Shaw | AREVA
MOX SERVICES, LLC

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

DCS-NRC-000344
01 April 2013

Subject: Docket Number 070-03098
Shaw AREVA MOX Services
Mixed Oxide Fuel Fabrication Facility
Submittal of MPQAP Revision 11, Change 2

RE: NRC-DCS-000669, letter from David Tiktinsky to Dealis Gwyn, dated March 11, 2013, Second Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility

Shaw AREVA MOX Services, LLC (MOX Services) hereby submits to the U.S. Nuclear Regulatory Commission (NRC) for review and approval MPQAP Revision 11, Change 2. MPQAP Revision 11, Change 2 was developed in response to the referenced NRC Requests for Additional Information (RAIs) regarding MPQAP Revision 11, Change 1. Also, included are the responses to the subject RAIs (Enclosure 2).

In preparing the responses to the RAIs, MOX Services developed an applicability matrix for the existing MPQAP requirements that remain applicable to QL-1LR Items Relied on for Safety (IROFS). This applicability matrix has been included as part of Attachment B of the MPQAP to facilitate a common understanding of applicable MPQAP requirements to QL-1LR IROFS. In addition, with the inclusion of the QL-1LR criteria and a defined Augmented QA program in the MPQAP as project commitments, MOX Services eliminated the commitment to notify the NRC of any IROFS using the Augmented QA program. Consistent with other commitments in the MPQAP, these items may be the subject of future NRC inspections.

In order to preclude an impact to ongoing construction and procurement activities, MOX Services respectfully requests a timely review of the revised MPQAP by 01 May 2013.

P. O. Box 7097, Aiken, SC 29804-7097/Savannah River Site, F-Area, Building 706-5F, Aiken, SC 29808

If you have any questions, please feel free to contact me at (803) 819-2156 or Dealis Gwyn, Licensing and Nuclear Safety Manager, at (803) 819-2780.

Sincerely,

Kelly Trice

Kelly D. Trice
President and COO

Enclosures:

(1) MOX Project Quality Assurance Plan, Revision 11, Change 2
(2) MOX Services Response to Second Request for Additional Information regarding MPQAP Rev. 11, dated March 11, 2013

cc (w/encl):

David Tiktinsky, USNRC/HQ

cc (w/o encl.):

Mark Gober, MOX Services
Sam Glenn, NNSA/SRS
William Gloersen, USNRC/RII
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EDMS: Corresp\Outgoing\NRC\2013 NRC\DCS-NRC-000344

Enclosure 1

MOX Project Quality Assurance Plan, Revision 11, Change 2

Shaw AREVA MOX Services, LLC

MOX Project

Quality Assurance Plan

Docket Number 070-03098

Revision 11

Change 2

Prepared by

Shaw AREVA MOX Services, LLC

Under

U. S. Department of Energy

Shaw | AREVA
MOX SERVICES, LLC

QUALITY ASSURANCE PROGRAM
POLICY STATEMENT
7 June 2010

It is the policy of MOX Services to design, construct and operate the MOX Fuel Fabrication Facility (MFFF) so that it can be maintained and operated in such a manner to ensure the health and safety of the public, the personnel onsite, and protect the environment. One way to accomplish this critical objective is to have an aggressive and comprehensive QA program in place for those activities that can impact safety and quality.

One of the fundamental aspects of any quality assurance (QA) program is that the individuals performing the work determine the quality that is achieved. Though plans, procedures, and instructions are a basic part of any quality program, it should be recognized that people make quality happen. Each individual, when properly trained and motivated, must achieve the highest quality of performance of which he or she is capable.

The MOX Services President has directed the establishment of a formal and comprehensive QA program for the project. This program places accountability for quality on each person working on the project. In addition, it emphasizes the creation of an atmosphere in the workplace where the reporting and resolution of conditions adverse to quality are encouraged and expected at all levels.

QA objectives shall not be subordinate to cost or schedule objectives. To ensure compliance with the QA program requirements, independent verifications and assessments shall be conducted to provide management a measure of the program's effectiveness and adequacy in meeting the requirements of the QA program and its' implementing procedures and instructions.

MOX Services personnel are given authority commensurate with their responsibility, including the authority to call "time-out" (stop work) when work does not conform to established requirements. Time-out authority, including investigation, resolution, completion of corrective actions and authorization for resumption of work, is to be exercised in accordance with approved procedures.

This program has my total support and is to be followed at all times. Compliance with the provisions of this QA Program is mandatory. The authority to administer the MOX Services QA Program described in the MPQAP and QA procedures is assigned to the MOX Services Manager Project Assurance who reports directly to me.

All matters concerning quality that cannot be resolved at the normal organizational interfaces shall be referred to me for final resolution.

Kelly Trice

Kelly Trice
President & Project Manager

P. O. Box 7097, Aiken, SC 29804-7097/Savannah River Site, Road 2, Bldg. 730-2B, Aiken SC 29808

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Revision 11 Change 2 was initiated to clarify the MOX Services approach to an Augmented QA Program for IROFS (Low Relative Importance to Safety).

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 11
Section 2	• Sections 2.2.G and 2.2.3.C were revised in response to the NRC request for additional information. Letter from David Tiktinsky to Dealis Gwyn, dated March 11, 2013, Second Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility.
Section 7	• Sections 7.2.8 and 7.2.10 (added) were revised in response to the NRC request for additional information. Letter from David Tiktinsky to Dealis Gwyn, dated March 11, 2013, Second Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility. Section 7.2.6.2 clarified regarding CMTR/MTR requirements for QL-1LR.
Attachment B	• Attachment B was revised in response to the NRC request for additional information. Letter from David Tiktinsky to Dealis Gwyn, dated March 11, 2013, Second Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility.

Revision 11 Change 1 was initiated to clarify the MOX Services approach to an Augmented QA Program for IROFS (Low Relative Importance to Safety).

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 11
Attachment B	• Attachment B was revised in response to the NRC request for additional information. Letter from David Tiktinsky to Dealis Gwyn, dated July 31, 2012, Request for Additional Information regarding the review of the MOX Project Quality Assurance Plan, Revision 11 for the Mixed Oxide Fuel Fabrication Facility.

Revision 11 was initiated to clarify the MOX Services approach to an Augmented QA Program for IROFS (Low Relative Importance to Safety).

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 11
Sections 2	• Revised paragraph 2.2.G to add a paragraph to define the term QL-1LR. • Revised paragraph 2.2.3.C to clarify that a list of QL-1 IROFS using an augmented QA program will be periodically transmitted to the NRC.
Section 4	• Added paragraph 4.2.1.J to direct the user to Attachment B for procurement requirements for QL-1LR items.
Section 7	• Added paragraph 7.2.2.E to direct the user to Attachment B for exceptions and clarifications fo supplier requirements for QL-1LR items.
Section 10	• Added paragraph 10.2.2.D to direct the user to Attachment B for inspection exception for QL-1LR installations.
Section 17	• Added "Safety Ranking Evaluation Reports" to "Figure 17-1: Examples of Typical Lifetime QA Records"
Section 18	• Added paragraph 18.2.3.D to address that audits are being focused on high importance to safety IROFS.
Attachment B	• Attachment B was added to address the MOX Services Augment QA Program for IROFS (Low Relative Importance to Safety)

Revision 10 Change 1 was initiated in response to the Safety Evaluation Report (SER) received from the NRC on the MPQAP Rev 10 which had been submitted to review.

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 10 Change 1
Sections 2	• **Deleted sentences 2 and 3 from Section 2.1.1, Third Paragraph as requested in the letter from the NRC dated June 17, 2011 with subject "Partial Approval of Changes to the Mixed Oxide Project Quality Assurance Program, Revision 10"**
Attachment A	• **Deleted First Paragraph in the Attachment as requested in the letter from the NRC dated June 17, 2011 with subject "Partial Approval of Changes to the Mixed Oxide Project Quality Assurance Program, Revision 10"**

Revision 10 was initiated to revise and update organization names and responsibilities to reflect the current MOX Project Organization.

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 10
Section 1, 4, 8, 9, 10, 13, 15	• **Added title of Regulatory Guide 1.28 Revision 3 – editorial change**
Section 2, 3, 5, 6, 11, 12, 16, 17	• **Added "and" in sentence prior to Regulatory Guide 1.28 (Rev.3) – editorial change**
Section 1	• **Changed "Manager Project Assurance" to "VP Project Assurance" in several places and changed "Manager ES&H" to "VP ES&H". Changed the Organizational charts to reflect the change in titles.** • **Section 1.2.2, Fourth paragraph – added that the QA/QC Manager has direct access to the Project Manager.**
Section 2	• **Section 2.1.1, Third paragraph - added clarification to describe how MOX Services will address Codes and Standards when the previous edition has been cancelled or superceded. The rationale for this change is described as follows: (1) ASME NQA-1, Part II, Introduction assigns the user responsibility for ensuring proper utilization of the requirements of the subparts; and (2) The Subparts have not always been updated as evidenced by Subpart 2.5 - as an example, this subpart has not been used in several years and consequently has not been revised to address the current methods, practices and industry standards surrounding soil placement . Further, this is consistent with the lower safety significance of fuel facilities compared to nuclear plants as recognized by NRC and documented in other NRC correspondence such as Digital Instruments & Controls (DI&C-ISG-07), Introduction section. Based on the above MOX Services considers the change to be reasonable and prudent.**

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 10
Section 3	• **Section 3.2.7.I – corrected numbering – editorial change** • **Section 3.2.7.A – revised to clarify that software is developed and controlled by activities.** • **Section 3.2.7 – revised several areas to replace the word "phase or phases" with "activity or activities". – editorial changes** • **Section 3.2.7.B – revised to reflect control of activities during the software development.**
Section 7	• **Section 7.2.2.C 4) – added clarification on calibration suppliers accepted by the NRC (reference from Mr. Patrick L. Hiland, Director Division of Engineering, Office of Nuclear Reactor Regulation, to Mr. R Douglas Leonard, Jr. Managing Director Laboratory Accreditation Bureau, dated April 22, 2008)** • **Section 7.2.8.A.1 – Changed "would" to "could" to align with the definition of Basic Component in 10CFR21.**
Section 10	• **Section 10.2.3 Statistical Sampling – corrected the numbering to Section "10.2. 4 Statistical Sampling" – editorial change**
Section 14	• **Section 14.2.2.B – removed and extra "s" from the end of the sentence – editorial change** • **Section 14.2.2.C – corrected the spelling of "Status" – editorial change**
Section 17	• **Section 17.2.4.A – deleted "and" from 17.2.4.A 8) and added "and" to Section 17.2.4.A 9) – editorial change**
Attachment A	• **Added to Attachment A - added clarification to describe how MOX Services will address Codes and Standards when the previous edition has been cancelled or superceded. The rationale for this change is described as follows: (1) ASME NQA-1, Part II, Introduction assigns the user responsibility for ensuring proper utilization of the requirements of the subparts; and (2) The Subparts have not always been updated as evidenced by Subpart 2.5 - as an example, this subpart has not been used in several years and consequently has not been revised to address the current methods, practices and industry standards surrounding soil placement . Further, this is consistent with the lower safety significance of fuel facilities compared to nuclear plants as recognized by NRC and documented in other NRC correspondence such as Digital Instruments & Controls (DI&C-ISG-07), Introduction section. Based on the above MOX Services considers the change to be reasonable and prudent.**

