

MFFFPEm Resource

From: Tiktinsky, David
Sent: Tuesday, July 21, 2009 8:17 AM
To: Morrissey, Kevin; Matula, Thomas; Jacobs, Frank
Cc: Roman, Cinthya; MFFFHearingFile Resource; Kotzalas, Margie
Subject: FW: Draft Management Measure RAI Responses, Draft LA Chapter 15
Attachments: tech.gif; Mgmt Meas RAIs - Draft Responses 20Jul09.doc; Draft LA Ch 15 Management Measures 20Jul09.doc

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From: Gwyn, Dealis W. [mailto:DWGwyn@moxproject.com]
Sent: Monday, July 20, 2009 11:10 AM
To: Tiktinsky, David
Subject: Draft Management Measure RAI Responses, Draft LA Chapter 15

Dave,

Attached are our draft responses to the Management Measures RAIs. Also, attached is a revised draft Chapter 15. These are being provided to facilitate the Management Measures Draft RAI Response meeting next week.

Dealis

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Hearing Identifier: MixedOxideFuelFabricationFacility_Public
Email Number: 60

Mail Envelope Properties (C56E360E9D804F4B95BC673F886381E71FBC5B57B3)

Subject: FW: Draft Management Measure RAI Responses, Draft LA Chapter 15
Sent Date: 7/21/2009 8:16:42 AM
Received Date: 7/21/2009 8:16:44 AM
From: Tiktinsky, David

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Post Office: HQCLSTR02.nrc.gov

Files	Size	Date & Time
MESSAGE	1192	7/21/2009 8:16:44 AM
tech.gif	927	
Mgmt Meas RAIs - Draft Responses 20Jul09.doc		175682
Draft LA Ch 15 Management Measures 20Jul09.doc		524354

Options

Priority: Standard
Return Notification: No
Reply Requested: No
Sensitivity: Normal
Expiration Date:
Recipients Received: Follow up



MOX Fuel Fabrication Facility Responses to Management Measures Requests for Additional Information

Configuration Management

MM-1

In Chapter 15, Section 15.2.1 of the license application (LA) you commit to apply configuration management to "maintain effective control of the MFFF as-designed and as-built arrangement and operation." However, some commitments discussed in Section 15.2 are not consistent with those presented in the MOX Fuel Fabrication Facility Configuration Management Plan (CMP). Revise Section 15.2 of the LA to address the commitments regarding how the organization(s) responsible for construction, operation, maintenance, modification, testing and decommissioning of the facility will implement the CMP. Revise Section 15.2 of the LA to commit to management support for CM. Consistent with the information in the CMP, provide the definitions for key terminology.

10 CFR 70.72(a) "Facility changes and change process" requires each licensee to establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel.

Reply:

The revision to Section 15.2.1 is consistent with the information presented in the MFFF Configuration Management Plan (CMP). Section 15.2 was revised to describe the organizational responsibility for implementation of configuration management during design, construction, testing, operation, and deactivation. The discussion in Section 15.2 for configuration management, as revised, received management review and approval prior to submittal and therefore represents management support for configuration management. The requirements identified in the MFFF Configuration Management Plan are described in implementing procedures and other project documents that provide detailed implementation directions and work instructions. These procedures and other project documents also receive management review and approval and further demonstrate the management commitment to configuration management. Within Section 15.2, terms have been defined as necessary.

MM-2

In Section 15.2.6.2 of the LA you state that "a technical review allows for evaluation of safety, environmental as well as the identification of affected SSCs and facility documentation." Clarify the description of the configuration review process to describe the evaluation of the changes to the technical basis of SSCs.

10 CFR 70.72(a)(1) "Facility changes and change process" requires the configuration system to be documented in written procedures and that the process assure that the technical basis for the change is evaluated.

Reply:

Section 15.2.5.2, Review and Approval of Changes has been rewritten to provide clarification of the configuration review and approval process.

MM-3

Section 15.2.6.2 of the LA does not address how the configuration management system will track changes to site systems, equipment, components, processes, systems, computer programs, and activities of personnel. Describe how the configuration management system evaluates, implements, and tracks changes to site systems, equipment, components, processes, computer programs, and activities of personnel.

10 CFR 70.72(a) "Facility changes and change process" requires each licensee to establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel.

Reply:

Section 15.2.5, Change Control has been revised to address the change control process.

MM-4

Clarify in Section 15.2 of the LA how the work control processes ensure that work activities are performed correctly and the CM is maintained for documents, procedures, and the physical configuration of the facility.

10 CFR 70.72(a) "Facility changes and change process" requires each licensee to establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel.

Reply:

Section 15.2.5 has been revised to provide additional detail as to how the change control process is implemented for MOX Services.

MM-5

A "graded approach" is a process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with:

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard involved;
- the life cycle stage of a facility;
- the programmatic mission of a facility;
- the particular circumstances of a facility;
- the relative importance of radiological and non-radiological hazards; and
- other relative hazards

Describe in Section 15.2 of the LA how the graded application of management measures applied to the safety program is used to demonstrate compliance to the performance requirements of 10 CFR 70.61. Additionally, describe how the graded approach is applied to the most important equipment or to scenarios which could potentially have serious off-site personnel safety consequences. Discuss how management resources are applied in the CM program for systems that prevent, detect, or mitigate consequences of accidents.

10 CFR 70.62(a)(1) states that each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61. The safety program may be graded commensurate with the reduction of risks attributable to that item.

Reply:

MOX Services does not currently employ a graded approach to the application of management measures.

MM-6

Describe the specific measures taken to eliminate or minimize redundant facility configuration information particularly during modifications to structures, systems, and components.

10 CFR 70.72(a) "Facility changes and change process" requires each licensee to establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel. Additionally, 10 CFR 70.72(a)(6) further states that the impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, shall be developed in accordance with §70.62.

Reply:

Application of configuration management, as identified in Section 15.2 will minimize or eliminate redundant facility configuration information.

MM-7

Describe how the configuration management program objectives incorporate facility configuration information and the elements required to maintain operational configuration.

10 CFR 70.72 require the establishment of a configuration management system that will evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel.

Reply:

Section 15.2.5 was revised to describe that during the operations phase, changes to design will be documented, reviewed, and approved prior to implementation. As discussed in Section 5.1.4 and Section 15.2, MOX Services will implement a change process that fully implements the provisions of 10 CFR 70.72 upon issuance of the MFFF Possession and Use License.

MM-8

Describe the commitments to comply with recognized consensus codes and standards for software acquisition and management.

