiratory protection procedures are reviewed as appropriate whenever the MFFF undergoes a modification, change in process or

replacement of equipment. Emergency procedures are reviewed annually for the first two years of MFFF operation and at least every two years thereafter. These periodic reviews are performed by qualified individuals assigned by the functional management responsible and accountable for the associated operation. Reissue/approval of a procedure meets the requirements for procedure periodic review. Additionally, if procedural inadequacy is identified as a root cause from an incident investigation, applicable procedures are reviewed and modified, as necessary.

15.6 AUDITS AND ASSESSMENTS

MOX Services maintains the program for audits and assessments described in the MPQAP, Section 18, *Audits*. MPQAP changes are reviewed to ensure that audit and assessment program revisions are reflected in the program description. MOX Services will have a tiered approach to verifying compliance to procedures and performance to regulatory requirements. Audits are focused on verifying compliance with regulatory and procedural requirements (including compliance with selected operating limits) and licensing commitments. Assessments are focused on effectiveness of activities and ensuring that IROFS, and items that affect the function of IROFS, are reliable and are available to perform their intended safety functions. This approach includes performing Assessments and Audits on critical work activities associated with facility safety, results of the ISA, environmental protection and other areas as identified via trends.

Assessments are divided into two categories that will be owned and managed by the line organizations as follows:

- Management Assessments conducted by the line organizations responsible for the work activity
- Independent Assessments conducted by individuals not involved in the area being assessed.

Audits of the Quality Level 1 work activities and items required to satisfy regulatory requirements for which Quality Level 1 requirements are applied will be the responsibility of the QA Department.

Audits and assessments are performed to assure that facility activities are conducted in accordance with the written procedures and that the processes reviewed are effective. As a minimum, they shall assess activities related to radiation protection, criticality safety control, hazardous chemical safety, industrial safety including fire protection, and environmental protection. Technical and programmatic audits and assessments are performed internally and externally to provide a comprehensive independent verification and evaluation of procedures and activities for IROFS.

Audits and assessments shall be performed routinely by qualified staff personnel that are not directly responsible for production activities. Deficiencies identified during the audit or assessment requiring corrective action shall be forwarded to the responsible manager of the applicable area or function for action in accordance with the CAP procedure. The audit and assessment program provides for on-the-spot corrective actions with appropriate documentation in accordance with the CAP procedure. Future audits and assessments shall include a review to evaluate if corrective actions have been effective.

The Quality Assurance Department shall be responsible for audits. Audits shall be performed in accordance with a written plan that identifies and schedules audits to be performed. Audit team members shall not have direct responsibility for the function and area being audited. Team members shall have technical expertise or experience in the area being audited and shall be indoctrinated in audit techniques. Audits shall be conducted on an annual basis.

The results of the audits shall be provided in a written report in a timely manner to the Plant Manager and the Managers responsible for the activities audited. Any deficiencies noted in the audits shall be responded to promptly by the responsible Managers or designees, entered into the CAP and tracked to completion and re-examined during future audits to ensure corrective action has been completed.

Records of the instructions and procedures, persons conducting the audits or assessments, and identified violations of license conditions and corrective actions taken shall be maintained.

15.6.1 Activities to be Audited or Assessed

Audits and assessments are conducted for the areas of:

- Radiation safety
- Nuclear criticality safety
- Chemical safety
- Other ISA safety areas
- Industrial safety including fire protection
- Environmental protection
- Emergency management
- QA
- Configuration management
- Maintenance
- Training and qualification
- Procedures
  CAP/Incident investigation
- Records management.

Assessments of nuclear criticality safety, performed in accordance with ANSI/ANS-8.19, will ensure that operations conform to criticality requirements.

15.6.2 Scheduling of Audits and Assessments

A schedule is established that identifies audits and assessments to be performed and the responsible organization assigned to conduct the activity. The frequency of audits and

assessments is based upon the status and safety importance of the activities being performed and upon work history. Major activities will be audited or assessed on an annual basis. The audit and assessment schedule is reviewed periodically and revised as necessary to ensure coverage commensurate with current and planned activities.

Nuclear Criticality safety audits are conducted and documented such that aspects of the Nuclear Criticality Safety Program will be audited at least every two years. The Operations Group is assessed periodically to ensure that nuclear critical safety procedures are being followed and the process conditions have not been altered to adversely affect nuclear criticality safety. The frequency of these assessments is based on the controls identified in the NCS analyses and NCS evaluations. Assessments are conducted annually.

15.6.3 Procedures for Audits and Assessments

Internal and external audits and assessments are conducted using approved procedures that meet the QA Program requirements. These procedures provide requirements for the following audit and assessment activities:

- Scheduling and planning of the audit and assessment
- Certification requirements of audit personnel
- Development of audit plans and audit and assessment checklists as applicable
- Performance of the audit and assessment
- Reporting and tracking of findings to closure
- Closure of the audit and assessment.

The applicable procedures emphasize reporting and correction of findings to prevent recurrence.

Audits and assessments are conducted by:

- Using the approved audit and assessment checklists as applicable
- Interviewing responsible personnel
- Performing plant area walkdowns (including accessible out-of-the way and limited access areas)
- Reviewing controlling plans and procedures
- Observing work in progress
- Reviewing completed QA documentation.

Audit and assessment results are tracked in the CAP. The data is periodically analyzed for potential trends and needed program improvements to prevent recurrence and/or for continuous program improvements. The resulting trend is evaluated and reported to applicable management. This report documents the effectiveness of management measures in controlling activities, as

well as deficiencies. Deficiencies identified in the trend report require corrective action in accordance with the applicable CAP procedure. The QA organization also performs follow-up reviews on identified significant deficiencies and verifies completion of corrective actions reported as a result of the trend analysis.

The audit and /or assessment team leader is required to develop the audit and /or assessment report documenting the findings, observations, and recommendations for program improvement. These reports provide management with documented verification of performance against established performance criteria for IROFS. These reports are developed, reviewed, approved, and issued following established formats and protocols detailed in the applicable procedures. Responsible managers are required to review the reports and provide any required responses due to reported findings.

Corrective actions following issuance of the audit and/or assessment report require compliance with the CAP procedure. Audit reports are required to contain an effectiveness evaluation and statement for each of the applicable QA program elements reviewed during the audit. The audit/assessment is closed with the proper documentation as required by the applicable audit and assessment procedure. The QA organization will conduct follow-up audits or assessments to verify that corrective actions were taken in a timely manner. In addition, future assessments will include a review to evaluate if corrective actions have been effective.

15.6.4 Qualifications and Responsibilities for Audits and Assessments

The QA Manager initiates audits. The responsible Lead Auditor and QA Manager determine the scope of each audit. The QA Manager may initiate special audits or expand the scope of audits. The Lead Auditor directs the audit team in developing checklists, instructions, or plans and performing the audit. The audit shall be conducted in accordance with the checklists, but the scope may be expanded by the audit team during the audit. The audit team consists of one or more auditors.