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 10
Attachment A	• **Added exception to SUBPART 5.2 (c)** **Justification - ASTM D1557 and D698 are the "industry standards" used to determine maximum dry density of a soil at an optimum moisture content and one is chosen as the basis for specifying the compaction control of placed fill materials. The difference in these two methods is the compactive effort used during the determination of the moisture-density relationship. For the purposes of construction at the MOX site, the higher compactive effort test is specified (ASTM D1557) for use in compaction control. This test is acceptable if well-defined moisture-density curves are obtained on the samples of fill material proposed for use. MOX Services has seen well-defined moisture density curves for the fill used at the site.** **ASTM D4253 and D4254 are soil type specific tests used to determine the maximum and minimum densities of a cohesionless, free-draining soil, with less than 15% fines. Maximum and minimum density testing is used when the soil does not provide clear moisture-density relationships due to their gradation characteristics. Published data indicates that the results of ASTM D4253 and D4254 have a high degree of variability, making their results much less reliable than ASTM D1557.** **Maximum and minimum density determinations using ASTM D4253 and D4254 are performed when relative density is used as a guide for density control of placed materials. It is important to note that percent relative density (using ASTM D4253 and D4254) is not the same as percent maximum dry density per ASTM D1557. Relative density is determined by the equation:** $$Dd = \gamma dmax\ (\gamma d - \gamma dmin)/\gamma d\ (\gamma dmax - \gamma dmin)$$ **Relative density expresses the degree of compactness of a cohesionless soil with respect to the loosest and densest condition as defined by standard laboratory procedures. An absolute minimum density is not obtained by ASTM D4254.** **In conclusion, since the MOX Services fill material shows a well defined moisture-density relationship, MOX Services will use test method ASTM D1557. ASTM D4253 and D4254 are not applicable to the current soils being used by MOX Services. If MOX Services uses soils for backfilling operations that are cohensionless, free-draining soils with fines less than 15%, such as pure sand, then referenced standards of ASTM D4253 and D4254 will be used.**

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 10
Attachment A	• **Added clarification to SUBPART 2.5, Section 5.3 and 5.5(e)** **Justification - Detailed requirements for compaction equipment used to compact material within utility trenches are usually not included in construction specifications. This is due to the fact that the type of equipment used is dependent on the accessibility of the area being backfilled and for trenches; the equipment is usually much smaller than that used for large backfilling operations, as may be the case for structures. The requirements within the specification used at MOX are clear regarding the lift thickness and the required degree of compaction. Additionally, the use of hand tampers and vibratory compactors is stated within the specification. The specification for utility trenches will also contain requirements for the implementing entity (Contractor or MOX Construction Services) to prepare a backfill plan. This plan shall take into account the specified lift thickness, the materials to be used in backfill operations, the equipment required, the minimum number of passes to be specified, and the minimum overlap of the passes to achieve the specified compaction. This plan will be written and during the first lift of backfill work, it will be validated or changed as appropriate. Further, the specification indicates that the inspection report shall contain information regarding the compaction equipment used and number of passes. If the desired compaction is not achieved, then the placement is rejected and additional measures (different equipment, more passes, etc.) are implemented to achieve satisfactory compaction. Therefore, we make these clarifications to the requirement to include details regarding compaction equipment as stated in Items 6 and 7 for utility backfill operations.**

INTRODUCTION

This Introduction identifies the basis of the Shaw AREVA MOX Services, LLC (MOX Services) Quality Assurance (QA) Program and includes background information relative to the MOX Services QA Program and its application to the overall project. The Introduction does not contain requirements or commitments for MOX Services implementation of QA requirements. The requirements and commitments are contained in Sections 1 through 19 of this document.

The consortium of Shaw Project Services Group, Inc., Shaw Environmental and Infrastructure and AREVA NC Inc., has formed a Limited Liability Company called Shaw AREVA MOX Services, LLC (MOX Services) to assist the U.S. Department of Energy (DOE) in their mission of disposing of US owned, surplus, weapons-usable plutonium in accordance with DOE Contract No. DE-AC02-99CH10888. MOX Services is the licensee for the construction and operation of the Mixed Oxide (MOX) Fuel Fabrication Facility. This MOX Project Quality Assurance Plan (MPQAP) establishes the quality assurance requirements and management measures to control quality-affecting activities related to the design, construction, and operation of Fuel Fabrication Facilities licensed under Title 10 Code of Federal Regulations (CFR) Part 70 (10CFR70). 10CFR70 requires a QA Program meeting the requirements of Title 10 CFR Part 50 (10CFR50), Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.*

QA Program Basis

As identified in Paragraph 2.1, this document complies with 10CFR50, Appendix B and applies to all levels of the organization who perform quality-affecting activities. "Quality-affecting" means deeds, actions, processes, tasks or work which influence the achievement or verification of quality requirements and objectives necessary for 1) fabrication and delivery of MOX fuel assemblies to the mission reactors and 2) Quality Level 1 and 2 structures, systems and components (SSCs) and their associated activities. Quality Levels are defined in Paragraph 2.2.2.

Applicable requirements from Parts I and II of ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications*, as revised by NQA-1a-1995 Addenda; Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)* and Regulatory Guide 1.33 (Rev.2), *Quality Assurance Program Requirements (Operation),* were used in conjunction with 10CFR50, Appendix B to develop the quality assurance requirements for the MOX Services QA Program. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2). This MOX Project Quality Assurance Plan describes MOX Services' overall commitments to 10CFR50 Appendix B and ASME NQA-1.

The Quality Assurance Program Policy Statement, MOX Project Quality Assurance Plan, and QA procedures make up the MOX Services QA Program. MOX Services Quality Assurance oversight verifies: that work activities are performed in compliance with committed QA requirements; performed in a consistent manner; and properly

documented. This document states MOX Services policies, assigns responsibility, and specifies requirements governing implementation of quality assurance. Specific processes and controls, which implement this document, are specified in QA procedures developed and controlled in accordance with Sections 5 and 6 of this document.

The QA Program provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The MOX Services QA Program provides for any special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality. Applicable QA requirements contained in this document are invoked on MOX Services subcontractors for their contracted scope of work.

MOX Project Quality Assurance Plan Structure

This document satisfies the requirements of 10CFR50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.* Sections 1 through 19 of this document describe the quality assurance requirements for quality-affecting activities on the project and the first 18 sections coincide with the 18 criteria of 10CFR50, Appendix B. The hierarchy of QA documents for the project is further discussed in Section 2, *Quality Assurance Program*. Quality Level definitions and the requirements for applying graded QA to principal SSCs[1] during design and construction and items relied on for safety (IROFS) after completion of the Integrated Safety Analysis (ISA) are found in Paragraphs 2.2.2, 2.2.3, 2.2.4, and 2.2.5. QA requirements in this document address the management controls applicable to project activities with emphasis on controls being established in applicable implementing QA procedures for Design, Construction, and Operations phases of a fuel fabrication facility.

Provisions for Continuing QA

This document is a living, controlled document that controls the MOX Services QA Program. MOX Services maintains and updates the MPQAP as necessary to support ongoing MOX Services activities. Prior to Deactivation, the MPQAP will be revised as necessary to identify the QA controls applicable for deactivation activities. See Paragraph 2.2.9, *Provisions for Continuing QA* for the requirements on maintaining the MPQAP.

BACKGROUND INFORMATION

DOE Mixed Oxide Fuel Project

DOE Contract No. DE-AC02-99CH10888 divides the MOX Fuel Project into four phases:

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[1] Principal SSCs are those SSCs expected to be confirmed as IROFS by the Integrated Safety Analysis. As used throughout this document the term IROFS includes Principal SSCs.

Base Contract:	MOX (Mixed Oxide) Fuel Fabrication Facility (MFFF) plant design and license application Fuel qualification program Identification and design of mission reactor modifications Mission reactor license amendment requests
Option 1:	Construction of the MFFF Installation of mission reactor modifications
Option 2:	Startup and operation of the MFFF Irradiation of MOX fuel
Option 3:	Deactivation

This revision of this document provides the quality assurance requirements needed for Base Contract, Option 1, and Option 2 quality-affecting activities for the MOX Services scope of work. Throughout this document the contract phases (Base Contract, Option 1, and Option 2) are referred to as the Design, Construction, and Operations phases (respectively).

Shaw Project Services Group, Inc., Shaw Environmental and Infrastructure and AREVA Federal Services, LLC are the equity owners of MOX Services LLC. Subcontracted to MOX Services are two major subcontractors with the following specific elements of the DOE Contract DE-AC02-99CH10888 Statement of Work:

- AREVA NP Inc., for the design and qualification of the fuel; and
- Nuclear Fuel Services (NFS) for design input for safeguards and security functions requisite for Category I Special Nuclear Material;

Additional technical support to the MOX Fuel Project activities is provided through subcontracts with AREVA Federal Services LLC, an affiliated company of AREVA NC Inc., and other AREVA affiliates in France as follows:

- Société Générale des Techniques Nouvelles (SGN) for process design, fuel process and facility design;
- Euriware, SA for software design;
- Mecachimie SA and Mecagest, SA for fabrication; and
- AREVA NC SA and MELOX for technology support services and fuel operating experience.

Subcontractors for quality-affecting activities are evaluated under the controls of the MOX Services QA Program.

Application of Quality Assurance Program Requirements to MFFF Design

QA requirements contained in this document apply to Quality Level 1 and 2 structures, systems and components (SSCs) during design, construction, and operations. Quality Level 1 (QL-1) SSCs as defined in Section 2 of this document include all Items Relied on for Safety[2] (IROFS) including principal SSCs[3] identified during the design phase prior to the completion of the Integrated Safety Analysis. Completion of the Integrated Safety Analysis (ISA) will validate final classification of principal SSCs as IROFS. Quality Level 2 (QL-2) SSCs are those SSCs supporting normal operations of the facility, which reduce public, worker, and environmental radiological and chemical risks but are not relied on to satisfy the performance requirements of 10CFR70.61.

