

MFFFPEm Resource

From: Tiktinsky, David
Sent: Wednesday, September 30, 2009 4:38 PM
To: Kotzalas, Margie; Morrissey, Kevin; Roman, Cinthya; Arroyo, Damaris
Cc: MFFFHearingFile Resource
Subject: FW: DCS-NRC-000248
Attachments: DCS-NRC-000248.pdf

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From: Mulcahy, Terri N. [mailto:TNMulcahy@moxproject.com]
Sent: Wednesday, September 30, 2009 2:58 PM
To: Tiktinsky, David
Subject: DCS-NRC-000248

Attached please find letter DCS-NRC-000248, Responses to a Request for Additional Information Regarding the Review of the Management Measures Aspects of the License Application and Integrated Safety Analysis Summary.

Regards,

<<DCS-NRC-000248.pdf>>

Terri Mulcahy

Manager, Engineering Administrative Services

Shaw AREVA MOX Services, LLC

Savannah River Site

PO Box 7097

Aiken, SC 29804-7097

803.819-2911(P)

803.819.8941 (F)

tnmulcahy@moxproject.com

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Sent Date: 9/30/2009 4:38:18 PM
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From: Tiktinsky, David

Created By: David.Tiktinsky@nrc.gov

Recipients:

"MFFFHearingFile Resource" <MFFFHearingFile.Resource@nrc.gov>
Tracking Status: None
"Kotzalas, Margie" <Margie.Kotzalas@nrc.gov>
Tracking Status: None
"Morrissey, Kevin" <Kevin.Morrissey@nrc.gov>
Tracking Status: None
"Roman, Cinthya" <Cinthya.Roman@nrc.gov>
Tracking Status: None
"Arroyo, Damaris" <Damaris.Arroyo@nrc.gov>
Tracking Status: None

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Expiration Date:
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DCS-NRC-000248
30 September 2009

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJECT: Docket No. 070-03098
Shaw AREVA MOX Services
Responses to a Request for Additional Information Regarding the
Review of the Management Measures Aspects of the License
Application and Integrated Safety Analysis Summary

REFERENCE: 1. Letter from Kevin Morrissey to Dealis Gwyn dated March 26,
2009 entitled "Request for Additional Information Regarding the
Review of the Management Measures Aspects of the License
Application and Integrated Safety Analysis Summary for the
Mixed Oxide Fuel Fabrication Facility"

Shaw AREVA MOX Services hereby responds to the Request for Additional Information (RAI) contained in Reference 1. Our response to the RAIs is contained in the Enclosure. The License Application (LA), which includes associated LA changes, will be transmitted under separate cover.

If you have any questions, please contact Dealis Gwyn, Licensing and Regulatory Compliance Manager, at (803) 819-2780.

Sincerely,

A handwritten signature in black ink, appearing to read "D Stinson". The signature is fluid and cursive, with a large initial "D" and a long horizontal stroke at the end.

David Stinson
President and COO

Attachment: Response to Request for Additional Information Regarding the Review of the Management Measures Aspects of the License Application and Integrated Safety Analysis Summary for the Mixed Oxide Fuel Fabrication Facility

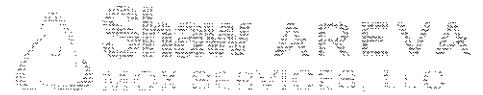
cc: (w/ attachment)

David Tiktinsky, USNRC/HQ
EDMS: Corresp\Outgoing\NRC\2009 NRC\DCS-NRC-000248

cc: (w/o attachment)

Roger Alley, MOX Services
Eric Chassard, MOX Services
Mostafa Dayani, NNSA/SRS
Carol R. Elliott, NNSA/SRS
Walter Elliott, MOX Services
Sam Glenn, NNSA/SRS
William Gloersen, USNRC/RII
Dealis Gwyn, MOX Services
William Hennessy, MOX Services
Anna Johnson, MOX Services
Dave Kehoe, MOX Services
Jean Michel Marin, MOX Services
Kevin Morrissey, USNRC/HQ
Deborah Seymour, USNRC/RII
Donald Silverman, Esq., ML&B LLP

DCS-NRC-000248
Attachment
30 September 2009



Attachment

**Response to Request for Additional Information Regarding the
Review of the Management Measures Aspects of the License
Application and Integrated Safety Analysis Summary for the Mixed
Oxide Fuel Fabrication Facility**

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.

MM-1 Response:

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.

MM-2 Response:

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.

MM-3 Response:

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.

MM-4 Response:

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.

MM-5 Response:

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.

MM-6 Response:

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.

MM-7 Response:

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.

MM-8 Response:

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.

MM-9 Response:

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.

MM-10 Response:

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 identified 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.

MM-11 Response:

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.

MM-12 Response:

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.

MM-13 Response:

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.

MM-14 Response:

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.

MM-15 Response:

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.

MM-16 Response:

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.

MM-17 Response:

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.

MM-18 Response:

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.

MM-19 Response:

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.

MM-20 Response:

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.

MM-21 Response:

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.

MM-22 Response:

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.

MM-23 Response:

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.

MM-24 Response:

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.

MM-25 Response:

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.

MM-26 Response:

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.

MM-27 Response:

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.

MM-28 Response:

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.

MM-29 Response:

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.

MM-30 Response:

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.

MM-31 Response:

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.

MM-32 Response:

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.

MM-33 Response:

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.

MM-34 Response:

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.

MM-35 Response:

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.

MM-36 Response:

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.

MM-37 Response:

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.

MM-38 Response:

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.

MM-39 Response:

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.

MM-40 Response:

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.

MM-41 Response:

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.

MM-42 Response:

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.

MM-43 Response:

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.

MM-44 Response:

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.

MM-45 Response:

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.

MM-46 Response:

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.

MM-47 Response:

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.

MM-48 Response:

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.

MM-49 Response:

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.

MM-50 Response:

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.

MM-51 Response:

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.

MM-52 Response:

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.

MM-53 Response:

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.

MM-54 Response:

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.

MM-55 Response:

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.

MM-56 Response:

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.

MM-57 Response:

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.

MM-58 Response:

LA Section 5.2.5 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.

MM-59 Response:

The evaluation and assessment of IROFS failure mechanisms is now provided in LA Section 5.1.5.