Auditors and lead auditors are responsible for performing audits in accordance with the applicable QA procedures. Auditors and lead auditors hold certifications as required by the QA Program. Before being certified under the MFFF QA Program, auditors must complete training on the following topics:

- MFFF QA Program
- Audit fundamentals, including audit scheduling, planning, performance, reporting, and follow-up action involved in conducting audits
- Objectives and techniques of performing audits
- On-the-job training.

Certification of auditors and lead auditors is based on the QA Manager's evaluation of education, experience, professional qualifications, leadership, sound judgment, maturity, analytical ability, tenacity, and past performance and completion of QA training courses. A lead auditor must also have participated in a minimum of five QA audits or audit equivalent within a period of time not to exceed three years prior to the date of certification. Audit equivalents include assessments,

pre-award evaluations or comprehensive surveillances (provided the prospective lead auditor took part in the planning, checklist development, performance, and reporting of the audit equivalent activities). One audit must be a nuclear-related QA audit or audit equivalent within the year prior to certification.

Personnel performing assessments do not require certification, but they are required to complete QA orientation training, as well as training on the assessment process. The nuclear criticality safety assessments are performed under the direction of the criticality safety staff. Personnel performing these assessments do not report to the production organization and have no direct responsibility for the function or area being assessed.

15.7 INCIDENT INVESTIGATIONS

MOX Services implements two programs for investigating discrepancies: the Corrective Action Process and Incident Investigations. This section describes these programs.

15.7.1 Corrective Action Process

The MFFF Corrective Action Process is used for identifying, investigating, reporting, tracking, correcting, and preventing 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 corrective action process is performed in accordance with MPQAP Section 16, "Corrective Action". Nonconforming materials, parts, or components are identified and controlled in accordance with MPQAP Section 15, *Nonconforming Materials, Parts, or Components*. The MPQAP requires regularly scheduled audits and assessments to ensure that needed corrective actions are identified. MOX Services employees have the authority and responsibility to initiate the corrective action process if they discover deficiencies. Reports of conditions adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to senior management in accordance with corrective action process procedures.

15.7.2 Incident Investigations

Incident investigations are used for investigating abnormal events, other than those that involve conditions adverse to quality identified in Section 15.7.1. Identification of the need for an incident investigation may come from anyone in the MFFF organization. An incident investigation is performed by one or more individuals assigned by the manager of production. The process used for the investigation may be similar to that of the CAP. Each event will be considered in terms of its requirements for reporting in accordance with regulations and will be evaluated to determine the level of investigation required. The process of incident identification, investigation, root cause analysis, environmental protection analysis, recording, reporting, and follow-up shall be addressed in and performed by written procedures. Radiological, criticality, hazardous chemical, other ISA related safety requirements shall be addressed. Guidance for classifying occurrences shall be contained in procedures, including examples of threshold off-normal occurrences. The depth of the investigation will depend upon the severity of the classified incident in terms of the levels of special nuclear material released and/or the degree of potential for exposure of workers, the public or the environment.

MOX Services shall maintain a record of corrective actions to be implemented as a result of off-normal occurrence investigations in accordance with CAP procedures. These corrective actions shall include documenting lessons learned, and implementing worker training where indicated, and shall be tracked to completion.

Specifics of the Incident Investigation process are as follows:

1. MOX Services will establish a process 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 report to the NRC as required by 10 CFR 70.50 and 70.74. The investigation process will include a prompt risk-based evaluation and, depending on the complexity and severity of the event, one individual may suffice to conduct the evaluation. The investigator(s) will be independent from the line function(s) involved with the incident under investigation and are assured of no retaliation for participating in investigations. Investigations will begin within 48 hours of the abnormal event, or sooner, depending on safety significance of the event. The record of IROFS failures required by 10 CFR 70.62(a)(3) for IROFS will be reviewed as part of the investigation. Record revisions necessitated by post-failure investigation conclusions will be made following completion of the investigation.
2. Qualified internal or external staff are appointed to serve on investigating teams when required. The teams will include at least one process expert and at least one team member trained in root cause analysis.
3. MOX Services will monitor and document corrective actions through completion.
4. MOX Services will maintain auditable records and documentation related to abnormal events, investigations, and root cause analyses so that "lessons learned" may be applied to future operations of the facility. For each abnormal event, the incident report includes a description, contributing factors, a root cause analysis, findings, and recommendations. Relevant findings are reviewed with affected personnel. Details of the event sequence will be compared with accident sequences already considered in the ISA. As appropriate, the ISA and the ISA Summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.

MOX Services will develop CAP procedures for conducting an incident investigation, and the procedures will contain the following elements:

1. A documented plan for investigating an abnormal event.
2. A description of the functions, qualifications, and/or responsibilities of the manager who would lead the investigative team and those of the other team members; the scope of the team's authority and responsibilities; and assurance of cooperation of management.
3. 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.
4. Retention of documentation relating to abnormal events for two years or for the life of the operation, whichever is longer.

5. 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.
6. Requirements to make available original investigation reports to the NRC on request.
7. A system for monitoring the completion of appropriate corrective action~~s~~ and that actions are completed in a timely manner.

15.8 RECORDS MANAGEMENT

Records management shall be performed in a controlled and systematic manner in order to provide identifiable and retrievable documentation during design, construction and operation of the MFFF. Applicable design specifications, procurement documents, or other documents specify the QA records to be generated by, supplied to, or held, in accordance with approved procedures. QA procedures are not considered valid until they are authenticated by authorized personnel.

The MPQAP requires procedures for reviewing, approving, handling, identifying, retention, retrieval and maintenance of quality assurance records. These records 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. These records are maintained at locations where they can be reviewed and audited to establish that the required quality has been assured.

Classified records are managed in accordance with an approved project procedure which identifies both the physical protection and access control measures for classified records. A limited area has been established as a satellite records retention facility in accordance with the records management procedure.

For computer codes and electronic data used for IROFS, procedures are established for the control and management of computer codes over the life cycle of the facility. The Records Center maintains control over access and use of records entered into the EDMS. Documents in EDMS shall be legible and shall be identifiable as to the subject to which they pertain. Documents shall be considered valid only if stamped, initialed, signed or otherwise authenticated by authorized personnel. Documents in EDMS may be originals or reproduced copies. Computer storage of data may be used in EDMS.

In order to preclude deterioration of records in EDMS, the following requirements are applicable:

- Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature and pressure.
- For hardcopy records, approved filing methods shall require records to be:

  - Firmly attached in binders, placed in folders, or placed in envelopes for storage in steel file cabinets; or
  - In containers appropriate for the record medium being stored on shelving.

- The storage arrangement shall 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 EDMS shall provide for the accurate retrieval of information without undue delay. Records shall be stored and preserved in the Records Center in accordance with an approved QA procedure that provides:

- 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.

One-of-a-kind records shall be stored in 2 hour fire rated cabinets to assure records are adequately protected from damage.

Records related to environment, safety and health, including radiological protection, shall be maintained in accordance with the records management procedural requirements. Records shall be retained for at least the periods indicated in accordance with the records management procedures that specify retention periods.