Design control, document control, configuration control, and records management QA requirements are applied to QL-3 and -4 SSCs at the discretion of management as these SSCs do not impact the regulatory basis of the facility. During licensed operation, 10CFR70.72 provides for evaluation, implementation, and tracking of changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. These provisions include evaluation of changes to non-IROFS (i.e., including QL-2, -3, and -4 SSCs) to ensure no inadvertent changes or impacts to IROFS occur as a result.

Use of Subcontractor QA Programs

As the overall controlling QA plan for Design, Construction, and Operations phases of a fuel fabrication facility, this document invokes QA requirements for controlling MOX Services performed quality-affecting activities as well as providing controls for subcontractors, addressed by Section 4 and 7, to perform their assigned quality-affecting activities to their own QA Programs.

Quality-affecting transportation activities during Design, Construction, and Operations involves shipping package design, licensing and fabrication for the fresh MOX fuel assemblies to be transported between the MFFF and mission reactors as well as design of equipment to load the fuel assemblies into the shipping packages. AREVA Federal Services, LLC performs this work under subcontract from MOX Services. This activity is performed under the AREVA Federal Services, LLC QA Plan. MOX Services maintains AREVA Federal Services, LLC on the Approved Suppliers List in accordance with Section 7 of this document.

Fuel design and qualification is assigned to AREVA NP Inc., formerly Framatome Cogema Fuels (FCF). Quality-affecting Design activities, including Design activities that extend into and through Construction, for AREVA NP Inc.,'s assigned work scope is

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[2] The phrase Items Relied on for Safety and the acronym IROFS, when used in this MPQAP, is used in the context of the 10 CFR 70.4 definition of **Items Relied on for Safety**; i.e., associated with the prevention of, or the mitigation of potential consequences from, potential accidents that could exceed the performance requirements of 10 CFR 70.61.

[3] Principal SSCs are those SSCs expected to be identified as IROFS.

controlled by the AREVA NP Inc., Fuel Sector Quality Management Manual and associated implementing QA procedures. MOX Services QA provides oversight of AREVA NP Inc., quality-affecting activities and maintains AREVA NP Inc., on the Approved Suppliers List.

1 ORGANIZATION

1.1 GENERAL

The Shaw AREVA MOX Services, LLC (MOX Services) Quality Assurance (QA) Program described in this section and associated QA procedures implement the committed requirements of Criterion 1 Organization of 10CFR50, Appendix B; and Basic Requirement 1 and Supplement 1S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*.. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

The MOX Services functional organization structure is shown in Figure 1-1. This covers the design, construction, and operation for the DOE Mixed Oxide (MOX) Fuel Fabrication Facility.

MOX Services is responsible for the design, construction management, and operation of the MOX Fuel Fabrication Facility, including the transportation of MOX fresh fuel assemblies to the mission reactors. As construction begins, the organizational structure will shift toward an increased work scope and resources for Construction.

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

1.2 ORGANIZATION RESPONSIBILITIES

The Shaw AREVA MOX Services, LLC (MOX Services) functional organizational structure indicates the lines of communication and control of activities. The reporting structure, along with functional responsibilities and levels of authority, for the various organizational entities is described below in the position descriptions.

MOX Services establishes and maintains management measures as necessary and appropriate to ensure availability and reliability of IROFS. Responsible managers have the authority to delegate tasks to other individuals; however, the responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

1.2.1 MOX Services President/COO/Project Manager

The MOX Services President/COO/Project Manager is responsible for MOX fuel project activities and is accountable to the MOX Services Board of Governors. The members of the Board of Governors are corporate executives of the two corporate owners of MOX Services (Shaw Project Services Group, INC., Shaw Environmental and Infrastructure, and AREVA NC Inc.). The MOX Services President/COO/ Project Manager is the highest level of management responsible for the MOX Services Employee Concerns Program, safety program and establishing MOX Services quality policies, goals, and objectives. He has documented the team's commitment to quality in the *Quality Assurance Program Policy Statement*. He approves the MOX Project Quality Assurance Plan. The President/COO/Project Manager is responsible for ensuring the integration of the functional areas discussed in the paragraphs below.

1.2.2 Vice President Project Assurance

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

The size of the Project Assurance organization is commensurate with the duties and responsibilities. The Project Assurance Organization is shown in Figure 1-2.

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

The Manager of QA/QC is independent of the managers responsible for performing quality-affecting work and is independent of cost and schedule considerations, in addition he has a direct line of communication to the Project Manager. He is responsible for maintaining the MOX Project Quality Assurance (QA) Plan and verifying its effective implementation at applicable MOX Services work locations. Procedures are approved by the manager responsible for the performance of the activities being controlled. Procedures that directly implement the QA Program requirements will obtain the concurrence of the quality assurance organization. MOX Services Quality Assurance will witness and/or perform specified testing and inspections of IROFS.

Reporting to the Manager Quality Assurance/Quality Control is the Quality Control Manager and the Quality Assurance Manager.

The Quality Control Manager is responsible for the QC inspection program, performance of in-process and final inspections, certification of inspectors, performance of shop inspections and managing the

nonconforming item program. The QA Manager is responsible for the performance of internal oversight (audits, assessments, monitoring of activities, supplier oversight, audits, surveillances, supplier QA Manual review, review of technical documents and procedures, managing the corrective action program, and performing trend analysis). Both Quality Managers are independent of the managers responsible for performing quality-affecting work and are independent of cost and schedule considerations. Both Quality Managers have the same access to the President as the line managers of the various functional areas of the project. Both Quality Managers have an effective line of communications with other senior management. Individuals assigned the responsibility for ensuring effective execution of any portion of the QA program at any location have direct access to the Manager of Project Assurance. This organization will evolve to support activities throughout the life of the project.

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

The Manager Quality Assurance/Quality Control may be assigned other duties; however, none of these duties are allowed to compromise the independence of this function or to prevent needed attention to QA matters. The Manager Quality Assurance/Quality Control has direct access to the President on matters relating to quality.

This position is able to:

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

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

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

1.2.3 Vice President Facility Design and Construction

The Vice President Facility Design and Construction reports to the MOX Services Project Manager during design and construction. This position is responsible for integration of facility engineering and construction activities.

Reporting to the Vice President Facility Design and Construction are the Vice President Engineering and the Vice President Construction.

1.2.3.1 The Vice President Engineering provides the engineering and design services throughout the life of the MFFF Project. This function is responsible for safety analysis; and nuclear criticality safety. Design authority and engineering program management/configuration control is the responsibility of this position.

During the design phase the process design function provides the design of the MFFF process. During the construction phase, this function provides process design support of MFFF construction and equipment fabrication and installation. This function supports Plant Operations in the development and performance of in-plant startup testing and the development of operating and maintenance procedures. The software function, process unit function, and the laboratory function report to the VP Process Unit Design and Commissioning and receive functional direction and day to day priorities from the VP Process Unit Design and Commissioning. However, they receive technical direction from the VP Engineering.

The design function provides the design of the facility and site-related interfaces for the MFFF. During the construction phase, this function provides design support to both procurement and construction and is responsible for maintaining configuration management from design through construction to operations. In the operations phase, this function transitions to Plant Operations to support maintenance and maintain configuration control of the facility.

The engineering services function is responsible for development and maintenance of engineering integration processes,

configuration management, technical baseline, design requirements documents, and designated risk management activities during the design and construction phases. The configuration management functions transition to Plant Operations during the operations phase.

1.2.3.2 The Vice President of Construction is responsible during the design phase for construction review of the MFFF design, the construction cost estimate and construction schedule, construction subcontracting, and procurement planning. During construction, this function is responsible for managing the total construction of the MFFF. Construction Services provides oversight and management of the direct workforce, subcontractors and vendors that are subcontracted to execute specific construction work scopes. During construction, this function manages field ES&H activities.

Configuration change control is managed through a formal process that authorizes and documents changes to the design after subcontract award. Configuration management of the MFFF basis of design in accordance with the design documents generated, approved, and issued for construction under the controls of the MOX Services QA Program ensures the plant is built as designed. Construction changes require approval from the Engineering and Construction functions. Design documents are periodically reviewed by construction personnel during the performance of the work and the documents are updated at subcontract completion for operations use.

Construction acceptance testing (CAT) is performed in accordance with approved procedures. The purpose of the CAT is to confirm proper installation of components and readiness for startup testing.

1.2.4 Vice President Environmental Safety & Health

Reports directly to the MOX Services President This function is responsible for Environment, Safety, and Health (ES&H) requirements, Environmental Management, Industrial Safety, Environmental Health, Emergency Preparedness and Radiation Protection to ensure consistent interpretations of ES&H requirements, support licensing, perform design reviews, and manage development of the Environmental Report. During operations, this function continues to ensure compliance with ES&H requirements. During the operations phase, this function also includes nuclear material control and accounting and the safety disciplines of criticality safety, radiation protection, fire safety, chemical safety, and industrial safety.

1.2.5 Vice President Business Services

The Vice President Business Services provides training, contract administration, human resources, facilities management, project security control, communications, and procurement. This function includes the functions of Corporate Secretary, Treasurer, and Facility Security Officer.

1.2.6 Vice President Operations

The Vice President of Operations develops and implements a comprehensive Project Management Program for the MFFF Startup, Operations, Fuel Services, Material Control & Accountability (MC&A) and Physical Security.

Plant Operations provides operability reviews for design and licensing support of the MFFF. During construction, this function provides development and qualification of operational and maintenance processes, procedures, operations readiness, and input regarding identification of functional testing in preparation for start-up testing and transition to operations. This function is responsible for directing all start-up activities, test programs, and test procedures for Onsite Cold Start-up Tests.

During operations, this function is responsible for operation and maintenance of the facility, including configuration management, preparation of operating procedures, staffing and training of qualified plant personnel, implementation of a maintenance program and preparation of maintenance procedures, implementation of safe work practices and emergency response programs. For the operations phase, this function is a direct report to the President.

This function is also responsible for Fuel Qualification, fuel assembly mechanical design, and support for licensing. This function includes the development and implementation of the plan for the design, manufacture, and transportation of lead assemblies.