10 CFR 70.64(a)(1) states that the design must be developed and implemented in accordance with management measures to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Additionally, 10 CFR 70.72 requires the establishment of a configuration management system that will evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel.

Reply:

The MFFF MPQAP, in part, follows the guidance of NQA-1 Subpart 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications. MOX Services implements these requirements through approved project procedures for Acquisition of Computer Software, Software Problem/Error Notice, and Software Development and Acceptance.

MM-9

Explain in Section 15.2 of the LA how the configuration management system is used to evaluate facility changes that may alter the parameters of an accident sequence evaluated in ISA as required by 10 CFR 70.72(d)(1) .

10 CFR 70.72(d)(1) states that for changes that require approval under §70.72, the licensee shall submit an amendment request to the NRC in accordance with §70.34 and §70.65.

Reply:

As discussed in Section 15.2.5, MOX Services will implement the provisions of 10 CFR 70.72. Any change that requires Commission approval as required in 10 CFR 70.72(d)(1), will be submitted as an amendment request in accordance with 10 CFR 70.34 and 10 CFR 70.65.

MM-10

Section 5.1.3 of the LA states that "management measures supplement IROFS by providing the administrative and programmatic framework for these measures." Clarify the meaning of "supplemental" to be consistent with the definition of management measures in 10 CFR 70.4.

10 CFR 70.4 states that management measures mean the functions performed by the licensee, generally on a continuing basis that are applied to items relied on for safety.

Reply:

In Section 5.1.3, the term "supplement" has been replaced with "are applied to" in order to clarify the discussion.

Maintenance

MM-11

Describe in Section 15.3 of the LA the programmatic elements of the maintenance program. Provide a description of the methods used for planning and implementing repairs to IROFS (corrective maintenance), preplanned or periodic maintenance (preventive maintenance), performance monitoring (surveillance/monitoring), and post maintenance testing (functional testing).

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

10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are indentified as IROFS pursuant to §70.61(e) are designed, implemented and maintained as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of §70.61.

Reply:

Section 15.3 was rewritten to describe the programmatic elements of the maintenance program. A description of the program has been provided for the elements of surveillance/monitoring, preventive maintenance, corrective maintenance, and functional testing.

MM-12

Revise Section 15.3.1.1 of the LA to describe the organization that is responsible for the surveillance and monitoring functions that will occur during operation and maintenance. In Section 15.3.1.1 of the LA describe and commit to conducting surveillance/monitoring at specified frequencies to measure the degree to which safety functions or safety controls meet performance specifications.

10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are designed, implemented and maintained as necessary, to ensure they are available and reliable to perform their function when needed to comply with the performance requirements of §70.61.

Reply:

Section 15.3.1.1 was revised to specify that surveillance of IROFS is performed at specified intervals and that the purpose of the surveillance program is to measure the degree to which IROFS meet performance specifications.

MM-13

Describe in Section 15.3.1.1 of the LA how surveillance/monitoring are used in setting preventive maintenance frequencies and determining performance trends for IROFS.

10 CFR 70.62(a)(1) states that each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61.

Reply:

Section 15.3.1.1 was revised to indicate that 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.

MM-14

Describe in Section 15.3.1.1 of the LA how the results derived from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring.

10 CFR 70.62(a)(1) states that each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61.

Reply:

Section 15.3.1.1 was revised to indicate that 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.

MM-15

Revise Section 15.3.1.2 of the LA to describe the objectives of the preventative maintenance function. Explain how the preventative maintenance function will provide reasonable assurance of the reliability and availability of IROFS.

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

10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are designed, implemented and maintained as necessary, to ensure they are “available and reliable” to perform their function when needed, to comply with the performance requirements of 70.61.

Reply:

Section 15.3.1.2 was revised to indicate that 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. Planning for preventive maintenance includes consideration of results of surveillance and monitoring, including failure history. PM also includes instrument calibration and testing.

MM-16

Describe how the results of surveillance monitoring and instrumentation calibration are used in the evaluation of preventative maintenance intervals.

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

10 CFR 70.64(a)(10) states that the design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

Reply:

Section 15.3.1.2 was revised to indicate planning for preventive maintenance includes consideration of results of surveillance and monitoring, including failure history. PM also includes instrument calibration and testing.

MM-17

Revise Section 15.3.1.3 of the LA to describe the criteria for determining the frequency for conducting corrective maintenance of IROFS.

10 CFR 70.64(a)(8) states that the design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed. Additionally, 10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are indentified as items relied on for safety pursuant to §70.61(e) are designed, implemented and maintained as necessary to ensure they are available and reliable to perform their function when needed to comply with the performance requirements of §70.61.

Reply:

As described in Section 15.3.1.3, 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. As such, a predetermined frequency for this maintenance cannot be assigned.

MM-18

Section 15.3.1.4 of the LA does not describe the commitments associated with functional testing program. Commit to evaluate the results of post-maintenance testing and the functional testing of IROFS after corrective or preventive maintenance or calibration. Describe how functional tests are used as a surveillance technique and the applicability of the tests to assure performance of the IROFS.

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

10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are indentified as items relied on for safety pursuant to §70.61(e) are designed, implemented and maintained as necessary to ensure they are available and reliable to perform their function when needed to comply with the performance requirements of §70.61.

Reply:

Section 15.3.1.4 was revised to indicate that 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 IROFS function when required.

MM-19

Revise Section 15.3.2 of the LA to provide a general description of maintenance-related work control methods. Describe how those methods are applied in a structured work control program.

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

10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are designed, implemented and maintained as necessary to ensure they are available and reliable to perform their function when needed to comply with the performance requirements of §70.61.

Reply:

Section 15.3.3 was revised to address how maintenance related work is performed through a coordinated and structured work control process and how modification packages are developed.

MM-20

Revise Section 15.3.3 of the LA to provide a discussion of how the maintenance function uses, interfaces, and is linked to the other seven management measures.

10 CFR 70.62(3)(d) states in part that management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are designed, implemented and maintained as necessary to ensure they are available and reliable to perform their function when needed to comply with the performance requirements of §70.61.

Reply:

Section 15.3.4 has been revised to indicate how maintenance relates to the other seven management measures.

MM-21

Are audits or assessments conducted for the maintenance function? Revise Chapter 15.3.1 of the LA, as necessary, to describe how and when audits or assessments of the maintenance function are conducted.

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

Reply:

Section 15.3.1 was revised to indicate that 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.

Training and Qualification

MM-22

Revise Section 15.4 of the LA to describe the requirements for training and qualification of all personnel.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4 has been rewritten to describe the requirements for training and qualification of plant personnel.