The following are examples of records that will be retained:

- Operating logs
- Procedures
- Supplier QA documentation for equipment, materials, etc.

- Nonconforming item reports
- Test documentation/test results – preoperational/operational
- Facility modification records
- Drawings/specifications
- Procurement documents (e.g., purchase orders)
- Nuclear material control and accounting records
- Maintenance activities including calibration records
- Inspection documentation (plant processes)
- Audit reports
- Reportable occurrences and compliance records
- Completed work orders
- License conditions records
- Software verification records
- System description documents
- Dosimetry records
- Effluent records
- As-built design documentation packages
- Regulatory reports and corrective action

Other retention times are specified for other facility records as necessary to meet applicable regulatory requirements. These retention times are indicated in facility administrative procedures.

Section 17, "*Quality Assurance Records,*" of the MPQAP provides additional details regarding records management requirements.

Table 15-1. Management Measures for IROFS

MANAGEMENT MEASURES/ ELEMENTS	IROFS CONTROL CLASSIFICATIONS*			
Quality Assurance				
Organization	AEC	PEC	EAC	AC
Quality Assurance Program	AEC	PEC	EAC	AC
Design Control	AEC	PEC	EAC	AC
Procurement Document Control	AEC	PEC	EAC	AC
Instructions, Procedures, and Drawings	AEC	PEC	EAC	AC
Document Control	AEC	PEC	EAC	AC
Control of Purchased Material, Equipment, and Services	AEC	PEC	EAC	AC
Identification and Control of Materials, Parts, and Components	AEC	PEC	EAC	AC
Control of Special Processes	AEC	PEC	EAC	AC
Inspection	AEC	PEC	EAC	AC
Test Control	AEC	PEC	EAC	AC
Control of Measuring and Test Equipment	AEC	PEC	EAC	AC
Handling, Storage, and Shipping	AEC	PEC	EAC	AC
Inspection, Test, and Operating Status	AEC	PEC	EAC	AC
Nonconforming Materials, Parts, or Components	AEC	PEC	EAC	AC
Corrective Action	AEC	PEC	EAC	AC
Quality Assurance Records	AEC	PEC	EAC	AC
Audits	AEC	PEC	EAC	AC
Configuration Management				
Design/Technical Requirements	AEC	PEC	EAC	AC
Change Control	AEC	PEC	EAC	AC
Document Control	AEC	PEC	EAC	AC
Audit and Assessment	AEC	PEC	EAC	AC
Maintenance				
Surveillances	AEC	PEC		
Preventive Maintenance	AEC	PEC		

Table 15-1. Management Measures for IROFS (Continued)

MANAGEMENT MEASURES/ ELEMENTS	IROFS CONTROL CLASSIFICATIONS*			
Maintenance				
Corrective Maintenance	AEC	PEC		
Work Control	AEC	PEC		
Post Maintenance Testing/Restoration	AEC	PEC		
Training and Qualification				
Analysis and Identification of Functional Areas Requiring Training or Qualification	AEC	PEC	EAC	AC
Position Training Requirements	AEC	PEC	EAC	AC
Basis for and Objectives of Training	AEC	PEC	EAC	AC
Organization of Instruction	AEC	PEC	EAC	AC
Evaluation of Trainee Learning	AEC	PEC	EAC	AC
Conduct of On-the-Job Training	AEC	PEC	EAC	AC
Systematic Evaluation of Training Effectiveness	AEC	PEC	EAC	AC
Personnel Qualification	AEC	PEC	EAC	AC
Provisions for Continuing Assurance	AEC	PEC	EAC	AC
Procedures				
Identification and Preparation of Procedures	AEC	PEC	EAC	AC
Review/Approval	AEC	PEC	EAC	AC
Revisions	AEC	PEC	EAC	AC
Use of Procedures/Compliance	AEC	PEC	EAC	AC
Control of Procedures	AEC	PEC	EAC	AC
Audits and Assessments				
Audits	AEC	PEC	EAC	AC
Assessments	AEC	PEC	EAC	AC
Incident Investigations				
Corrective Action Process	AEC	PEC	EAC	AC
Incident Investigations	AEC	PEC	EAC	AC
Records Management				
Generation of Records	AEC	PEC	EAC	AC
Classification of Records	AEC	PEC	EAC	AC
Record Receipt and Processing	AEC	PEC	EAC	AC

Table 15-1. Management Measures for IROFS (Continued)

MANAGEMENT MEASURES/ ELEMENTS	IROFS CONTROL CLASSIFICATIONS*			
Records Indexing and Filing	AEC	PEC	EAC	AC
Records Storage	AEC	PEC	EAC	AC
Records Preservation	AEC	PEC	EAC	AC
Records Retrieval	AEC	PEC	EAC	AC
Records Correction	AEC	PEC	EAC	AC
Records Retention	AEC	PEC	EAC	AC

*For the enhanced administrative controls (EAC), the specific management measures for the physical device are covered under the active engineered controls (AEC) classification.

MOX Clarification Questions on Draft Revision 9 of the MPQAP

Section 1 – Organization

1. Section 4.2.2, "Quality Assurance Function," of the MOX License Application states that "The manager of the quality assurance QA function is responsible for maintaining the MOX Services Project Quality Assurance Plan (MPQAP) and reports directly to the MOX Services President. This function is independent of the organizations responsible for performing quality affecting work and is independent of cost and schedule considerations. This function may be assigned other duties; however, these duties are not allowed to compromise the independence of this function or to prevent attention to quality assurance matters. The manager of the QA function has the same access to the MOX Services President as the line managers of other functional areas of the MFFF.

   The manager of the QA function is responsible for identifying quality problems, recommending and verifying implementation of solutions, and ensuring further work is controlled until the unsatisfactory conditions has been corrected. The manager of the QA function is responsible for approval of the subcontractor quality assurance programs, oversight, and audit functions. The manager of the QA function also interfaces with NRC, stakeholders and other governmental agencies regarding the QA requirements, compliance with QA requirements, and resolution of QA concerns. These functions are accomplished by delegating and assigning responsibility to qualified personnel.

   The QA manager is the only key management position in the QA organization. The minimum qualifications for the QA Manager position are a Bachelor's degree (or equivalent), four years of quality assurance-related experience, two years of nuclear industry experience, and one year of supervisory or management experience."

   Section 1.2.2, "Vice President Project Assurance," of the MPQAP states that:

   The MOX Services Vice President Project Assurance reports directly to the MOX Services President. He is responsible for the Quality Assurance Program, Licensing and Regulatory Compliance.

   Reporting to the Vice President Project Assurance is the Director of Quality Assurance, Licensing Manager and the Regulatory Compliance Manager.

   The Director of Quality Assurance is independent of the managers responsible for performing quality-affecting work and is independent of cost and schedule considerations. He is responsible for maintaining the MOX Project Quality Assurance (QA) Plan and verifying its effective implementation at applicable MOX Services work locations. This position is independent of the managers responsible for performing quality-affecting work and is independent of cost and schedule considerations. Procedures are approved by the manager responsible for

the performance of the activities being controlled, procedures that directly implement the MPQAP requirements will obtain the concurrence of the quality assurance organization. MOX Services Quality Assurance will witness and/or perform specified testing and inspections of IROFS.