NOTE: *The quality-affecting activities related to license modifications of the mission reactors, including the implementation of those modifications is the responsibility of the mission reactor and performed entirely under the scope of their 10 CFR 50 License, not the MOX Services 10 CFR 70 MFFF License.*

The Vice President Operations is also responsible for Irradiation Services and Packaging & Transportation for the project. This function provides oversight and control of the change management processes, oversight of programs executed within and for the MFFF Project, and provides an independent review of overall project performance. This organization serves as the lead interface with the Department of Energy for scope, cost and schedule performance.

Irradiation Services provides support for core design, core physics, license modifications to the mission reactors, and development of the irradiation plan during the design phase. During construction, this function is also responsible for coordination with the mission reactors on implementation of modifications for use of the MOX fuel. Irradiation Services provides the interface between the mission reactors and MOX Services.

Packaging & Transportation supports the development and implementation of the MOX fresh fuel package planning, transportation integration planning, MOX fuel package design, and lead assembly transportation. In the operations phase, Irradiation Services continues to provide the interface between MOX Services and the mission reactors, providing the transportation and logistics support necessary to deliver the MOX fresh fuel assemblies to the mission reactors for irradiation.

1.2.7 Vice President Project Services

The Vice President Project Services is responsible for implementing a comprehensive schedule and risk management program for the MFFF Project. Project Services manages the performance measurement process and ensures effective implementation and operation of the MOX Services Earned Value Management System. Project Services also provides technical direction and oversight of the Construction Project Control function.

Project Services is responsible for Document Control files, distributes and maintains all project records associated with the administration, operation and maintenance of the facility in the project's Electronic Document Management System. The Project Records Center group maintains and stores all Project Records and Quality Assurance Records. The activities performed by this group include transmittal and periodic inventories of all controlled documents. The group's scope of work includes revision control of engineering, licensing, quality assurance, procurement, vendor, project management records and archival storage of official project records which produce objective evidence of project activities.

Project Services is responsible for all Information Technology design tools used by the project to support engineering, construction, startup and operations. This position is also responsible for software development, certification, rollout and support of IT systems.

1.2.8 Vice President Process Unit Design and Commissioning

The Vice President Process Unit Design and Commissioning is responsible for the design, procurement, fabrication, assembly, functional component, and equipment checkouts and commissioning (in-advance testing) of the MFFF process units in the U.S. and Europe. The VP

Process Unit Design and Commissioning oversees the Process Unit, Software and Lab design group functions. The VP Process Unit Design and Commissioning ensures effective interfaces with Construction, Engineering, Quality Assurance and Start-Up to meet overall project technical, cost and schedule performance.

The software function, process unit function, and the laboratory function report to the VP Process Unit Design and Commissioning and receive functional direction and day to day priorities from the VP Process Unit Design and Commissioning. However, they receive technical direction from the VP Engineering.

The software design function is responsible for the design of the software needed to operate the integrated control system for the MFFF. This function provides support to Plant Operations for the development of operating procedures, operator training modules, equipment acceptance tests, and start-up tests. This function also supports the performance of equipment acceptance and start-up testing. In the operations phase, this function transitions to Plant Operations to support maintenance and maintain configuration control of the operations software.

The process unit design function performs design of the MFFF Process Units, AP and MP Units, Laboratory Units, Chemical Units, including internal equipment/subassemblies and associated mechanical, electrical and long lead equipment. The design managers have a technical reporting relationship with the VP Engineering. This function is also responsible for glove box and equipment technical specifications for detailed design and procurement. This function coordinates with Procurement and QA to ensure engineering and QA requirements are included in procurement documents and are satisfied by the suppliers of purchased equipment. During construction, this function coordinates equipment design support of construction including installation of equipment. This function provides support to Plant Operations for the development of operating procedures, operator training modules, equipment acceptance tests, and start-up tests. This function also supports the performance of equipment acceptance and start-up testing. In the operations phase, this function transitions to Plant Operations.

The VP Process Unit Design and Commissioning ensures effective interfaces with Construction, Engineering, Quality Assurance, Start-Up and Operations to meet overall project technical, cost, schedule and quality performance.

1.3 REQUIREMENTS

1.3.1 Organizational Interfaces

The organizational interfaces between MOX Services, subcontractors, the DOE Offices, Savannah River Site M&O and DOE, and project applicable

regulatory agencies are identified in the appropriate plans, work task agreements, basic ordering agreements, subcontracts, and procedures. These documents contain the appropriate protocols, applicable roles, responsibilities, and approval authorities for the specific topics for which they apply.

1.3.2 Organization Structure

MOX Services maintains organization charts identifying the management positions responsible for implementing the functional organization described in Paragraph 1.2 of this document.

1.3.3 Delegation of Work

A. The delegation of work between MOX Services team locations and subcontractors is identified in applicable plans, work task agreements, basic ordering agreements, subcontracts, and procedures. In cases of delegation, MOX Services retains the overall responsibility for work performed under the direction of MOX Services. When work is delegated, periodic evaluations will be performed.

B. Responsible managers have the authority to delegate activities to others provided the designees possess the required qualifications for the activities delegated.

C. Delegations are in writing. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

1.3.4 Resolution of Disputes

A. Disputes involving differences of opinion on quality matters or issues are brought to the attention of line management, and if not resolved by the individual's manager, are elevated progressively to the Vice President Project Assurance.

B. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the MOX Services President for final resolution.

1.3.5 Stop Work Authority

Stop work authority within MOX Services is vested in each employee whenever the health and safety of our 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.

ATTACHMENTS:

Figure 1-1: MOX Services Functional Organization
Figure 1-2: Project Assurance Organization

Figure 1-1: MOX Services Functional Organization

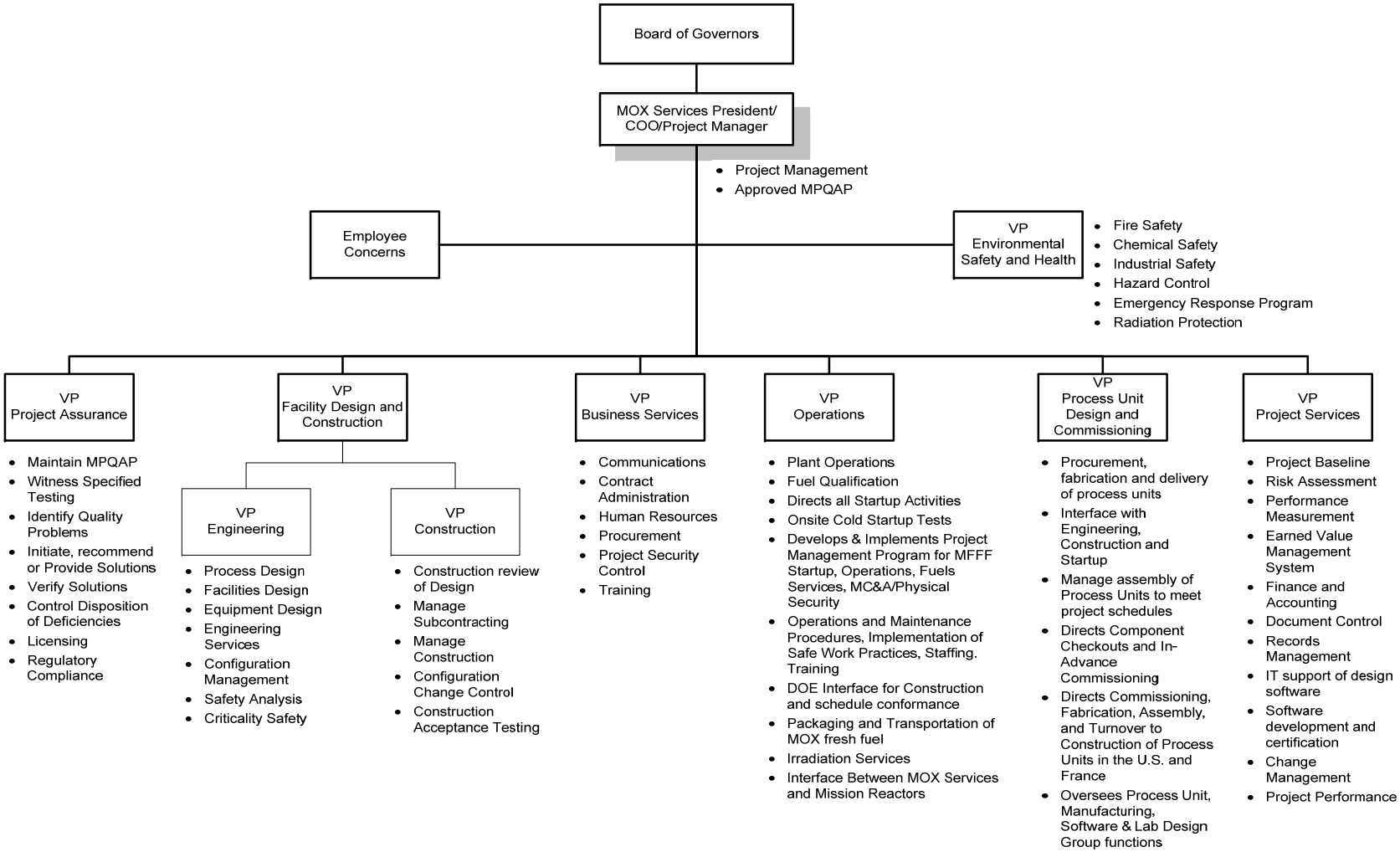
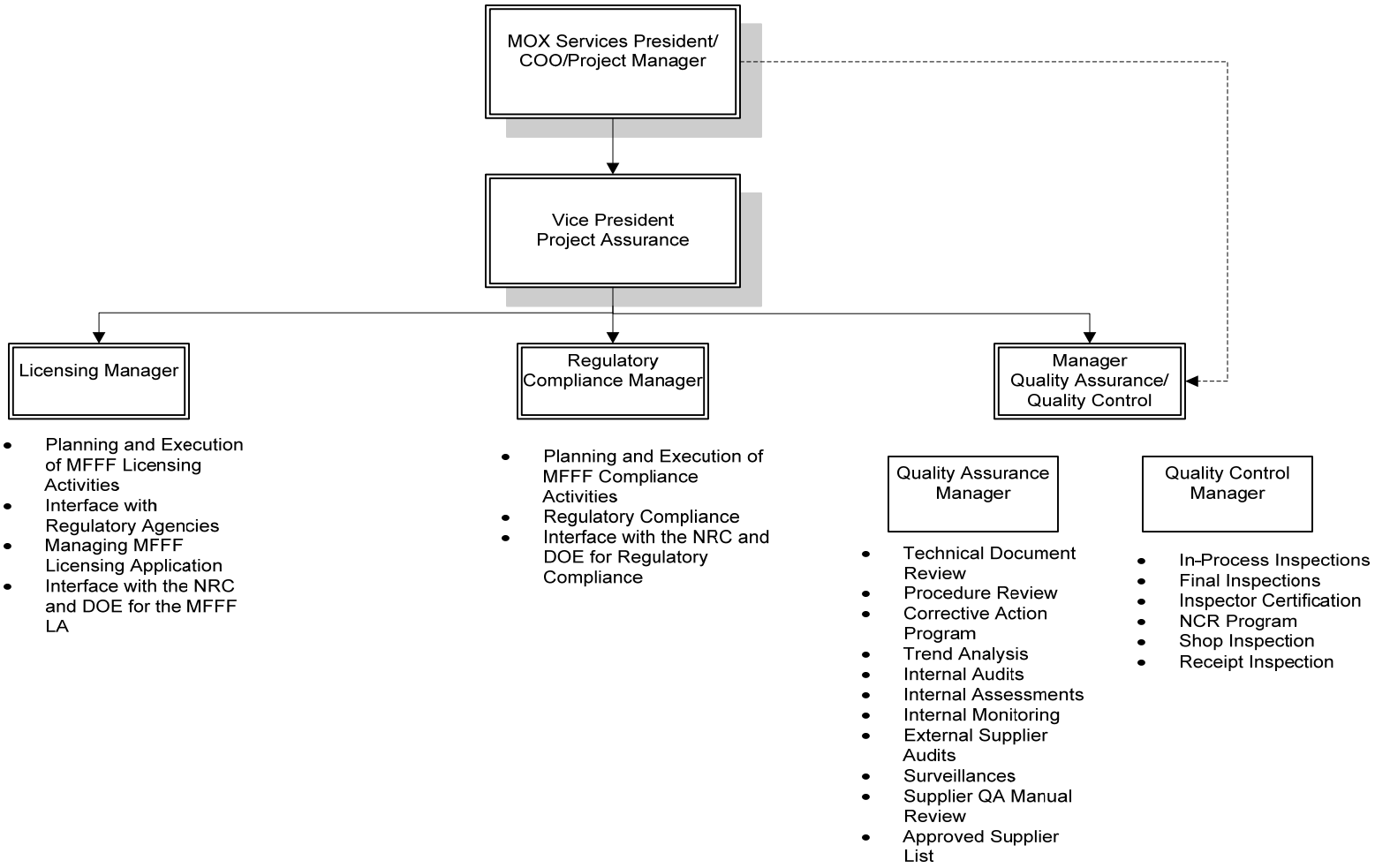