MM-23

Revise Section 15.4 of the LA to include a description of the process used for training and qualification of all personnel.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4 has been rewritten to describe the process used for training and qualification of plant personnel. This process includes organization and management of training, analysis and identification of functional area requiring

training or qualification, position training requirements, basis for and objectives of training, organization of instruction, evaluation of trainee learning, conduct of on-the-job training, systematic evaluation of training effectiveness, personnel qualification, and provisions for continuing assurance.

MM-24

Revise Section 15.4.3 of the LA to describe or reference the commitments to radiation training requirements. Address the commitments as they relate to training and qualification for the standards specified in "ALARA, ASTM -C986, Developing Training Programs for the Nuclear Fuel Cycle, ASTM E1 168, Standard Guide for Radiological Protection Training for Nuclear Facility Workers, and NRC Regulatory Guide 8.10, Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as is Reasonably Achievable."

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.3 was revised to indicate that 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. All 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. Additional radiation training requirements are discussed in Chapter 9.

MM-25

Revise Section 15.4.1 of the LA to describe or reference the training process used to incorporate results from the human factor engineering analysis IROFS for startup, operation, maintenance, and modification to the facility.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.1 has been revised to indicate that 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.

MM-26

Describe or reference in Section 15.4.1 of the LA how the training and qualification program is applied to administrative IROFS. In addition, provide specific commitments on required training for positions or performance activities associated with IROFS. Describe the requirements for the performance training process that is applicable for working with processes that are relied on for safety. Further, state the objectives of the training and describe the training criteria and personnel who will be providing the training or retraining.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

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. 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.

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.

MM-27

Revise Section 15.4.1 of the LA to describe the relationship between job functions and training requirements. Describe the requirements for responsibility, authority, and accountability of

personnel involved in managing, supervising and implementing training. Describe and commit to performance based training as the primary method for analyzing, designing, developing, conducting, and evaluating training.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.2 was revised to indicate that a needs/job analysis is performed and tasks are identified to ensure that appropriate training is provided to 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.

Section 15.4.1 was revised to identify the responsibility, authority and accountability of personnel implementing training. Section 15.4.1 also identifies that MOX Services will employ performance-based training.

MM-28

Revise Section 15.4.1 of the LA to expand on the discussion of how training documents are linked to the configuration management system and how training documents will provide reasonable assurance that the design change and plant modification process are included in the training.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.8 was revised to indicate that training materials are updated prior to use to reflect plant modifications and changes to procedures when applicable.

MM-29

Revise Section 15.4.1 of the LA to describe the process for managing and maintaining individual training information. If the training and qualification program information is maintained by an automated database, describe how the database is maintained.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

10 CFR 70.62(3) requires that records of IROFS failures be kept and updated. Provide a description of how this information will be collected and maintained.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.1 was revised to reflect that 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, job performance, and qualification. Records are maintained on each employee's qualifications, experience, and training. The employee training file shall include records of all 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 are maintained so that they are accurate and retrievable. Training records are retained in accordance with the records management procedures. Training and qualification program 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.

MM-30

Revise Section 15.4.2 of the LA to describe how the need for training is evaluated and how the functional areas requiring training and qualification are identified.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.2 was revised to describe the use of needs/job analysis and interaction with relevant subject matter experts to specify job specific tasks to aid in determining training needs.

MM-31

Revise Section 15.4.4 of the LA to describe process for determining the training content for individual training requirements. Describe how training content is established through needs/job analysis and position description requirements.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.4 was revised to describe how personnel training content is established through needs/job analysis and position description requirements.

MM-32

Revise Section 15.4.4 of the LA to describe the requirements for the knowledge, skills, and abilities that a trainee is required to demonstrate; the conditions under which required actions will take place; and, the standards of performance the trainee is required to achieve at the completion of the training activity. Additionally, revise Section 15.4.4 of the LA to describe and define the review and approval requirements for plans/guides and other training materials before inclusion in the training program requirements and use.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.4 was revised to describe the training requirements and learning objectives including the knowledge, skills, and abilities the trainee should demonstrate and how objectives are used based on job analysis and position specific requirements. Lesson plan development, review and approval is discussed in Section 15.4.5.

MM-33

Revise Section 15.4.5 of the LA to describe how lesson plans and guides are used in classroom training and on-the-job training. Describe the plans/guides used for classroom training and on-the-job training and describe the criteria used for evaluating acceptable trainee performance.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.5 has been revised to discuss the use of lesson plans for classroom and on-the job training. Evaluation of trainee learning is discussed in Section 15.4.6.

MM-34

Revise Section 15.4.7 of the LA to clarify the commitment for conducting on-the-job training for activities that are safety related. Describe how on-the-job training is organized to include the use of performance-based training materials. Describe the training requirements for conducting on-the-job training.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.3.2 has been revised to discuss that technical training, which included on-the-job training, is designed, developed and implemented to assist facility employees in gaining an understanding of applicable fundamentals, procedures, and practices related to IROFS and that technical training is also used to develop manipulative skills necessary to perform assigned work related to IROFS. Section 15.4.7 has been revised to discuss the use of on-the-job training for selected activities. Completion of on-the-job training is demonstrated by task performance, where feasible and appropriate. In addition, the use of task simulations and the use of references, tools and equipment (when the actual task cannot be performed in the work environment) is discussed.

MM-35

Revise Section 15.4.8 of the LA to describe and commit to the process for performing periodic evaluations of individual training programs by qualified individuals to identify program strengths and weaknesses.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.8 was revised to discuss how the training program is evaluated to identify program strengths and weaknesses and that activities are monitored by designated facility personnel. In addition, the QA organization audits the training and qualification system.

MM-36

Revise Section 15.4.8 of the LA to describe how improvements and changes to the training program are systematically initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Section 15.4.8 has been revised to describe the systematic evaluation of training effectiveness and how program effectiveness is maintained through the use of corrective actions.

MM-37

Revise Section 15.4.9 and Section 15.4.2 of the LA to describe the minimum qualification requirements for technical personnel.

10 CFR 70.22 states that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff that engage in the proposed activities in accordance with the regulations.

Reply:

Sections 15.4.9 and 15.4.3 have been revised to describe qualification requirements for technical personnel.

Plant Procedures

MM-38

Revise Section 15.5 of the LA to describe the program commitments for developing written procedures used to control facility operations and IROFS.

10 CFR 70.22 states each application for a license shall contain proposed procedures to protect health and minimize danger to life or property.

Reply:

Section 15.5 has been revised to indicate that approved written procedures are used to control overall facility operations, including IROFS.