Reporting to the Director of Quality Assurance is the Quality Control Manager and the Quality Assurance Manager.

This organization is shown in Figure 1-2, Project Assurance Organization. The Quality Control Manager is responsible for the QC inspection program, performance of in-process and final inspections, certification of inspectors, performance of shop inspections and managing the nonconforming item program. The QA Manager is responsible for the performance of internal oversight (audits, assessments, monitoring of activities, supplier oversight, audits, surveillances, supplier QA Manual review, review of technical documents and procedures, managing the corrective action program, and performing trend analysis). This organization will evolve to support activities throughout the life of the project.

Note: *For this document, monitoring is defined as observing an activity as it is being performed or by review of documentation to verify conformance to established procedures. Condition Reports are issued for activities not complying with procedures. This activity is not used to document acceptance or approval of data or activities.*

The Director Quality Assurance may be assigned other duties; however, none of these duties are allowed to compromise the independence of this function or to prevent needed attention to QA matters. As a direct report, the Director Quality Assurance has the same access to the President as the line managers of the various functional areas of the project.

This position is able to:

- Identify quality problems
- Initiate, recommend, or provide solutions
- Verify implementation of solutions
- Assure, if applicable, that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

The Licensing Manager provides planning and execution of MFFF licensing activities, including interfaces with regulatory agencies, and managing the preparation and maintenance of the MFFF license application. This function is responsible for direct interface with the U.S. Nuclear Regulatory Commission (NRC) and the coordination between the U.S. Department of Energy (DOE) and the NRC for the MFFF license application.

The Regulatory Compliance Manager provides planning and execution of compliance activities, including interfaces with regulatory agencies, and managing the preparation and maintenance of the MFFF license application. This function is responsible for regulatory compliance and the direct interface with the U.S. Nuclear Regulatory Commission (NRC) and the coordination required between the U.S. Department of Energy (DOE) and the NRC for the MFFF regulatory application."

Section 1.1, "General," of the MPQAP states that "The MOX Services functional organization structure is shown in Figure 1-1. This covers the design, construction, and operation for the DOE Mixed Oxide (MOX) Fuel Fabrication Facility. … As construction begins, the organizational structure will shift toward an increased work scope and resources for Construction.

As the project progresses toward the completion of construction and the beginning of the operations phase, the focus of the organizational structure will shift from design and construction to operation. As the construction of systems is completed, the systems will undergo acceptance testing as necessary, followed by turnover from the construction organization to the operations organization. The turnover will include the physical systems and corresponding design information and records. Following turnover, the operations start-up organization will be responsible for system maintenance and configuration management. The design basis for the facility is maintained throughout the life-cycle under the configuration management system."

Please clarify the applicability of the MOX Organization structure shown in Figure 1.1 and how this organization is consistent with that identified in Chapter 4 of the License Application.

Please provide a pointer for the staff to identify where in the MPQAP and the License Application the scope of the two separate organization structures is discussed (i.e., the organization structure identified in Chapter 4 of the LA is only applicable to the operations phase; the organizational structure identified in the MPQAP is currently implemented).

Please review these position descriptions and provide verification of the responsibilities of the VP of QA, Director of QA, and QA Manager. There is a lot of overlap in certain aspects of the position descriptions, so it is unclear with whom certain QA program responsibilities and reporting authorities reside.

MOX Services response: The organization in the License Application reflects the organization that is currently planned for the time of operations (e.g., hotstartup) while the MPQAP describes the current organization structure and responsibilities. While there are changes to the current organization (and those changes are captured in the draft MPQAP), those changes do no impact the organization structure and responsibilities for the operations phase (as described in LA Chapter 4). Since the two documents describe organizations at two different points in time, there could appear to be overlap in responsibilities. As

the project progresses toward hot startup, it is expected that the organizations described in the MPQAP and LA Chapter 4 will converge until there are consistent at the time of hot startup. If MOX Services determines that the operations phase organization structure will be modified, then LA Chapter 4 will be updated. Similarly, the MPQAP will be revised if the current organization changes from that described in the MPQAP.

As indicated in LA Chapter 1.1.1, "This license application is written in the present tense. It describes the MFFF site, design features, processes, programs, commitments, etc., in effect in the time perspective of receipt of the U.S. Nuclear Regulatory Commission (NRC) approved license for possession and use of nuclear materials for operation of the facility."

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~~3.~~2. Please clarify what is meant by the term *MFFF regulatory application* in Section 1.2.2 of the MPQAP, which states: "The Regulatory Compliance Manager provides planning and execution of compliance activities, including interfaces with regulatory agencies, and managing the preparation and maintenance of the MFFF license application. This function is responsible for regulatory compliance and the direct interface with the U.S. Nuclear Regulatory Commission (NRC) and the coordination required between the U.S. Department of Energy (DOE) and the NRC for the MFFF regulatory application."

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MOX Services Response: The sentence should have ended with "and the NRC for MFFF regulatory compliance."

MPQAP Changes: The subject sentence in the MPQAP has been revised as described as above.

3. Please clarify why there is no line of reporting access shown between the QA Manager and the President of MOX Services in Figures 1-1 and 1-2.

MOX Services Response: The QA Manager as shown on Figure 1-2 as well as the QC Manager both report directly to the Manager QA/QC (new) who reports directly to the Manager Project Assurance. The Manager QA/QC (new) has a dotted line directly to the President of MOX Services. Organization chart has been revised to reflect this.

Section 2 – QA Organization/Training

1. Deleted: Commitments in Section 6.2.7 of MPQAP are adequate to satisfy this question. ~~Section G2 of NUREG-1718 requires that the QA organization reviews and documents concurrence in the quality-affecting procedures.~~

   ~~Please confirm that QA organization reviews and documents concurrence in the quality-affecting procedures and that all concurrences on QA documents will be in writing.~~

~~2.~~Deleted: Commitments in Section 2.2.6 of MPQAP are adequate to satisfy this question

~~Section G2.10 (c) of NUREG 1718 requires that, "For formal training and qualification, documentation includes a statement of the training objective and its content, the attendees, and the date of attendance."~~

~~3.~~2.

~~Please identify if the MPQAP commits to document the training objective and its content as well as the training date for formal training.~~

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~~4.~~3. Section 15.4.4.3 (A), "Organization and Management of training," of NUREG 1718 states that the following commitments regarding organization and management of training should be contained in license applications for MOX fuel fabrication facilities:

i. Line management should be responsible for the content and effective conduct of the training.

ii. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training should be clearly defined.

Section 2.3.3, "Organization and Management of Training," of the MPQAP states that "Line managers have responsibility for and authority to develop and effectively conduct training for their personnel. Training responsibilities for line managers are included in position descriptions."

Section 1.2.6, "Vice President Operations," of the MPQAP states that "During operations, this function is responsible for operation and maintenance of the facility, including configuration management, preparation of operating procedures, staffing and training of qualified plant personnel, implementation of a maintenance program and preparation of maintenance procedures, implementation of safe work practices and emergency response programs."