Figure 1-2: Project Assurance Organization



2 QUALITY ASSURANCE PROGRAM

2.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 2 Quality Assurance Program of 10CFR50, Appendix B; Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-4 and Appendix 2A-1[4] of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2).

2.1.1 Program Basis

The MOX Project Quality Assurance Plan complies with 10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, and applies to MOX Services, including subcontractors, who perform quality-affecting activities. "Quality-affecting" is defined as "deeds, actions, processes, tasks or work which influence the achievement or verification of quality requirements and objectives necessary for 1) fabrication and delivery of MOX fuel assemblies to the mission reactors and 2) Quality Level 1 and 2 structures, systems and components (SSCs) and their associated activities." Quality Levels are defined in Paragraph 2.2.2.

Part I basic and supplemental requirements and Part II (as clarified in Attachment A) of ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications*, as revised by NQA-1a-1995 Addenda; Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*; and Regulatory Guide 1.33 (Rev.2), *Quality Assurance Program Requirements (Operation)*, were used to provide detailed implementing guidance for 10CFR50, Appendix B quality assurance requirements for the MOX Services QA Program.

The applicability and any exceptions to NQA-1-1994 Part II subparts are shown in Attachment A of this MPQAP.

Specific processes and controls, implementing these requirements, are specified in QA project procedures and detailed work place procedures.

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[4] Regulatory Guide 1.28 (Rev.3) provides for the use of the NQA-1-1983 version of this appendix. MOX Services has compared the referenced appendix in NQA-1-1983 with NQA-1-1994 and due to verification of no lessening of the published requirements elects to use NQA-1-1994 in order to implement the later version of this national standard. The use of NQA-1-1994 as revised by NQA-1a-1995 addenda is consistent with the guidance of NUREG-1718.

Development, review, and approval of QA procedures occur prior to performance of the activities controlled by the procedures. The QA Program provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The MOX Services QA Program provides for any special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality.

2.1.2 Graded Quality Assurance

MOX Services is implementing a graded approach for quality-affecting SSCs and activities based on the significance of the SSC or activity to ensuring safety for workers, the public, and the environment. The graded approach provides a safety benefit by allowing preferential allocation of resources based on the safety significance of SSCs.

2.1.3 Transition to Operational MPQAP requirements.

During the transition from Option 1, Construction activities to Option 2, Startup and Operations, full implementation of the Operational QA requirements will be enforced after each System / Area Turnover. Also, the Operating Limits Manual shall be in place and functioning prior to the introduction of Special Nuclear Material into the Process Systems.

2.2 REQUIREMENTS

2.2.1 Application of QA Controls for Product

A. The mission reactors will require certain items and activities to be addressed under the MOX Services QA Program for the fabrication, handling, and delivery of MOX fuel assemblies. These items and activities may or may not have a function in satisfying performance requirements of 10CFR70.61.

B. The applicable QA Controls for these items and activities identified in contractual documents from the mission reactors, providing flowdown requirements from their license, are not graded by MOX Services. Operating procedures and maintenance procedures implement these QA Controls.

2.2.2 Categorization of Structures, Systems, and Components for MFFF

Quality levels are assigned to SSCs commensurate with their safety significance and a combination of the likelihood and consequences of

design basis events. The quality level (QL) is used to establish the level of programmatic requirements and procedural controls which will be applied to SSCs and associated activities using a graded approach.

A. The focus of the classification of SSCs and application of a graded approach to QA is to ensure that:

1) Applied QA controls are sufficient to ensure design integrity through meeting technical, engineering, and design requirements and

2) The SSC successfully performs its safety function.

B. Grading an SSC shall not degrade its performance or prevent it from meeting its intended safety function.

C. MFFF SSCs are initially assigned a quality level (or QA classification) commensurate with the function and safety significance of each SSC. The initial quality level designation for SSCs were established at a functional level based on engineering review of the following:

- Consideration of the MELOX and La Hague design and operating experience;
- Consideration of failure consequences (i.e., single failure and defense in depth);
- Design criteria and design requirements;
- Safety significance relative to 10CFR70.61 performance requirements; and
- MOX Project Quality Assurance Plan definitions for quality levels.

D. Upon completion of the safety assessment of the design bases of principal SSCs and the Integrated Safety Analysis (ISA), these initial SSC quality level assignments will be either confirmed or changed in accordance with the results of those evaluations.

E. Changes to quality level designations necessitate re-evaluation of any QA grading applied up to that time (see 2.2.5, *Feedback Mechanisms and Reassessing Safety Significance*).

F. Quality Levels are documented on applicable design documents to indicate where QA controls are needed.

G. Quality Level 1 (QL-1)

Quality Level 1 (QL-1) SSCs are IROFS credited in the Integrated Safety Analysis with a required function to prevent or mitigate design basis events such that high-consequence events are made highly unlikely; intermediate-consequence events are made unlikely; or to prevent criticality. For example, the failure of a QL- 1 item could cause:

i. Loss of a primary confinement feature leading to release of material resulting in exceeding 10CFR70.61 performance requirements;
ii. Failure to satisfy the double contingency principle for the prevention of a criticality accident; or
iii. Loss of other safety function required to meet 10CFR70.61 performance requirements.

QL-1LR SSCs are a subset of QL-1 IROFS where the relative importance to safety has been determined by evaluation to be low. Refer to the MPQAP applicability table in Attachment B for the MPQAP sections that apply to QL-1LR items.

H. Quality Level 2 (QL-2) SSCs are not relied on to satisfy 10CFR70.61 performance requirements. These SSCs perform one or more of the following functions:

1) Maintaining public and worker radiological exposure during normal operations and anticipated occurrences within normal operating limits (i.e., 10CFR20);

2) Managing radioactive waste;

3) QL-2 SSCs protect IROFS from physical interaction, including pressure boundary failure, because of a seismic or material handling event. They are not directly relied on to perform a safety function, subject to the following criteria:

i. QL-2 SSCs include those SSCs which could physically interact with and adversely impact IROFS that are required to function during and subsequent to a Design Earthquake (Regulatory Guide 3.14, Seismic Design Classification for Plutonium Processing and Fuel Fabrication Plants), such as some supports for QL-3 and QL-4 Systems or Non-Seismic Category-I IROFS SSCs; passive

devices such as rails stops, crane stops, etc., that prevent impact to IROFS; and shielding against internally generated missiles. The remaining classification of non-IROFS piping systems will be QL-3 or QL-4; or

4) Criticality monitoring and alarm features provided to alert workers to changes in conditions.

I. Quality Level 3 (QL-3) SSCs have no safety function but their performance may be important to ensuring operational or mission-critical goals are achieved. QL-3 is used to designate SSCs subject to management control for mission-related reasons such as throughput, cost, or schedule. This category of SSC's contain those items where the desired QA controls are not consistent with the QA controls associated with QL-1, QL-2 or QL-4 designations. (i.e. Those Mission Critical items that have unique requirements which are not covered by QL-1, QL-2 or QL-4 controls) Controls, appropriate to the application, are applied to these SSCs using the MOX Services QA Program for efficiency (i.e., to avoid creation of a separate or redundant management system for applying controls to SSCs and related activities), however they do not impact the regulatory basis of the facility.

J. Quality Level 4 (QL-4) SSCs are not QL-1, QL-2, or QL-3. QL-4 is used simply to designate that an SSC has been determined not to meet QL-1, -2, or -3 criteria; controls on those SSCs do not impact the regulatory basis of the facility. These SSC's are processed using the same QA procedures and processes, as appropriate to the application, for control of QL-1 and QL-2 SSC's.

NOTE: *Applicable requirements for design, document and configuration control, and records management are applied to Quality Level 3 and 4 SSCs as the project procedures controlling these activities cover all Quality Levels.*

2.2.3 Identification of QA Controls for MFFF

The grading process defines the identification of QA controls based on the safety significance of SSCs. The application of QA controls to SSCs or categories of SSCs is based on the quality level and functional requirements of the SSCs.