MM-39

Revise Section 15.5 of the LA to describe the plant procedure identification process for when plant procedures are needed based on the results derived from the ISA or changes in ISA results.

10 CFR 70.22 states each application for a license shall contain proposed procedures to protect health and minimize danger to life or property.

Reply:

Section 15.5.2.1 has been revised to discuss the identification and preparation of procedures including consideration of ISA results.

MM-40

Revise Section 15.5 of the LA to describe the elements of procedure validation and commit to a method that validates procedures through field tests or other appropriate methods.

10 CFR 70.22 states each application for a license shall contain proposed procedures to protect health and minimize danger to life or property.

Reply:

Section 15.5.2.1 discusses the preparation and validation of procedures through the use of field tests.

MM-41

Describe in Section 15.5 of the LA the program and methods for identifying, developing, approving, implementing, and controlling plant procedures through the quality assurance and configuration management programs. Clarify the mechanisms that will ensure that current procedures are readily accessible by all personnel and are used to control work.

10 CFR 70.22 states each application for a license shall contain proposed procedures to protect health and minimize danger to life or property.

Reply:

Section 15.5 has been revised to address the identification, preparation, approval, revision, implementation and control of procedures. Section 15.5.3 describes that procedural compliance is required and that procedures are readily accessible where needed to perform work.

MM-42

Revise Section 15.5.1.2.3 of the LA to describe the elements of the procedure for dealing with incidents and commit to review all applicable written procedures following an accident, unexpected transient, significant operator error, or equipment malfunction.

NUREG 1718, Section 15.5.4.3.H, provides guidelines for conducting a review of all applicable written plant procedures following an incident and is an acceptable approach for complying with regulatory requirements.

Reply:

Section 15.5.1.2.3 was revised to address responses to incidents and indicate that procedures will be reviewed following an accident, unexpected transient, significant operator error, or equipment malfunction.

MM-43

Describe in Section 15.5.1.1 of the LA the methods for performing procedure reviews and commit to a procedure review frequency not exceeding 5 years. This commitment should be used to ensure the accuracy of administrative and operational procedures described in Sections 15.5.1.1 and 15.5.1.2. In addition, identify the organization responsible for verification of the accuracy of administrative and operating procedures.

NUREG 1718, Section 15.5.4.3.O, provides guidance for conducting periodic reviews of plant procedures to ensure their continued accuracy and usefulness and is an acceptable approach for complying with regulatory requirements.

Reply:

Section 15.5.4 was revised to address the periodic reviews of plant procedures.

MM-44

Revise Section 15.5 of the LA to provide a description of the test control program, including commissioning and preoperational tests. Describe the elements of plant procedures for test control and the criteria for determining when tests are required or how and when testing activities are performed.

10 CFR 70.64(a)(8) states that new facilities must address inspection, testing and maintenance. The design of items relied on for safety must provide for adequate inspection, testing and maintenance to ensure their availability and reliability to perform their function when needed.

Reply:

Sections 15.5.1.2.2 and 15.3.1.4 were revised to address testing of IROFS to ensure their availability and reliability in performing their intended function and describe the test control program.

MM-45

Revise Section 15.5.1.2.2 of the LA to describe the functional elements of plant procedures for maintenance involving IROFS. Discuss corrective and preventive maintenance, functional testing after maintenance and surveillance/monitoring of maintenance activities and include commitments to:

- Control of work by comprehensive facility procedures to be followed by maintenance technicians;
- Pre-maintenance activities including pre-job briefs and reviews of maintenance procedures to verify accuracy and completeness;
- Steps that require notification of all affected parties (operators and supervisors) prior to commencement of maintenance and upon completion; and
- Control of work by comprehensive maintenance procedures.

10 CFR 70.64(a)(8) states that new facilities must address inspection, testing and maintenance. The design of items relied on for safety must provide for adequate inspection, testing and maintenance to ensure their availability and reliability to perform their function when needed.

Reply:

Section 15.5.1.2.2 was revised to address the functional elements of plant procedures for maintenance involving IROFS.

Audits and Assessments

MM-46

Revise Section 15.6 of the LA to describe the major program elements and objectives for conducting audits and assessments. Specify commitments for performance of audits and assessments as described in NUREG-1718, Section 15.6.4.3A (i) - (xiii), or propose an acceptable alternative.

NUREG 1718, Section 15.6.4.3.A.ii, describes guidance for performing assessments. This guidance recommends that the applicant describe the performance of assessments in all areas where the requirements for QA and other management measures are applicable.

Reply:

Section 15.6 has been revised to describe the areas where audits and assessments are conducted in addition to the elements that comprise the conduct of audits and assessments.

Incident Investigations

MM-47

Revise Section 15.7.2 of the LA by describing commitments for investigation of incidents. Describe commitments for determining the root cause(s) of the incident and any generic implications and corrective actions. In addition, describe how the two program functions of incident investigation and corrective action interface with each other.

NUREG 1718, Section 15.7.4.3.A(i) – (iii), describes acceptable guidance for the prompt investigation of incidents.

Reply:

Section 15.7.2 commits to an incident investigation process that includes as one of its elements, a systematic structured approach to determine the specific or generic root cause(s) and generic implications of the problem. The relationship between the corrective action process and incident investigations is also provided.

MM-48

NUREG- 1718, Section 15.7.4.3.A(ii), provides guidelines for monitoring and documenting corrective action effectiveness. Revise Section 15.7.2 of the LA to describe how corrective action effectiveness is monitored and documented through completion. Provide commitments consistent with the NUREG or propose an acceptable alternative.

Reply:

Section 15.7.2 commits to an incident investigation process that includes as one of its elements, a system for monitoring and documenting the completion of appropriate corrective actions.

MM-49

Describe in Sections 15.7.1 and 15.7.2 of the LA how the maintenance of documentation is applied to lessons learned and future operations of the facility. Describe actions taken to assure that the accidents sequences considered the ISA include evaluation of risks associated with accidents of the type actually experienced.

10 CFR 70.62(d) states that each applicant shall establish management measures to provide continuing assurance of compliance with performance requirements of §70.61.

Reply:

Section 15.7 discusses the application of lessons learned as well as how 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.