- Please fully define the job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training.

MOX Services Response: The first sentence in LA 15.4.1, has been changed to read "Line managers have the responsibility, accountability and the…."

- Please specify to whom the line managers report
    1. Do they report to the VP Operations?

MOX Services Response: Line managers are department heads for each box identified on the organizational chart. Some line managers report to the VP Operations, however, some report to other VPs.

MPQAP/LA Changes: None identified.

2. Do any of the line managers in the Project Assurance Organization (i.e, quality assurance/control managers) hold training responsibilities? No training responsibilities are called out for quality managers in Section 1 of the QAPD.

MOX Services Response: As stated in 15.4.1, "Line managers have responsibility for and authority to develop and effectively conduct training for their personnel. Training responsibilities for line managers are included in position descriptions." There is no specific direction for each group of line managers. The statement is inclusive of all line managers in all organizations within MOX.

MPQAP/LA Changes: None identified.

4. Section 15.4.4.3 (B), "Analysis and Identification of Functional Areas Requiring Training," of NUREG 1718 states that "Analysis and identification of areas requiring training should be acceptable if the areas required for competent and safe job performance are identified, documented, and addressed by the training."

   Please identify, document, and address the areas required for competent and safe job performance that will receive personnel training or include a commitment to do so in the MPQAP.

   MOX Services Response: Added text indicating "competent and safe job performance in Section 15.4 (1st paragraph).

5. Section 15.4.4.3 (B), "Analysis and Identification of Functional Areas Requiring Training," of NUREG 1718 states that "Operations personnel, training staff, and other subject matter experts, as appropriate, should have conducted or should conduct a needs/job analysis to develop a valid task list for specific jobs. The jobs treated in this manner should include, as a minimum, those responsible for managing, supervising, performing, and verifying the activities relied on for safety and those specified in the Integrated Safety Analysis Summary (ISA; see SRP Chapter 5.0) that prevent or mitigate accidents. Each task selected for training (initial or continuing) from the facility-specific task list should be matrixed to supporting procedures and training materials. The facility-specific list of tasks selected for training and the comparison to training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope."

Section 2.3.4 of the MPQAP states that, "A needs/job analysis is performed and tasks identified to ensure that appropriate training is provided to personnel working on tasks related to IROFS."

Please clarify the following ~~(and revise the MPQAP as necessary…please note that changing the language from "activities related to IROFS" to "IROFS and activities in the ISA Summary that prevent or mitigate accidents" may extend to other subsections):~~

i) Will the needs/job analysis include training for those responsible for managing, supervising, performing, and verifying ~~the~~ activities ~~specified in the Integrated Safety Analysis Summary that prevent or mitigate accidents~~related to IROFS?

MOX Services Response: Revised Section 15.4.2 to clarify that training is also for those responsible for managing, supervising, performing, and verifying activities.

ii) Will each task selected for training (initial or continuing) from the facility-specific task list be matrixed to supporting procedures and training materials?

MOX Services Response: Section 15.4.2 has been revised to indicate that tasks are matrixed to supporting procedures and training materials.

6. Section 2.3.13 states that the "qualification requirements for technical personnel are determined as discussed in Sections 15.4.2 and 15.4.3."

Please clarify this reference. (Should it be 2.3.4 and 2.3.5?)

MOX Services Response: Many of these references are no longer applicable since MPQAP Rev 9 will be a stand alone submittal (i.e., not include management measures). However, MPQAP and LA Chapter 15 references will be reviewed for consistency prior to submittal.

7. Section 2.3.3 of the MPQAP states that "Training records are maintained to support management information needs associated with personnel training, and qualification."

NUREG 1718 states that training records should support management information needs and provide required data on each individual's training, job performance, and qualifications.

Does the MOX QA Program have provisions for maintaining training records for management consideration related to employee job performance?

MOX Services Response: Human Resources (not training) maintains general employee job performance records. Section 15.4.1 (last paragraph) has been revised to clarify that training maintains records relative to the employee's performance in completing training and qualification activities.

8. Section 2.3.7 (E) of the MPQAP states that "Continuing training…may consist of periodic exercises, instruction, and review of subjects…" The paragraph later goes on to state that "Continuing training consists of computer-based or classroom and components performed on a frequency needed to maintain proficiency on the job."

   Please (1) clarify what continuing training will consist of. The term "exercises" infers practical, hands-on training which may occur outside of the classroom while the latter sentence indicates that continuing training is solely computer and classroom.

   MOX Services Response: Section 15.4.3.2, last paragraph has been revised for clarity. It now reads, "Continuing training courses shall be established when applicable to ensure that personnel remain proficient. Continuing training is any training not provided as initial qualification or basic training that maintains and improves job-related knowledge and skills. Continuing Training may consist of periodic exercises, computer-based or classroom instruction or any other type of training identified appropriate and performed on a frequency needed to maintain proficiency on the job. Once the objectives for continuing training have been established, the methods for conducting the training may vary. The method selected must provide clear evidence of objective accomplishment and consistency in delivery."

   (2) Please clarify the phrase "computer-based or classroom and components" in the second sentence to make sense.

   MOX Services Response: See above response to (1) above.

9. Section 15.4.4.3 (G), "Conduct of on the job training," of NUREG 1718 states that "On-the-job training should be conducted by designated personnel who are competent in the program standards and methods of conducting the training."

   Section 2.3.11 of the MPQAP states that OJT is conducted by personnel who are competent in the technical aspects of the job being performed.

   Please clarify if the technically knowledgeable personnel identified in the MPQAP for the conduct of OJT will also be competent in the program standards and methods of conducting the training.

   MOX Services Response: Section 15.4.7 (2nd sentence) has been revised to read, "On-the-job training is conducted by personnel who are competent in the program standards and methods of conducting the training."

10. Section 15.4.4.3 (G), "Conduct of on the job training," of NUREG 1718 states that "The conduct of on-the-job training should be acceptable if on-the-job training used for activities identified in the ISA Summary is fully described."

Section 2.3.7 (D) of the MPQAP states that "Applicable tasks and related procedures make up the OJT/qualifications program for each technical area."

Please describe the OJT that will be used for activities identified in the ISA Summary or identify where in the MPQAP this description is contained. Please identify the "technical areas" that will be part of the OJT/qualifications program.

MOX Services Response: Section 15.4.3.2, 5th paragraph, has been revised to add an additional sentence as follows: Technical areas will be derived based on the activities identified in the ISA Summary, job/task analyses and associated procedures.

11. Section 15.4.4.3 (G), "Conduct of on the job training," of NUREG 1718 states that "On-the-job training should be conducted using well-organized and current performance-based training materials."

    Please describe the training materials that will be used for OJT.

    MOX Services Response: Section 15.4.7 has been revised to add the following: Lesson plans are used for classroom training and on-the-job training as required using well-organized and current performance-based training materials and include standards for evaluating acceptable trainee performance.