A. The Grading Process shall be:

1) Identified in procedures;

2) Conducted by the technical organization responsible for the item or activity;

3) Reviewed and concurred with by the Licensing, Safety Analysis and Quality Assurance functions; and

4) Approved for implementation by management of the organization performing the grading.

B. Grading Criteria

The extent to which the requirements of this manual and its implementing documents are applied to an item or activity shall be based upon the following:

1) Function or end use of the SSC;

2) Consequence of failure of the SSC;

3) Importance of the data being collected or analyzed;

4) Complexity of design or fabrication of the item or design or implementation of the activity;

5) Reliability of the associated processes and components;

6) Reproducibility of results;

7) Uniqueness of the item or service quality;

8) Necessity for special controls or processes;

9) Degree to which functional compliance can be demonstrated through inspection or test; and

10) Other relevant factors.

C. The grading process for QL-1 SSCs evaluates the requirements in Sections 1 through 19 of the MPQAP and documents the basis for determining which QA requirements are not necessary to support reasonable assurance of the performance of specific IROFS (QL-1 items). Grading of QA controls for QL-1 SSCs, if justified, shall be on a case-by-case basis in discrete analyses. This justification may rely upon the nuclear industry's precedent in the application of QA requirements for augmented QA Programs.

The Augmented QA program for IROFS shall be described in an engineering procedure and will be concurred with by the QA

Organization. Attachment B contains details of the Augmented QA program for IROFS.

D. QL-2 SSCs and their associated activities – i.e., those SSCs that provide support of normal operations of the facility (e.g., occupational exposure, radioactive waste management) and SSCs that minimize public, worker, and environmental risks below 10CFR70.61 performance criteria (e.g., physical interaction protection, radiological and criticality alarms) – are also evaluated against the requirements in sections 1-19 of the MPQAP. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions. This evaluation may also include nuclear industry precedent in the application of augmented QA requirements. Augmented QL-2 programs shall be described in engineering procedures and will be concurred with by the QA Organization.

E. QL-3 and QL-4 SSCs and their associated activities may be voluntarily included under the controls of the MOX Services QA Program by management direction.

2.2.4 Application of Graded QA Controls

The results of the QA grading process will identify QA requirements for the design, construction, and operation of these SSCs. These requirements are implemented through applicable project procedures, analyses, specifications, and other QA Program documents. Revision and approval of these documents is in accordance with applicable procedures.

2.2.5 Feedback Mechanisms and Reassessing Safety Significance

A. Changes in design or equipment procurement requirements resulting from construction activities; lessons learned (from operating experience); corrective actions (from identified nonconformances and deficiencies); ISA completion; or elevation of an SSC to a higher quality level by management decision shall be evaluated for determining any needed changes to the application of QA controls. The change review process required for each of these feedback mechanisms necessitates review for impact on associated documents and processes. Any necessary changes in the application of QA controls determined as a result of these reviews shall be made in accordance with the applicable QA procedure in order to maintain reasonable confidence in SSC performance.

B. Design changes and changes from construction activities shall be in accordance with the requirements of Paragraph 3.2.5, *Design Change Control*.

C. Changes to procurement requirements shall be evaluated in accordance with the requirements of Paragraph 4.2.3, *Procurement Document Change*.

D. Changes because of lessons learned from adverse trends, corrective actions due to nonconformance and deficiencies from audits or assessments shall be evaluated in accordance with the requirements of Section 15, *Nonconforming Materials, Parts, and Components*, or Section 16, *Corrective Action*.

E. SSCs that are affected by changes from construction activities and changes in facility design shall be re-evaluated for safety significance and potential re-classification. Such changes would result in design changes that are required to be reviewed and evaluated in accordance with the requirements of Section 3, *Design Control*, using the applicable QA project procedures. Configuration control of changes to SSCs is established through the use of design control procedures that control design output.

F. Changes in QA categorization shall be performed and documented in accordance with applicable QA project procedures. Changes in safety significance shall necessitate review for potential changing of the application of QA controls.

G. QA categorization changes require updating of the applicable design documents for the particular SSC that was changed. These changes also necessitate review of applicable QA requirements for confirming or changing the previously established graded QA controls. Affected documents are revised in accordance with the requirements of the controlling procedures for the specific documents.

2.2.6 Personnel Indoctrination, Training, and Qualification

MOX Services shall establish a process to assure the necessary indoctrination, training, and qualification of personnel performing or managing quality-affecting activities is identified and provided, assuring suitable proficiency is achieved and maintained. This process shall:

A. Provide QA Indoctrination to personnel, performing quality-affecting activities under the controls of the MOX Services QA Program. QA indoctrination must include general criteria,

introduction to basis documents, QA Program structure, and responsibilities and authorities within the QA Program.

B. Require line management to be responsible for the content and effective conduct of necessary training to assure personnel performing quality-affecting activities under their supervision are appropriately trained.

C. Require periodic review of training and training requirements such that when necessary to maintain proficiency, retraining of personnel is provided and documented. The need for retraining is evaluated whenever changes to work methods, technology, or job responsibilities occur.

D. Provide a process for analyzing, designing, developing, conducting, and evaluating training.

E. If exemptions for training are granted, require documentation of justification and approval by management.

F. Require records of the implementation of indoctrination and training to include:

1) Attendance sheets;

2) Formal classroom training lesson plans;

3) Personnel training records;

4) Training objectives and content;

G. Require procedures for the qualification and certification of Nondestructive Examination (NDE) Personnel to be developed in accordance with American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, *Personnel Qualification and Certification in Nondestructive Testing*, approved edition which has been reviewed by MOX Services. Alternative national or international industry standards or guidelines meeting or exceeding the recommendations of SNT-TC-1A, as determined by MOX Services, may be used as the basis for these procedures.

H. Require procedures for certification of inspection and test personnel[5] to identify:

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[5] Regulatory Guide 1.28 (Rev.3), Quality Assurance Program Requirements (Design and Construction) provides for qualification of inspection and test personnel in accordance with Appendix 2A-1 and

1) Minimum requirements for such personnel;

2) Requirements for indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed;

3) Determination of need for a formal training program including the conduct of such training activities required to qualify personnel who perform inspections and tests. This program shall include on-the-job training, with emphasis on first-hand experience gained through actual performance of inspections and tests under the direct observation and supervision of a qualified person and verification of conformance is by the qualified person until certification is achieved.

4) Initial evaluation of capabilities of a candidate for certification by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration in performing the type of inspection or test commensurate with the job;

5) Reevaluation of job performance of inspection and test personnel at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or re-determination of capability of a candidate for certification by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. Any person who has not performed inspection or testing activities in his qualified area for a period of 1 year shall be reevaluated by a re-determination of required capability prior to performing inspection and test activities;

6) Qualification (or certification) records including as appropriate:

   i. employer's name;
   ii. identification of person being certified;
   iii. activities certified to perform;
   iv. basis used for certification, which includes such factors as :

Supplement 2S-1 of NQA-1-1983. See footnote 4 for justification for using NQA-1-1994 version instead of NQA-1-1983.

(a) education, experience, indoctrination, and training
(b) test results, where applicable
(c) results of capability demonstration
v. results of periodic evaluation;
vi. results of physical examinations, when required;
vii. signature of employer's designated representative who is responsible for such certification;
viii. examination results;
ix. date of certification and date of certification expiration.

7) Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.

8) If during this evaluation or at any other time, it is determined that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated.

I. MOX Services shall establish in written procedures for the control and administration of training and qualification of Audit and Lead Audit personnel; see Paragraphs 18.2.10, 18.2.11, and 18.2.12 for additional requirements. Audit personnel shall have completed appropriate training or orientation to the extent necessary to assure competence in auditing skills and performance. Records of personnel qualification for Auditors and Lead Auditors performing audits shall be established and maintained.

2.2.7 Management Assessments

MOX Services utilizes two distinct levels of activities 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. Those levels of evaluation are:

- Audits, which are independent planned and documented evaluations performed by the Quality Assurance organization under the requirements of Section 18, Audits, of this document. Audits evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of quality-affecting activities; and

- Assessments, which 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.

A. Quality-affecting activities shall be evaluated annually or at least once during the life of the activity, whichever is shorter. Operational activities may be extended to once every two years. The status and safety significance of the items being evaluated shall determine the audit and assessment schedule. Audits and Assessments shall be initiated early in the process to ensure effective implementation of QA Program elements and other management measures.

B. Assessments shall be conducted in accordance with written procedures that include the following:

1) Identification of training and qualification requirements for assessment personnel;

2) Authorization for the assessment team to investigate any aspect of the items under evaluation with access to relevant information;

3) Provision for immediate corrective actions with appropriate documentation;

4) Review of assessment results by management having responsibility for the area evaluated;

5) Documentation and distribution of assessment findings and recommendations to appropriate management for review and response; and

6) Interface to the corrective action program to ensure timely and effective corrective action.

C. During the Operations phase, assessments shall include detailed walkdowns of plant areas, including out-of-the-way and limited-access (not restricted-access) areas, with provisions for accurate, documented descriptions of any deficiencies.

2.2.8 Quality Assurance Program Status Reporting

A. The status of the QA Program shall be evaluated and periodically reported to MOX Services Management, addressing pertinent information from audit reports, corrective actions, nonconformances, management assessments, etc.

B. The frequency of this reporting shall be based on project activities and established in a QA procedure.

2.2.9 Provisions for Continuing QA

A. Revisions to this document are submitted to the NRC in accordance with 10CFR70 licensing requirements. Major and minor revisions may result from reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA changes.

B. A change to the previously accepted MOX Services MPQAP may be made without prior NRC approval, provided the change does not reduce the commitments in the plan description as accepted by the NRC. In addition to quality assurance plan changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

1) The use of a QA standard approved by the NRC which is more recent than the QA standard MPQAP at the time of the change;

2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

4) The elimination of quality assurance plan information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

C. Changes to the MPQAP that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows: The submittal of a change to the MPQAP must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised plan incorporating the change continues to satisfy the criteria of 10 CFR 50 appendix B and the MPQAP commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

D. Changes to the MPQAP shall be regarded as accepted by the NRC upon receipt of a letter to this effect from the appropriate reviewing office of the NRC.

E. Prior to Deactivation this document will be revised as necessary to detail the QA controls appropriate for deactivation activities.