MM-50

Revise Section 15.7.2 of the LA to describe the process for conducting incident investigations and include the following elements:

- Overall method for investigating incidents which is separate from any required emergency plan (i.e., reasonable, systematic, and structured approach should be used to determine the root cause of incidents and the level of investigation should be graded relative to severity of the incident);
- Functions, responsibility and scope of authority of investigation teams;
- Minimum qualifications of investigation team members (i.e., each team should include at least one process expert and one team member trained in root cause analysis);
- Independence of the investigation process and team members (i.e., the investigation process and the team members should be independent from the line function(s) involved with the incident under investigation and participants should be assured of protection from retribution for participating in investigations);
- Maintenance of auditable records and documentation related to incidents, investigations, and root cause analysis;
- For each incident, preparation of a report that includes a description of the incident, contributing factors, root cause analysis, findings and recommendations;
- Commitments that relevant findings are reviewed with all affected personnel, and reports are made available to NRC upon request;
- Documented corrective actions are taken within a reasonable period to resolve findings from incident investigations.

NUREG 1718, Section 15.7.4.3.B.(i) – (viii), describes acceptable guidance to establish and use a plan for investigating incidents and may be followed or an acceptable alternative can be proposed.

Reply:

Section 15.7.2 has been revised to discuss the various elements of incident investigations.

Records Management

MM-51

Revise Section 15.8 of the LA to describe the records management program objectives, particularly with regard to classified records.

NUREG 1718, Section 15.8.3.B, describes acceptable guidance for handling and storage of classified records. Follow the guidance described in the NUREG or propose an acceptable alternative.

Reply:

Section 15.8 has been revised to address the management of classified records.

MM-52

Revise Section 15.8 of the LA to describe or reference the requirements for records management that relate to 10 CFR Part 19, Notices, Instructions, and Reports to Workers: Inspection and Investigations, 10 CFR Part 20, Standards for Protection Against Radiation, and 10 CFR Part 21, Reporting Defects and Noncompliance.

NUREG 1718, Section 15.8.4.1.A - D, provides guidance for records management and may be used or an acceptable alternative may be proposed.

Reply:

Section 15.8 identifies effluent and dosimetry records as records that are retained. Training records, as discussed in Section 15.4.1, are controlled by the training department.

MM-53

Describe in Section 15.8 of the LA, the commitments that address the updating in the records management system.

NUREG 1718, Section 15.8.4.3.E, describes guidance and acceptable elements for updating the facility records management system to reflect any changes in the license application between the construction approval review and the review for a license to possess and use special nuclear material. This guidance may be followed or an acceptable alternative may be proposed.

Reply:

LA Section 15.8 has been revised to clarify commitments. The revised section reflects any changes since construction approval.

MM-54

Revise Section 15.8 of the LA to describe how records are categorized. Specify which records require controlled access and the procedures used to ensure the records management system remains effective.

10 CFR 70.62(d) states that each applicant shall establish management measures to provide continuing assurance of compliance with performance requirements of §70.61.

Reply:

LA Section 15.8 has been revised to include a discussion of categorization and access control. Audits and Assessments (see LA Section 15.6.1) are used to evaluate the effectiveness of management measures including Records Management.

MM-55

Describe the process for maintaining records of computer codes/computerized data relied on for safety that are used for maintaining readability and usability of older codes and data as computing technology changes.

10 CFR 70.72(a) states that the licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, procedures, systems, equipment, components, computer programs and activities of personnel.

Reply:

LA Section 15.8 has been revised to indicate that procedures are established for the control and management of computer codes over the life cycle of the facility, for computer codes and electronic data used for IROFS.

MM-56

Revise Section 15.8 of the LA to describe the requirements for identifying, storing and protecting quality affecting records.

10 CFR 70.64(a)(1) states that the design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

Reply:

LA Section 15.8 has been revised to address the requirements for identifying, storing and protecting quality affecting records.

Quality Assurance

MM-57

Revise Section 15.1 of the LA to describe and commit to update the MOX Project Quality Assurance Plan for start-up testing, operations and decommissioning.

10 CFR 70.22(f) states in part, that each application for a license to possess and use special nuclear material in a plutonium processing and fuel fabrication plant shall contain, in addition to other information required a description of the quality assurance program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the plant.

Reply:

LA Section 15.1 has been revised to address updating of the MPQAP during start-up, operations and deactivation.

Integrated Safety Analysis (Chapter 5)

MM-58

Revise LA Section 5.2.2.7 of the LA to describe how management measures are applied to individual IROFS.

10 CFR 70.62(2)(d) states that each applicant shall establish management measures to ensure compliance with the performance requirements of §70.61. The measures applied to a particular engineered or administrative control system may be graded commensurate with the reduction of risk attributable to that control or control system. The management measures shall assure that the engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are designed implemented and maintained as necessary to ensure they are available and reliable to perform their safety function when needed.

Reply:

LA Section 5.2.1.6 has been revised to provide a discussion on the application of management measures to individual IROFS.

MM-59

Revise LA Section 5.2.2.7 of the LA to describe how IROFS failure mechanisms will be evaluated and assessed for the impact on reliability and availability.

10 CFR 70.62(3) states that each applicant shall maintain records of IROFS failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of §70.61 are not satisfied.

Reply:

The evaluation and assessment of IROFS failure mechanisms is now provided in LA Section 5.2.1.6 under incident investigations.

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 15.1-1. This table illustrates how the various management measures elements apply to the different IROFS classifications. For the enhanced administrative](#)

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controls (EAC), the specific management measures for the physical device are covered under the active engineered controls (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 MOX Project Quality Assurance Plan (MPQAP) and established in accordance with Title 10 of the Code of Federal Regulations (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 implements the QA program described in the MPQAP. 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-SSCs). 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 ~~maintain effective control of the MFFF as designed and as built arrangement and operation. 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. This provides reasonable assurance that IROFS safety functions are properly controlled, and that changes to the facility are properly addressed, evaluated, and approved, so as not to inadvertently create an unanalyzed condition.

Configuration management is provided throughout facility design, construction, testing, operation and deactivation. Configuration management provides the means to establish and maintain a technical baseline for the facility based on clearly defined requirements. During design, the Vice President – Engineering has responsibility for configuration management through an engineering established design control process. Selected documentation, including the integrated safety analysis (ISA), is controlled under the configuration management system in accordance with procedures associated with design control, document control, and records management. Design changes undergo formal review, including interdisciplinary reviews as appropriate, in accordance with these procedures. This interdisciplinary review includes as a minimum the review for ISA impacts. 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 testing, operation, and deactivation, the Plant Manager has responsibility for configuration management.

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

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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.

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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 all 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, all 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 all 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.

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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 Assurance 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.