12. Section 2.3.13 of the MPQAP states that that qualification requirements for technical personnel are determined as discussed in Sections 15.4.2 & 15.4.3. Please clarify this reference. Also, please perform a comprehensive search of the MPQAP for other references to Section 15 which may no longer be valid.

    MOX Services Response: Many of these references are no longer applicable since MPQAP Rev 9 will be a stand alone submittal (i.e., not include management measures). However, MPQAP and LA Chapter 15 references will be reviewed for consistency prior to submittal.

13. SRP 15.4.4.3 (I) of NUREG 1718 states that "Commitments should be provided regarding minimum qualifications for personnel required to meet NRC regulations. Minimum qualifications should be commensurate with the assigned functional responsibility and authority of the respective personnel. The following commitments should be in the application regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel, and other plant staff required to meet NRC regulations:

    i. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management experience or technical experience in nuclear facilities or activities similar to the mixed oxide (MOX) facility or activities that they are to manage.

ii. Supervisors should have at least the qualifications required of personnel being supervised and either 1 additional year experience supervising the technical area at a similar facility or completion of the supervisor training.
iii. Technical staff identified in the ISA Summary whose activities are relied on for safety to satisfy the performance requirements identified in 10 CFR Part 70, should have a B.S. or equivalent in an appropriate technical field and experience and training appropriate for their activities, authority, and responsibilities.
iv. Facility operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.
v. Candidates for process operators positions should be required to meet minimum qualifications described in the application. Candidates for job functions other than process operators should also be required to meet minimum qualifications, but these minimum qualifications need not be described in the application."

Section 4.3.4 of the MOX License Application states that "The minimum qualifications for Operations Shift Managers are a high school diploma, one year of operations or manufacturing production experience in a nuclear facility, and one year of supervisory or management experience."

(a) Please explain why the operations shift management function does not require a BS/BA degree.

MOX Services Response: This has been corrected in LA Section 4.2.3.

(b) Please describe where in the MPQAP or the MOX License Application the minimum qualification requirements for positions other than managers (supervisors, technical staff, facility operators/technicians/maintenance personnel/staff, and candidates for process operator positions) can be found. Please ensure that the requirements for personnel qualification for all of the following positions are addressed in your response: managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel, and other plant staff required to meet NRC regulations.

MOX Services Response: LA Sections 4.2.2 through 4.2.5 have been revised to reflect the minimum qualifications from NUREG 1718, 15.4.4.3 (I).

Section 3 – Design Control/Configuration Management

~~1.Section G3.10(a) of NUREG 1718 states the following regarding design control verification: "The verifier is qualified, and neither the verifier nor the verifier's immediate supervisor is directly responsible for the design. In exceptional~~

~~circumstances, the designer's immediate supervisor may perform the verification provided:~~

~~(i)The supervisor is the only technically qualified individual;~~
~~(ii)The need is individually documented and approved in advance by the supervisor's management; and~~
~~(iii) QA audits and self-assessments cover frequency and effectiveness of the use of supervisors as design verifiers to guard against abuse."~~

~~In Section 3.2.4 of the MPQAP, MOX identifies the following justification criteria for the use of a designer's immediate supervisor as a verifier:~~

~~1."The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or~~
~~2.The supervisor is the only individual in the organization competent to perform the verification.~~
~~3.The justification to use the supervisor shall be documented."~~

1. ~~Please identify (1) if MOX will (a) document the need for supervisory verification, (b) if the documentation will be done prior to the verification, and (3) if it will be approved by the supervisor's management. Please identify (2) if MOX QA audits and self-assessments cover frequency and effectiveness of the use of supervisors as design verifiers to guard against abuse.~~Deleted.

~~2.~~2. ~~Section G3.11 provides provisions that should be included for the use of testing as the method of design verification. The section calls for the following provisions:~~
~~"(a) Procedures provide criteria that specify when verification should be by test.~~
~~(b)Prototype, component, or feature testing is performed as early as possible before installation of plant items or before such installation would become irreversible."~~

~~Please clarify if MFFF procedures will provide criteria that specify when test should be used as the method of design verification. Also, please identify when testing will be performed (i.e., before installation).~~Deleted.

3. Section 3.3.2 of the MPQAP states that "Configuration control is accomplished during design through…"

   Please clarify the meaning of the word design in this context and confirm that it applies to design control/design activities rather than the design phase of the facility, since Section 3.3 of the MPQAP is labeled "Operations."

   Also, the first paragraph of Section 3.3.9 discusses the design and construction phases of the project. Please clarify the intent of this information in the operations section of the MPQAP. ****This can be acceptable as background info since it supports licensing basis****

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MOX Services Response: Retaining the management measures text within the LA should resolve questions regarding applicability of controls with project phases.

4. Section 15.2.4.3 (E) of NUREG 1718 states that the applicant should perform initial and annual assessments of the CM program to determine the system effectiveness and to correct deficiencies.

   Section 3.3.11 of the MPQAP states that periodic assessments are conducted in accordance with Section 18.3 of the MPQAP.

   Section 18.3 has provisions for annual assessments.

   Please identify MFFF controls for performing initial assessments of the CM program upon entering the operations phase.

   MOX Services Response: Added the following to Section 15.2.7, "Initial assessment(s) of the configuration management program is performed as part of system turnover upon entering the operations phase."

Section 5 – Procedures

1. Please provide references to MPQAP Sections or add further guidance to describe how MFFF will meet the provisions of Sections 15.5.4.3 (L), (M), and (Q) of NUREG 1718.

   MOX Services Response: Revised LA Section 15.5.4, 2nd paragraph, last sentence to add design output, records and interfaces.

   The test control program discussion is provided Section 15.3.1.4.

   Revised LA Section 15.3.1.4, 5th paragraph, to add the term "surveillance" to text discussing preoperational and operational testing programs.

2. SRP Section 15.5.4.3 states that "Plant procedures should be written or planned for the conduct of all operations involving controls identified in the ISA as activities relied on for safety and for all management control systems supporting those controls."

   Section 5.1 of the MPQAP states that "Quality-affecting activities are prescribed by and performed in accordance with documented, approved QA programs…"

   Section 5.3.3 of the MPQAP states that "The results of the ISA and other processes are used to identify specific operating and administrative procedures that are developed."

Please verify that plant procedures have been or will be written for the conduct of all operations involving controls identified in the ISA as activities relied on for safety and for all management control systems supporting those controls.

MOX Services Response: Revised LA Section 15.5 to add text after 2nd sentence stating, "This includes procedures for the conduct of all operations involving controls identified in the Integrated Safety Analysis (ISA) as activities relied on for safety and for all management control systems supporting those controls."

3. SRP Section 15.5.4.3 states that operating procedures should contain certain elements, including:
   - Regulations, policies, and guidelines governing the procedure
   - Initial startup

   Section 5 of the MPQAP states that production procedures (which control process operations and apply to utility, workstation, and control room operations) will contain the following elements:
   - Policies and guidelines governing the procedure
   - Periodic startup/shutdown

   Please clarify (1) if production procedures will contain regulations that govern the procedure and (2) if initial startup will be included in the procedures in addition to the periodic startup guidance.