3 DESIGN CONTROL

3.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 3 Design Control of 10CFR50, Appendix B; Basic Requirement 3 and Supplement 3S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)***.** During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*. The MOX Services QA Program implements requirements for computer software qualification and use from ASME NQA-1-1994 Part II, Subpart 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications* and Part I, Supplement 11S-2, *Supplementary Requirements for Computer Program Testing,* both as revised by NQA-1a-1995 addenda.

Measures are established in MOX Services QA procedures to assure that applicable requirements are correctly translated by MOX Services into design documents. Design inputs are specified on a timely basis to support design milestones. Controls are established for the selection and suitability of application of design methods, materials, parts, equipment and processes that are essential to the functions of structures, systems and components. Design interfaces to ensure completeness and efficiency of design are established in applicable QA procedures. MOX Services QA procedures detail the controls for design input, design process, design verification, design changes and approval. These procedures include appropriate quantitative and/or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. Design documents are prepared, reviewed, and approved by qualified individuals. QL-1 design is verified by one or more of the following verification methods: design reviews, alternate calculations or qualification tests. The method of design verification and results are documented. Design changes are governed by control measures commensurate with those applied to the original design. Computer software is verified and validated in accordance with the requirements of ASME NQA-1-1994 Part II Subpart 2.7 as revised in NQA-1a-1995 and Part I Supplement 11S-2. Configuration management is maintained in accordance with the applicable QA project procedures controlling changes to the various types of design documents.

3.2 REQUIREMENTS

3.2.1 Design Input Control

Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) shall be controlled according to the following requirements:

A. Design inputs shall be identified/documented and their selection reviewed/approved.

B. Design inputs shall be specified and approved in a manner to support the schedule. Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

C. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

D. Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate QA procedures.

3.2.2 Design Process

The design process shall be controlled according to the following requirements:

A. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a compliant and efficient manner.

B. Design documents shall be adequate to support design, fabrication, construction, test, inspection, examination and operation schedule milestones.

C. Appropriate standards shall be identified/documented and their selection reviewed/approved.

D. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented and controlled.

E. Procedural controls shall be established for selecting and reviewing design methods, materials, parts, equipment and processes that are essential to the function of an item and suitability of application.

F. Applicable information derived from experience reports, or other documentation, shall be made available as design input.

G. The final approved design output documents and changes thereto shall be relatable to design input by documentation in sufficient detail to permit design verification.

H. Procedural controls for identifying sub-assemblies or components that are part of the item being designed shall be established.

I. When a commercial grade item (assembly or component item) is modified and/or tested to new requirements that are more restrictive than the supplier's published product description, the component part shall be traceable to documentation noting that it is different from the originally approved commercial grade item.

J. The use of previously proven foreign designs shall comply with applicable codes and standards and be documented in accordance with the applicable QA procedures.

K. Design drawings, specifications or other design output documents shall contain appropriate inspection, examination and testing acceptance criteria.

L. Drawings- Procedures shall be established for the preparation and control of drawings. Typical subjects to be covered by such procedures include:

a. Drafting room standards

b. Standardized symbols

c. Identification system

d. Indication of status

e. Checking methods

f. Review and approval requirements

g. Issuance and distribution

h. Revisions

i. Nonconformance with drawing requirements

M. Specifications- Procedures shall be established for the preparation and control of specifications. Typical subjects to be covered by such procedures include:

a. Format requirements

b. Identification system

c. Review and approval requirements

d. Issuance and distribution

e. Revisions

f. Indication of status

g. Nonconformance with specification requirements

N. Other Design Output Documents- Procedures shall be established for the preparation and control of other design documents such as installation instructions and test procedures. Typical subjects to be covered include:

a. Format requirements

b. Identification system

c. Review and approval requirements

d. Issuance and distribution

e. Revisions

f. Indication of status

g. Nonconformance with design document requirements

3.2.3 Design Analysis

A. Design analyses shall be planned, controlled and documented.

B. Design analysis shall be sufficiently detailed as to purpose, method, assumptions, design input, references and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator of the document.

C. Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval, and under configuration control.

D. Design calculations shall be identifiable by subject (including structure, system or component to which the calculation applies), originator, reviewer and date, or by other designators in order that approved calculations are traceable.

E. Computer software used to perform design analyses shall be developed and/or qualified, and used according to the requirements of Paragraph 3.2.7. Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

1) The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within define limits for each parameter employed; and

2) The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including the evaluation of the effects of these changes on 1) and 2) above.

F. Design analyses documentation shall include:

1) Definition of the objective of the analyses,

2) Definition of design inputs and their sources,

3) Results of literature searches or other applicable background data,

4) Identification of assumptions and designation of those that must be verified as the design proceeds,

5) Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs evidence of or reference to computer program verification and the bases (or reference thereto) supporting application of the computer program to the specific physical problem,

6) Identification of analysis methods utilized,

7) Identification of the design analysis results and demonstration that applicable acceptance criteria is met,

8) Conclusion of the design analysis, and

9) Design analysis final review and approval.

3.2.4 Design Verification (QL-1 Only)

The following design control requirements shall be applied to verify the adequacy of design:

A. Design verification is required for Quality Level 1 (IROFS) design and shall be performed using one or a combination of the design review, alternate calculations and/or qualification testing methods.

B. The particular design verification method used shall be documented.

C. Results of design verification shall be documented and shall include the identification of the verifier(s).

D. Competent individuals or groups, other than those, who performed the original design (but may be from the same organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided:

1) The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or

2) The supervisor is the only individual in the organization competent to perform the verification.

3) The justification to use the supervisor shall be documented.

E. Design verification shall be performed at appropriate times during the design process, to include:

1) Verification shall be performed before release for procurement, manufacture or construction, or release to another organization for use in other design work.

2) In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and procedurally controlled.

3) In all cases, design verification shall be completed before relying on the item to perform its function.

F. Extent of design verification required shall be a function of the importance to safety, complexity of design, degree of standardization, state of the art and similarity with previously proven designs.

G. Use of previously proven designs shall be controlled according to the following requirements:

1) The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.

2) Known problems affecting standard or previously proven designs and their effects on other features shall be considered.

3) The original design and associated verification measures shall be adequately documented and referenced in the files for subsequent application of the design.

4) Changes in previously verified designs shall require re-verification. Such verifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

H. Design Review

Design reviews shall be controlled and performed to ensure:

1) The design inputs were correctly selected and incorporated.

2) Assumptions necessary to perform the design work were adequately described, reasonable and, where necessary, re-verified.

3) An appropriate design method was used.

4) The design output is reasonable compared to the applicable design inputs.

5) The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing documents.

I. Alternate Calculations

These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

J. Qualification Testing

If design adequacy is to be verified by qualification testing, the tests shall be identified, procedurally controlled and documented according to the following:

1) The test configuration shall be defined and documented.

2) Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse design conditions.

3) If the tests verify only specific design features, then the other features of the design shall be verified by other means.

4) Test results shall be documented and evaluated to ensure that test requirements have been met.

5) If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and re-tested or otherwise verified to ensure satisfactory performance.

6) Scaling laws shall be established, verified and documented when tests are being performed on models or mockups.

7) The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

3.2.5 Design Change Control

Design changes shall be controlled according to the following requirements:

A. Changes to final designs and nonconforming items dispositioned "use-as-is" or "repair," shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.

B. Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.

C. Changes shall be approved by the same groups that reviewed and approved the original design documents, with the following clarifications:

1) If the group that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.

2) The designated groups shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

D. The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented according to Section 16, *Corrective Action*. If these deficiencies cause constructed or partially constructed items (systems, structures or components) to be deficient, the affected items shall be controlled in accordance with Section 15, *Nonconforming Materials, Parts, or Components*.

E. When a field change is approved other than by revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

F. Design changes that impact related implementing documents or training programs shall be communicated in writing to affected organizations. Configuration management shall be maintained in accordance with the applicable QA project procedure.

3.2.6 Design Interface Control (Internal and External)

A. Design internal and external interfaces shall be identified and procedurally controlled.

B. Design efforts shall be coordinated among interfacing organizations as detailed in applicable QA procedures.

C. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among interfacing design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

D. Design information transmitted across interfaces shall be documented and procedurally controlled.

E. Transmittals of design information or documents shall reflect the status of the transmitted information and documents. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified as incomplete.

F. When it is necessary to initially transmit the design information orally or by other informal means, design information shall be promptly confirmed through a controlled document.

G. Quality Assurance shall review design documents to assure inclusion of the applicable quality requirements as specified in procedures.

3.2.7 Computer Software Control

These computer software requirements apply to the software used to produce or manipulate data used directly in the design, analysis, and operation of structures, systems, and components. The application of specific requirements shall be prescribed in plans for computer software quality assurance and written policies and procedures.

A. Software Life Cycle

The Software Life Cycle must encompass the following activities:

Requirement
Design
Implementation
Test
Installation and Checkout
Operation and Maintenance
Retirement

It is not the intent of this section to endorse or restrict a particular Software Lifecycle Model. The software lifecycle must proceed in a traceable, planned and orderly manner. The number of phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software. Software development may be performed in an iterative or sequential manner.

1) Requirements Activity

i. The requirements that the software must satisfy that pertain to functionality, performance, design constraints, attributes

and external interfaces shall be specified, documented and reviewed. These requirements shall define the response of the software to anticipated classes of input data, and shall provide the detail and information necessary to design the software.

ii. A software requirements specification is prepared to outline the requirements that the proposed software must satisfy. An item can be called a software requirement only if its achievement can be verified and validated. Software requirements shall be traceable throughout the remaining stages of the software development cycle. These requirements, as applicable, address the following:

(a) Functionality – the functions the software is to perform;
(b) Performance – the time-related issues of software operation, such as speed, recovery time, response time, etc.;
(c) Design constraints imposed on implementation activities – any elements that will restrict design options;
(d) Attributes – non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability, etc.;
(e) External interfaces – interactions with peoples, hardware, and other software.

iii. A Software Requirements review is performed at the completion of the software requirements documentation, and shall assure that the requirements are complete, verifiable, consistent, and technically feasible. The review shall also assure that the requirements will result in feasible and usable code.