~~Configuration management is implemented as an essential part of the design control process meeting the requirements of MPQAP Section 3, *Design Control*. The engineering function generates design documents according to approved procedures that meet the requirements of~~

~~MPQAP Section 5, Instructions, Procedures, and Drawings, and MPQAP Section 3, Design Control. Design documents are distributed for use according to the requirements of MPQAP Section 6, Document Control. Completed design documents are maintained in the records~~

~~management system according to the requirements of MPQAP Section 17, *Quality Assurance Records*. Configuration control of installed SSCs, for example, is assured through MPQAP Sections 7 and 8, *Control of Purchased Material, Equipment, and Services*, and *Identification and Control of Materials, Parts, and Components*, respectively. Audits of the CM program are performed in accordance with MPQAP Section 18, *Audits*. Configuration management processes maintain the design requirements, the design basis documentation, and the facility to as designed and evaluated for safety conditions. Changes to the MFFF are documented, reviewed, and processed in accordance with the requirements of 10 CFR §70.72, as described in Chapter 5.~~

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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.~~

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

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~~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. The MFFF organization is described in Chapter 4. The plant manager is responsible for ensuring the overall successful implementation of the CM program. This includes development and approval of plans and policies necessary to provide overall program direction within MOX Services including identification of management expectations.~~

~~The production function has primary responsibilities for the performance of CM program requirements.~~

15.2.4 Scope of CM Program

~~The scope of configuration management includes all 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.~~

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~~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.~~

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~~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.

~~The MOX Services CM program applies to SSCs and associated documentation whose alteration or modification could affect the facility's licensed design or operation.~~

~~Configuration management requirements are implemented through use of procedures and other MOX Services implementing documents as described in Section 15.5.~~

15.2.5 Training

~~Personnel training requirements are described in Section 15.4.~~

~~15.2.6~~ **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.

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Procedures control changes to the ~~technical baseline~~ 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.

Configuration change control manages changes to approved documents and also is used to manage changes to physical and operational configurations.

15.2.6.115.2.5.1 Identification of Changes

Design requirements and associated design bases are established and maintained by the Engineering organization during design and construction and by the Operations organization 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 Technical Baseline 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.

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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 of the design bases 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.

~~This list will be augmented and maintained current as appropriate as IROFS are identified in more detail during detailed design.~~

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 checked/reviewed by another individual qualified in the same discipline and is reviewed for concept and conformity with the design inputs. 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 ~~check and~~ review, emphasis is placed on assuring conformance with applicable codes, standards and license application design commitments. The individuals in engineering assigned to perform the ~~check and~~ 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 accomplishes 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 ~~all~~ 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 ~~this need is documented, approved in advance by the supervisor's management, and 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~~ provided the supervisor is the only individual in the organization competent to perform the verification. The verification by a supervisor of their own design constraints, design input, or design work would only occur in rare instances. This would occur only when the supervisor is the only individual in the organization competent to perform the verification. These instances are ~~authorized and documented in writing on a case by case basis.~~

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. In all cases, the design verification shall be completed before relying on the item to perform its function, or installation becomes irreversible. Any changes to the design and procurement documents, including field changes, must be reviewed, checked and approved commensurate with the original approval requirements. Proposed changes that can lead to a temporary or permanent change in design requirements or physical configuration are identified. These changes may result in document changes, facility modifications, maintenance changes, or operational changes. Changes to documents controlled under the MOX Services CM program are described adequately to support technical reviews, management reviews, and approvals. Design changes are initiated and processed in accordance with procedures.

Documents included in the CM program are subject to an approval process that includes revision control. Original issue and revisions to documents in the CM program are approved and

~~controlled in accordance with procedures that address design control. MOX Services documents prepared by organizations other than the engineering function that are included in the CM program are also subjected to an approval process that includes a revision control process.~~

~~15.2.6.2~~ 15.2.5.2 **Review and Approval of Changes**

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~~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 A 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 and testing, this 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. also extends to verification that as-built configurations are consistent with the design, and that testing that is specified to demonstrate performance of IROFS is accomplished successfully.~~

~~The MPQAP requires procedures that specify 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.~~

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~~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.~~

~~The MOX Services CM program requires that changes to documents included in the CM program receive an evaluation and approval of the change prior to implementation. A technical review allows for evaluation of safety, environmental, and operational impacts of the change, as well as the identification of affected SSCs and facility documentation. Management review of changes considers design, performance, cost and schedule, compliance with safety requirements, operational effectiveness, logistics support, environmental requirements, and training.~~

~~15.2.6.3~~ 15.2.5.3 **Implementation of Changes**

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~~After design documents have been properly prepared, ~~checked~~, 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 ~~all~~ 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 ~~principal~~ Functional Area Managers. Methods by which this is accomplished include the following:~~

- ~~• Design documents are reviewed by the responsible engineer or authorized representative. As appropriate, subsequent review or waiver of review by the other area engineers is documented.~~
- ~~• Project review 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 ~~principal~~ organizations.~~
- ~~• Reports of nonconformances are transmitted and controlled by procedures. As required by the nonconformance procedure, the QA Manager or designee approves resolution of nonconformances.~~

~~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. Proper identification of procedures and organizational interfaces are major elements of configuration management during the change process. To validate that changes meet the acceptance criteria and are compliant with the design requirements, verification of change implementation is a requirement of configuration control.~~

~~15.2.7~~15.2.6 Document Control

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~~15.2.7.1~~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 (EDMS Documentum). ~~The EDMS 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* ~~in conjunction with dual storage provisions and maintained as hard copy.~~

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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.

~~15.2.7.2~~15.2.6.2 Identification of Documents

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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, ~~etc.~~) 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 ~~the following~~ various documents. For example:

- Design requirements, ~~through the controlled copy of design requirements documents~~
- Design bases, ~~through the controlled copy of the basis of design documents~~
- The integrated safety analysis ~~of the design bases of IROFS~~, through the controlled copies of supporting analyses

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- Nuclear Safety Evaluations
- Nuclear Criticality Safety Evaluations
- Drawings
- Specifications
- Calculations
- Technical Reports
- All Project procedures that are IROFS Procedures involving training
- QA Documents
- Maintenance Documents
- Audit and assessment reports
- Emergency Operating procedures
- Emergency response plans
- System modification documents

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~~To ensure uniformity in the MOX Services CM program, the MFFF document control function has the following responsibilities as they relate to configuration management:~~

- ~~• Receipt, electronic filing, and controlled release of approved documents~~
- ~~• Development of reports to identify approved documents, including those documents released for construction, procurement, or fabrication~~
- ~~• Documents supplied by other, external sources (e.g., vendor or supplier documentation, design input documents) are identified and included in the CM program~~

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~~15.2.8~~15.2.7 Audits and Assessments

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 and system walk-downs. 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.