   MOX Services Response: Added "regulations" to 2nd bullet and "initial startup" to 5th bullet in Section 15.5.1.2.1,

4. Section 15.5, "Plant Procedures," of NUREG 1718 requires in Section 15.5.4.3 (G) that "The applicant should discuss plant procedure categories used at the facility. An acceptable discussion should clearly state areas for which a plant procedure is required. The applicant should provide a list of the types of activities that are covered by the plant procedures. This list should include the topics of administrative plant procedures; system plant procedures that address startup, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures. Appendix H to this SRP provides an acceptable list of the items to be included under each topic."

   Appendix H, "Checklist for Plant Procedures," includes a list of activities that should be covered by written procedures. The list includes the following:

   H1. Operating Procedures
   Procedures that address startup, operation, shutdown, control of process operations, and recovery after a process upset include: (a) Ventilation; (b) Criticality alarms; (c) Shift routines, shift turnover, and operating practices; (d) Decontamination operations; (e) Plant utilities (air, other gases, cooling water, firewater, steam); (f)

Temporary changes in operating procedures; and (g) Abnormal operation/alarm response including: (i) Loss of cooling water; (ii) Loss of instrument air; (iii) Loss of electrical power; (iv) Loss of criticality alarm system; (v) Loss of containment; (vi) Fires; and (vii) Chemical process releases.

Maintenance activities that address repair, calibration, surveillance, and functional testing include: (a) Repairs and preventive repairs of items relied on for safety (IROFS); (b) Testing of criticality alarm units; (c) Calibration of IROFS; (d) High efficiency air particulate (HEPA) filter maintenance; (e) Functional testing of IROFS; (f) Relief valve replacement/testing; (g) Surveillance/monitoring; (h) Pressure vessel testing; (i) Piping integrity testing; and (j) Containment device testing.

Emergency procedures include: (a) Response to a criticality, and (b) Hazardous process chemical releases.

H2. Management Control Procedures
1. Training; 2. Audits and assessments; 3. Incident investigation; 4. Records management; 5. Configuration management; 6. Quality assurance; 7. Equipment control (lockout/tagout); 8. Shift turnover; 9. Work control; 10. Management control; 11. Procedure management; 12. Nuclear criticality safety; 13. Fire protection; 14. Radiation protection; 15. Radioactive waste management; 16. Maintenance; 17. Environmental protection; 18. Chemical process safety; 19. Operations; 20. Calibration control; 21. Preventive maintenance; 22. Design control; 23. Test control.

Please identify where in the MPQAP the commitments to establish plant procedures for H1 (1), H1 (2), and H2 can be found or revise the MPQAP to include these commitments.

MOX Services Response: Procedural lists from H1 and H2 have been added as applicable to Section 15.5.1

5. Section 15.5.4.3 (C) of NUREG 1718 states that management control procedures should exist for the following activities:

    - Configuration management
    - Human systems interface
    - Audits and assessments
    - Incident investigations
    - Records management
    - Design control
    - Test control

These items are not included in the lists of administrative and operating procedures in Section 5.3.2 of the MPQAP. Please identify where the MPQAP commits to develop

and implement these procedures or explain the justification for omitting them from the lists.

MOX Services Response: Section 15.5.1.1 on administrative procedures has been revised to include the procedures as applicable.

6. SRP Section 15.5.4.3(O) states that the applicant should perform periodic reviews of plant procedures and should, at a minimum, review ALL procedures every 5 years.

   Section 5.3.7 of the MPQAP commits to review radiation protection procedures, respiratory protection procedures, operating and maintenance procedures every 5 years and establishes review requirements for emergency procedures (1-2 years).

   Please identify what review requirements are applicable to administrative procedures.

   MOX Services Response: Language has been added Section 15.5.4 to reflect a 5 year periodic review cycle for administrative procedures as well.

7. SRP Section 15.5.4.3(O) also requires that all applicable procedures be reviewed for major facility or process modifications.

   The MPQAP states that emergency procedures will be reviewed after modifications to a system. Please clarify if the other types of procedures used at MFFF will undergo review in response to major facility or process modifications and, if so, please identify where these requirements are contained in the MPQAP.

   MOX Services Response: Added new MPQAP section in 6.2.11 to address this. MPQAP now states "Applicable procedures are reviewed following any modification to a system."

8. Section 5.3.7 of the MPQAP refers to the MFFF training program and states that it is addressed in Section 15.4. Please clarify this reference.

   MOX Services Response: Many of these references are no longer applicable since MPQAP Rev 9 will be a stand alone submittal (i.e., not include management measures). However, MPQAP and LA Chapter 15 references will be reviewed for consistency prior to submittal.

Section 7 – Control of Purchased MES

1. Please identify if any particular means of verification (i.e., technical verification of data produced; surveillance and/or audit of the activity, review of objective evidence for conformance to the procurement document requirements) will be employed to

accept quality-related services. Section 7.2.6 of the MPQAP covers the requirements of item 8.2 of Basic Requirement 7 of NQA-1-1994. The requirements of item 8.3 for the acceptance of "services only," however, are not explicitly covered by the content of Section 7 of the MPQAP. Please revise the MPQAP to include the requirements of item 8.3 of NQA-1 Basic Requirement 7, either by adding a separate section for the acceptance of services only or by revising section 7.2.6 to cover this information (i.e., acceptance of services only would require "technical verification of data produced," whereas MPQAP section 7.2.6 only includes provisions for the "technical verification of product produced."

MOX Services Response: Revised Section 7.2.6, "Acceptance of Items or Services," by removing "or services" from Section 7.2.6A., and adding new paragraph 7.2.6B., (moved existing 7.2.6B as 7.2.6C) and moved Section 7.2.6A items 3), 4) and 5) to new 7.2.6B. See below:

A. Methods for accepting supplier/subcontractor services only such as third party inspections; engineering and consulting services; and installation, repair, overhaul, or maintenance work, shall accept the service by any or all of the following methods, as appropriate to the services being procured:

1) Technical verification of the product produced;

2) Surveillance and/or audit of the activity or work;

3) Review of objective evidence (such as certifications, stress reports or personnel qualifications) for conformance to procurement document requirements.

Section 11 – Test Control

1. In Section 11.3.1, "Operations Tests," the MPQAP mentions that there are two major testing programs; however, the programs list starts with a (B.) letter. Please clarify if there is an additional testing program not already identified in the MPQAP or if this is just an editorial error.

   MOX Services Response: Many of these references are no longer applicable since MPQAP Rev 9 will be a stand alone submittal (i.e., not include management measures). However, MPQAP and LA Chapter 15 references will be reviewed for consistency prior to submittal.

2. In Section 11.3.6, "Periodic Testing," the MPQAP mentions that testing is scheduled such that the safety of the plant is not dependent on the performance of an IROFS that has not been tested within its specified testing interval. Please clarify how the

program ensures that periodic testing will not compromise the availability of those already tested IROFS.

MOX Services Response: Added text to Section 15.3.1.4 under periodic testing, 3rd paragraph, "Testing is scheduled consistent with the limiting conditions for operation as identified in the Operating Limits Manual such that the performance requirements of 70.61 continue to be met."