Audits and assessments are used to help define facility configuration management needs and to measure the implementation of the basic relationships between design requirements, physical configuration, and the operational configuration information. Compliance with CM requirements is then verified through QA audits and assessments as described in the MPQAP Section 18, *Audits*.

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 ~~facility items relied on for safety~~IROFS, measures are implemented to ensure that the quality of ~~these items relied on for safety~~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 ~~facility items relied on for safety~~IROFS and ~~all~~ maintenance activities. The design and implementation of modifications are performed in a manner so as to assure quality is

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~~maintained in a manner commensurate with the remainder of the system which is being modified, or as dictated by applicable regulations. MOX Services 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 designed functions in accordance with the integrated safety analysis (ISA).~~

~~The Maintenance Program uses a graded approach to maintenance of MFFF equipment where the level of maintenance applied is commensurate with the importance of the equipment and functions.—~~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.

~~The following sections describe the primary elements of the MFFF maintenance program.~~

~~The maintenance function is responsible for implementing the maintenance program, working closely with 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.~~

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*.

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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

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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

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degradation, preventive maintenance frequencies are adjusted or other appropriate corrective action is taken.

Surveillances are planned and scheduled systematic procedures conducted at required intervals to monitor the performance of IROFS equipment for assurances they continue to meet their performance specifications, including availability and reliability goals. 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 all 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 all the safety disciplines to determine any impact on the ISA and any updates needed. The results of surveillances are monitored, and when degradation appears, appropriate corrective action is taken, which may include adjustments to the surveillance or preventive maintenance methods and frequencies.

Surveillance procedures prescribe compensatory measures, when required, that are applied during the performance of the surveillance activities.

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. 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 or to nationally accepted calibration techniques, as appropriate) 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 SSC, 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.

All 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 all safety disciplines to determine any impact on the ISA and any whether updates are needed. Preventive maintenance activities are preplanned and scheduled for performance with approved procedures at specified time intervals. Preventive maintenance may include refurbishment, partial or complete overhaul, inspections, and instrument calibrations to ensure the equipment's designed functions, which include availability and reliability goals, will respond as designed. Post maintenance functional tests are performed, as necessary, to confirm equipment functions have been restored to normal conditions.

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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 ~~all~~the safety disciplines to determine any impact on the ISA and whether updates are needed. ~~Corrective maintenance is performed to repair or replace equipment that has unexpectedly degraded below performance requirements or failed. Due to the variety of degraded performance and failures possible, specific procedures may not exist for all possibilities. For this reason, the degraded condition or failure mechanism is evaluated to prescribe the appropriate maintenance procedures necessary to correct the problem, including compensatory measures that may apply during the performance of this maintenance. This maintenance then restores the faulted equipment to the required conditions necessary to perform the designed functions. Restored functions are confirmed with appropriate post maintenance functional tests. Corrective maintenance activities are performed with approved procedures in accordance with the QA program.~~

15.3.1.4 Functional Tests

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. 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.

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

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• Special Testing

Results of surveillance/monitoring activities related to IROFS via the configuration management program will be evaluated by ~~at~~the safety disciplines to determine any impact on the ISA and any updates needed. In general, functional tests of equipment and controls are performed based on the extent of the maintenance activity to ensure that the disturbed functions have been properly restored to their design and safety basis. Functional tests may be used as a surveillance technique, and are applicable to the corrective and preventive maintenance functions. Functional tests are conducted using approved procedures.

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 ~~contractual, regulatory, and~~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 procedures are correct and that personnel have acquired the correct level of technical expertise.

Periodic testing at the facility consists of that testing conducted on a periodic basis to monitor various facility parameters and to verify the continuing integrity and capability of IROFS.

Special testing at the facility consists of that testing which does not fall under any other testing program. This testing is of a non-recurring nature and is intended to enhance or supplement existing operational testing rather than replace or supersede other testing or testing programs.

Preoperational Testing

Preoperation functional tests 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.

The Preoperational testing program comprises three parts:

- ~~Constructor turnover~~
- ~~Preoperational functional testing~~
- ~~Initial start up testing.~~

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Constructor Turnover

The constructor turnover test ensure that construction activities were performed in accordance with approved and issued design documents, industry practices, codes and standards, and to confirm that vendors have met or exceeded contractual quality requirements. As systems or portions of systems are turned over to Operations, preoperational testing shall begin.

Preoperational Functional 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. The preoperational test plan including test summaries for all systems is available to the NRC at least 90 days prior to the start of testing. Subsequent changes to the preoperational test plan are also made available to the NRC. Preoperational testing as a minimum includes all system or component tests required by the pertinent design code which were not performed by the constructor prior to turnover. In addition, preoperational tests include all testing necessary to demonstrate that the IROFS are capable of performing their intended function.

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 (QualityA Level 1) and certain QualityA 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 all IROFS.

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The use of properly reviewed and approved test procedures is required for all 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 preoperation functional tests. AHM 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 all Functional Area Managers to ensure that all 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 Shift Operations Manager and the Licensing Manager ensures that all 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 for all departments.

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.

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The facility periodic test program verifies that the facility:

- Complies with all 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 all 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 never not dependent on the performance of an IROFS that has not been tested within its specified testing interval. 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, the responsible department promptly notifies the on-duty Shift Manager and processes the condition in accordance with the Corrective Action Program. The responsible department lists the earliest possible date the test could be performed and the latest date along with the required system or unit mode condition. However, the responsible department will ensure that the test is performed as soon as practical once required conditions are met, regardless of the estimated date given earlier appropriate actions will be taken.

Periodic testing and surveillance associated with Quality A 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.

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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.

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15.3.2 Measuring and Test Equipment

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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.

~~15.3.2~~ 15.3.3 Work Control

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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 ~~functions~~ various organizations, such as radiation protection, safety, operations and others, as necessary, for complete pre-planning of the required work. ~~Coordinated w~~ Work support functions ~~coordinated~~ 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.

~~15.3.3~~ 15.3.4 Relationship of Maintenance Elements to Other Management Measures

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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.

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

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15.5.15.4 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.

The MPQAP provides training and qualification requirements, during the design, construction, and operations phases, for QA training of personnel performing Quality A 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 may be a graded approach that applies the level of detail needed relative to safety. A graded approach incorporates other acceptable methods to accomplish the analysis, design, development, implementation, and evaluation of training. Training and qualification of plant personnel is essential to the safe and successful design, construction, testing, and operation of the MFFF. Training of plant personnel is commensurate with the complexity of assigned tasks. Personnel are trained in the specific project and plant procedures identified by their supervisors as being needed for their assigned tasks. Training and retraining (e.g., to maintain proficiency or when changes to work methods, technology, or job responsibilities occur) meet the requirements of MPQAP paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*. Training records are maintained in the records management system in accordance with the requirements of MPQAP Section 17, *Quality Assurance Records*.

15.5.15.4.1 Organization and Management of Training

Line managers have responsibility for and authority to develop and effectively conduct training for their personnel. Line managers are responsible for the content and effective conduct of training for their personnel. Training responsibilities for line managers are included in position descriptions, and line managers are given the authority to implement training for their personnel. The training function organization provides support to line managers by facilitating the planning, direction, development, conduct, evaluation, and control of a systematic performance-based training process, which may include a graded approach that fulfills job-related training needs.

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~~Performance-based training is used as the primary management tool for 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. ~~indoctrination and training of personnel performing activities relied on for safety.~~ 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, job performance, and qualification. Records are maintained on each employee's qualifications, experience, and training. The employee training file shall include records of all 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 are maintained so that they are accurate and retrievable. Training records are retained in accordance with the records management procedures. ~~Training records are maintained to support management information needs associated with personnel training, job performance, and qualifications.~~ Training and qualification program 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. Continuing training courses shall be established when applicable to ensure that personnel remain proficient. The training may consist of periodic exercises, instruction, and review of subjects as appropriate to maintain proficiency of personnel assigned to the facility.

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15.5.215.4.2 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 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 ~~function~~ 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.

15.5.315.4.3 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. All 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. All personsPeople 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:

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- 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, 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. 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. The training may consist of periodic exercises, instruction, 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 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.

15.5.415.4.4 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

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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.

15.5.515.4.5 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 ~~function~~organization. Lesson plans are reviewed by the training ~~function-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.

15.5.615.4.6 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.

15.5.715.4.7 Conduct of On-the-Job Training

On-the-job training is used in combination with classroom training~~In addition to appropriate classroom training, on-the-job training is used~~ for selected activities when appropriate. On-the-job training is conducted by personnel who are competent in the 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.

15.5.815.4.8 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. Under the direction of the training function, 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. These evaluations identify program strengths and weaknesses, determine if program content matches current job needs, and determine if corrective

~~actions are needed to improve the program's effectiveness. The training function is responsible for leading the training program evaluations and for implementing 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.

15.5.915.4.9 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 given-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 given-provided in Chapter 4.

15.5.1015.4.10 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.

~~15.6~~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. 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. [StopTime-work-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*.

~~15.6.1~~ 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.

~~15.6.1~~ 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
- Reporting
- Quality Assurance
- Equipment control (lockout/tagout)
- Shift turnover
- Work control
- Procedure management
- Nuclear criticality safety
- Fire safety
- Radiation protection
- Radioactive waste management
- Environmental protection
- Chemical process safety

- Calibration control

~~15.6.1~~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. 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:

- ~~Overall Operating Rules~~—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

~~15.6.1.2.1~~15.5.1.2.1 **Production Procedures**

Production procedures control process operations and apply to utility, workstation, and control room operations ~~identified in the MFFF ISA as IROFS~~.

Production procedures contain the following elements, as applicable:

- Purpose of the activity
- Policies and guidelines governing the procedure
- Type of procedure
- Steps for each operating process phase
- ~~Initial~~[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

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- 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

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~~15.6.1.2.2~~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 function 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.

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.

~~15.6.1.2.3~~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.

~~15.6.2~~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

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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 all procedures. Applicable safety limits associated with IROFS are clearly identified in the procedures.

~~15.6.2.1~~ 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 ~~functional~~ 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.

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~~15.6.2.2~~ 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.

~~15.6.2.3~~ 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.

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~~15.6.3~~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.

~~15.6.4~~15.5.4 Control of Procedures

Following approval, plant procedures are processed for entry into the 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, processes, verification, changes, and approval.

To ensure technical accuracy, radiation protection procedures, respiratory protection procedures, operating and maintenance 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.

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~~15.7~~15.6 AUDITS AND ASSESSMENTS

MOX Services maintains the program for audits and assessments described in the MPQAP, Section 18, *Audits*. 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 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, 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

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- Independent Assessments conducted by individuals not involved in the area being assessed.

Audits of the Quality Assurance Level 1 work activities and items required to satisfy regulatory requirements for which Quality Assurance 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.

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. 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

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- 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. ~~MAI~~ 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 ~~quarterly~~ such that ~~all~~ 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 ~~at least semi~~ 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.

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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
- Reviewing controlling plans and procedures
- Observing work in progress
- Reviewing completed QA documentation.

Audit and assessment results are tracked in the Corrective Action Program. 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.

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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.

15.8.15.7 INCIDENT INVESTIGATIONS

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

15.8.15.7.1 Corrective Action Process

The MFFF Corrective Action Process is used for identifying, investigating, reporting, tracking, correcting, and preventing recurrence of conditions adverse to quality. It is performed in accordance with MPQAP Section 16, *Corrective Action*. The corrective action program provides a method for raising, evaluating, resolving and trending issues that may affect safety, quality, regulatory compliance, reliability, human performance or project performance. 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.

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~~15.8.2~~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. Incident investigations are less formal than the Corrective Action Process. 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 Corrective Action Process (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 CAP procedures. Radiological, criticality, hazardous chemical, other ISA related and industrial safety requirements shall be addressed. Guidance for classifying occurrences shall be contained in CAP 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 within five working days of the following completion of the investigation.
2. Qualified internal or external investigators 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

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description, contributing factors, a root cause analysis, findings, and recommendations. Relevant findings are reviewed with all-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 all-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 actions. Upon completion, a report on the incident and its investigation is made to the production manager, who initiates appropriate action(s), if determined necessary.

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15.915.8 RECORDS MANAGEMENT

MFFF records are managed in accordance with the records management program described in MPQAP Section 17, *Quality Assurance Records*. 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.

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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. ~~.....maintaining readability and usability of older codes and data as computer technology changes. For example, procedures allow older forms of information and codes for older computing equipment to be transferred to contemporary computing media and equipment. (SRP states, "For records consisting of computer codes/computerized data relied on for safety, the application should establish and describe procedure(s) for maintaining readability and usability of older codes/data as computing technology changes.") G. Bell/R. Alley to clarify.~~

The Records Center maintains control over access and use of records entered into the Electronic Document Management System (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;

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- 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.

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Tables

Table 15.1-1. Management Measures for IROFS

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

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Table 15.1-1. Management Measures for IROFS (Continued)

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

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Table 15.1-1. Management Measures for IROFS (Continued)

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

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

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