3. Please identify if any computer programs are being tested and, if so, what the testing requirements are for those programs and how the testing of such computer programs is documented.

   MOX Services Response: As discussed in LA Section 11.5 (I&C Systems), Application software for digital computers used in safety systems is developed, reviewed, and verified using the methods and practices identified in IEEE 1012-1998, *IEEE Standard for the Software Verification and Validation*.

4. Section 11.2.2 lists the requirements that will be in QA Procedure for performing tests. Please clarify if Test Control procedures will include, as required, provisions for (1) mandatory inspection hold points for witness by owner, contractor, or inspector (as applicable) and (2) methods of documenting or recording test data and results.

   MOX Services Response: MPQAP Section 11.2.1(E) requires mandatory hold points and methods to record data and results. Test Results is also addressed in Section 11.2.5, Test Documentation.

Section 14 – Inspection, Test, and Operating Status

1. Please clarify that procedures are established to control the alteration of the sequence of required tests, inspections and other operations relied on for safety and that such actions will be subjected to the same controls as those for the original review and approval.

   MOX Services Response: MPQAP Section 5.2.2C revised to read as follows:

   A sequential description of the work to be performed (unless otherwise specified) including controls for altering the sequence of required inspections, tests and other operations relied on for safety which will be subjected to the same controls as those for the original review and approval for the change. The organization responsible for preparing the document shall determine the appropriate level of detail.

Section 16 – Corrective Actions

1. Section 16.3.2 of the MPQAP states that incident investigations are used for investigating abnormal events, other than those that involve conditions adverse to quality identified in Section 15.7.1. Section 15.7.1 does not exist within the MPQAP, and Chapter 15 of the License Application has been revised to remove all technical content. Please clarify this reference.

   MOX Services Response: Many of these references are no longer applicable since MPQAP Rev 9 will be a stand alone submittal (i.e., not include management measures). However, MPQAP and LA Chapter 15 references will be reviewed for consistency prior to submittal.

2. Section 16.3.2 states that "[M]OX Services shall maintain a record of corrective actions to be implemented as a result of off-normal occurrence investigations in accordance with CAP procedures. These corrective actions shall include documenting lessons learned, and implementing worker training where indicated, and shall be tracked to completion." Also Section 16.3.3 includes the elements contained in the CAP procedures. Please clarify how the process ensures that documented corrective actions are taken within a reasonable period to resolve findings from incident investigations.

MOX Services Response: LA 15.7.2 bullet 7 has been revised to "A system for monitoring the completion of appropriate corrective action and that actions are completed in a timely manner."

Section 17 – Quality Assurance Records

1. Section 17.3, Quality Assurance Records for Operations, does not have clearly defined the commitment to:

   - Have procedures established and documented specifying the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.

   - Have an organization and procedures in place to promptly detect and correct any deficiencies in the records management system or its implementation.

   The two commitments can be found in the previous section, please clarify if these commitments are also applicable to the operations phase.

   MOX Services Response: MPQAP will ensure that these two commitments are also applicable to the operations phase.

2. Please clarify how the facility records management system will be updated to reflect any changes in the license application between the construction approval review and the review for a license to possess and use SNM.

MOX Services Response: The submittal of the LA and subsequent updates reflects any changes since construction approval review.

Section 18 – Audits and Assessments

1. The SRP requires that the internal and external audits to be conducted with a graded approach based on the results of the ISA. Please clarify if the results of the ISA are being considered in the conduct of audits and assessments.
   MOX Services Response: LA Section 15.6, 1st paragraph, has been revised to add text that the results of the ISA are being considered in the conduct of audits and assessments.

2. Section 18.3.4 includes the performance of plant area walkdowns as a method of conducting audits and assessments. Please clarify if these walkdowns include out-of-the way and limited access areas?
   MOX Services Response: Section 15.6.3 (2nd set of bullets) Revised text to change "performing plant area walkdowns" to "performing plant area walkdowns (including accessible out-of-the way and limited access areas)"

3. Please clarify if the audits and assessment program provides for on-the-spot corrective actions with appropriate documentation.

   MOX Services Response: MOX Services will include statement in LA 15.6 (5th paragraph) that states audits and assessment program provides for on-the-spot corrective actions with appropriate documentation in accordance with CAP.

4. Please clarify if technical and programmatic audits and assessments are performed internally and externally to provide a comprehensive independent verification and evaluation of procedures and activities for IROFS.
   MOX Services Response: Revised LA Section 15.6 (4th paragraph) to state that technical and programmatic audits and assessments are performed internally and externally to provide a comprehensive independent verification and evaluation of procedures and activities for IROFS.

5. Please clarify if internal audits will address compliance with selected operating limits during facility operation.

   MOX Services Response: Revised LA Section 15.6 (1st paragraph) to state that "Audits are focused on verifying compliance with regulatory and procedural requirements (including compliance with selected operating limits) and licensing commitments."

6. Section 18.3.3 of the MPQAP states that the audit and assessment schedule is reviewed periodically and revised as necessary to ensure coverage commensurate with current and planned activities. Please clarify if the audit and assessments system will be updated and revised to reflect changes in the license application between the construction approval review and the review for a license to possess and use SNM.

   MOX Services Response: The submittal of the LA and subsequent updates reflects any changes since construction approval review.

7. Please clarify that there are provisions to ensure that any changes in the audits and assessment program will be reviewed and reflected in the program description. Please provide a pointer to where in the MPQAP this information may be found.

   MOX Services Response: LA Section 15.6 was revised to clarify that MPQAP changes are reviewed to ensure that audit and assessment program revisions are reflected in the program description.

Section 19 – Maintenance

1. Please clarify that the PM will ensure the continued safety function of the IROFS even with unplanned outages per Section 15.3.4.3iii of NUREG 1718. Section 19.2.3 of the MPQAP identifies that PM activities will be implemented to ensure the continued safety function of IROFS. Please clarify that the PM activities that will be implemented by MOX will ensure the continued safety function of IROFS, even in the event of unplanned outages.

   MOX Services Response: Added "even with unplanned outages" to Section 15.3.1.2 (1st sentence).

2. Please provide a list of maintenance-related work control methods (*see NUREG 1718, Section 15.3.4.3 (C)*).

   MOX Services Response: LA Section 15.3.3 provides a description of work control process. Note: This section wasn't carried forward previous version of MPQAP.

3. Please explain how the maintenance function will use, will interface with, or will be linked to other management measures control sections.

   MOX Services Response: LA Section 15.3.4 describes the relationship of Maintenance Elements to other Management Measures (note this section wasn't carried forward previous version of MPQAP).

General

1. Please review the MPQAP for references that are out of place, such as those identified in these questions, and make modifications as needed. Such references include those to Section 15, management measures, etc.

   MOX Services Response: Many of these references are no longer applicable since MPQAP Rev 9 will be a stand alone submittal (i.e., not include management measures). However, MPQAP and LA Chapter 15 references will be reviewed for consistency prior to submittal.