2) Design Activity

During the Design Activity, a software design based on the requirements shall be developed, documented, and reviewed. The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation.

i. A software design specification shall include a document or series of documents that shall contain:
   (a) A description of the major components of the software design as they relate to the software requirements;
   (b) A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure;
   (c) A description of the allowable or prescribed ranges for inputs and outputs;
   (d) The design described in a manner that an be translated into code; and
   (e) Computer program listing(s).

ii. Design Activity software verification and validation activities shall consist of the following:
   (a) Generation of test plans based on the requirements and design;
   (b) Generation of design-based test cases;
   (c) Review of the software design to ensure that requirements are addressed. This review shall be held at the completion of the software design documentation and for IROFS Applications shall meet the design verification requirements of Paragraph 3.2.4. This review shall:
      - Evaluate the technical adequacy of the design approach;
      - Assure internal completeness, consistency, clarity, and correctness of the software design; and
      - Verify that the software design is traceable to the requirements.

3) Implementation Activity

During the Implementation Activity, the design shall be translated into a programming language, and the implemented software shall be analyzed to identify and correct errors.

Implementation activity software verification activities shall consist of the examination of computer program listings to assure adherence to coding standards and conventions.

4) Testing Activity

During the Testing Activity, the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plans and cases are required.

The code shall be validated to assure adherence to the requirements and to assure that the software produces correct results for the test cases. To evaluate technical adequacy, the software test case results can be compared to results from alternative methods, such as:

- Analysis without computer assistance;
- Other validated computer program;
- Experiments and tests;
- Standard problems with known solutions; or
- Confirmed published data and correlations

Test procedures or plans shall specify the following, as applicable:

- Required tests and test sequence;
- Required ranges of input parameters;
- Identification of the stages at which testing is required;
- Criteria for establishing test cases;
- Requirements for testing logic branches;
- Requirements for hardware integration;
- Anticipated output values;
- Acceptance criteria; and
- Reports, records, standard formatting, and conventions.

Test results shall be documented in a Software Verification Report. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

i. Verification Tests

(a) Verification tests shall demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test problem solutions are as follows:

- Hand calculations;
- Calculations using comparable proven programs; or
- Empirical data and information from technical literature.

(b) For operational control programs, testing shall demonstrate required performance over the full range of operation of the controlled function or process.

(c) Computer program testing shall vary with the complexity of the computer program. A single test or a series of tests (as applicable) shall be performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test. Verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

(d) Verification test records (e.g. Software Verification Report) shall, with justification provided for topics that do not apply to a specific application, identify the following:

- Computer program tested;
- Computer hardware used;
- Test equipment and calibrations, where applicable;
- Date of test;
- Tester or data recorder;
- Simulation models used, where applicable;
- Test problems;
- Results and acceptability (note any deviations or errors);
- Action taken in connection with any deviations noted; and
- Person evaluating test results.

ii. In-Use Tests

(a) Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

(b) Test problems shall be run whenever the computer program in installed on a different computer, or when significant hardware or operating system configuration changes are made.

(c) Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance.

(d) In-Use Test Results shall identify:

- Computer program tested;
- Computer hardware used;
- Test equipment and calibrations, where applicable;
- Date of test;
- Tester or data recorder; and
- Acceptability.

5) Installation and Checkout Activity

i. During the Installation and Checkout activity, the software becomes part of a system incorporating applicable software components, hardware, and data. The process of integrating the software with applicable components may consist of the following:

(a) Installation of hardware, if applicable;

(b) Installation of program;

(c) Reformatting or creating databases, if applicable; and

(d) Verifying that all components have been included.

ii. Verification and validation for the Installation and Checkout Activity shall consist of the following:

(a) Execution of tests for installation and integration;

(b) Documentation of approval of the software for operational use.

6) Operations and Maintenance Activity

i. Prior to the Operations and Maintenance Activity the software has been approved for operations use. Further activity shall consist of maintenance of the software to

remove latent errors (corrective maintenance), to respond to new or revised requirements (predictive maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance).

ii. Any software modifications shall be approved, documented, verified, validated, and controlled.

iii. In-use tests shall be performed in accordance with the requirements of Paragraph 3.2.7A.4).

7) Retirement Activity

During the Retirement Activity, the support for a software product is terminated, and the routine use of the software shall be prevented.

B. Configuration Control

1) Configuration Identification

i. A configuration baseline shall be performed at the completion of the following Software Lifecycle activities:

Requirement
Design
Implementation
Test
Installation and Checkout
Operation and Maintenance (According to Project Procedures)
Retirement

ii. A labeling system for configuration items shall be implemented that:

(a) Uniquely identifies each configuration item;
(b) Identifies changes to configuration items by revision; and
(c) Provides the ability to uniquely identify each configuration of the revised QA approved software available for use.

2) Configuration Change Control

i. Changes to MOX Services approved QA software shall be formally documented. Documentation shall contain a description of the change, the rationale for the change and the identification of affected baselines.

ii. Changes shall be formally evaluated and approved. Only authorized changes shall be made to software baselines.

iii. Software verification activities shall be performed for the change as necessary to ensure the change is appropriately reflected in software documentation, and to ensure that document traceability is maintained.

iv. Software validation shall be performed as necessary for the change.

v. QA shall verify that the requirements of this section are met prior to approving the software for use.

3) Configuration Status Accounting

Information needed to manage a configuration shall be documented. This information shall identify the approved configuration, status of proposed changes to the configuration, status of approved changes and information to support the functions of configuration identification and configuration control.

C. Plans for Software Quality Assurance

1) A plan (or plans) for assuring software quality assurance shall be developed for each new software program at the start of the software life cycle or for procured software. This plan may be prepared individually for each software program, or may exist as a generic document to be applied to software prepared within or procured by MOX Services.

2) The plan for controlling software program quality assurance shall identify:

i. Software products to which it applies;

ii. Organizations responsible for performing the work and achieving software quality and their tasks and responsibilities;

iii. Required documentation;

iv. Standards, conventions, techniques or methodologies which shall guide the software development, as well as methods to assure compliance to the same;

v. Required software reviews; and

vi. Methods for error reporting and corrective action.

D. Software Verification, Validation and Documentation

1) Software verification and validation documentation shall describe the tasks and criteria for accomplishing the verification of the

software in each phase, and the validation of the software at the end of the development cycle.

2) The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation.

3) The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design.

4) This documentation shall also contain the results of the execution of the software verification and validation activities, and shall include the results of reviews and tests, and a summary of the status of the software e.g., incomplete design performance and application requirements.

E. User Documentation

User documentation, as a minimum, shall include:

1) User instructions that contain an introduction, a description of the user's interaction with the software and a description of any required training necessary to use the software;

2) Input and output specifications;

3) Input and output formats;

4) A description of system limitations;

5) A description of user messages initiated as a result of improper input and how the user can respond; and

6) Information for obtaining user and maintenance support.

F. Software Problem Reporting and Corrective Action

1) A formal QA procedure for software problem reporting and corrective action shall be established for software errors and failures. This problem reporting system shall assure that problems are promptly reported to affected organizations to assure formal processing of problem resolutions.

2) Problems found in previously approved QA software are classified and forwarded to the organization responsible for the evaluation. Classification shall be defined based on the impact of the software output.

3) Corrective action by the responsible organization shall assure that:
   i. Problems are identified, evaluated, documented and, if required, corrected;
   ii. Problems are assessed for impact on past and present applications of the software by the responsible organization;
   iii. Corrections or changes shall be controlled in accordance with Paragraph 3.2.5; and
   iv. Preventive actions and corrective actions results are provided to affected MOX Services organizations.

G. Access Control

MOX Services shall administer physical and procedural controls to permit authorized and prevent unauthorized access to its computer system.

H. Software Acquisition

1) Software Acquired From Sources With MOX Services Approved QA Programs

   i. Individuals or organizations developing and supplying QA software under subcontract to MOX Services shall be required to have policies and QA procedures that meet the applicable requirements of this section as specified in procurement documents.
   ii. The documentation that is required by this section shall be delivered or made available by the supplier to MOX Services. Applicable requirements of this section shall become the responsibility of the MOX Services upon receipt of software. Typically this software enters the process at the start of the Installation and Checkout Activity.
   iii. Procurement documents shall require the supplier to report software errors or failures to MOX Services. MOX Services shall also report software errors to the supplier.

2) Software Acquired From Sources Without Approved QA Programs

   i. Existing software and procured or otherwise acquired software that has not been previously approved under a QA Program approved by MOX Services for use in its intended application shall be evaluated in accordance with the requirements of this section.
   ii. This software shall be uniquely identified and controlled prior to evaluation; and placed under configuration control

prior to use as approved software. The user organization shall perform and document an evaluation to:

(a) determine its adequacy to support software operation and maintenance, and

(b) identify the activities to be performed and documents that are needed in order for the software to be placed under configuration control. This determination shall be documented and shall identify as a minimum:

- User application requirements
- Test plans and test cases required to validate the software for acceptability
- User documentation required by Paragraph 3.2.7E.

iii. After the specified activities are performed, reviewed and approved, the software shall be placed under configuration control. The resulting documentation and computer program(s) shall establish the current baseline.

3) Procured Software Services

The organization providing software services, such as verification and validation, shall have a plan(s) for software quality assurance that meets the requirements of this section. The user organization shall determine the adequacy of this plan.

I. Software Release

1) Upon satisfactory completion of software qualification and completion of all requirements, the QA approved software program shall be released for use.

2) The approved software will be placed on a MOX Fuel Project approved computer software index. This index identifies the Software Name, Software Version, approved Software Platform, Software Program Manager, Software Description (ex: Finite Element Analysis, Dispersion, etc.), and any restrictions or limitations on the approved use of the software.

4 PROCUREMENT DOCUMENT CONTROL

4.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 4 Procurement Document Control of 10CFR50, Appendix B; and Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3), to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Applicable design bases and other requirements necessary to assure adequate quality are included or referenced in MOX Services procurement documents for procurement of QL-1 and QL-2 material, equipment and services. MOX Services procurement documents address and provide requirements for scope of work, technical requirements, tests, inspections, examinations, right of access, mandatory hold points for witness/inspection activities during manufacturing, supplier documentation and record retention, processing work stoppage, processing nonconformance, and spare parts. Procurement document changes are subject to the same degree of control as utilized in the preparation of the original procurement documents.

MOX Services procurements are issued to those suppliers that have been evaluated and determined to be acceptable for the particular scope of material, equipment and services to be procured. The material, equipment and services are procured by procurement requisitions and specifications, approved in accordance with QA procedures. Procurement documents require QL-1 suppliers to have a quality assurance program consistent with the applicable requirements of 10CFR50 Appendix B. The requirements of Title 10 CFR Part 21 (10CFR21), *Reporting of Defects and Noncompliance,* are invoked on IROFS procurements, as applicable.

4.2 REQUIREMENTS

4.2.1 Procurement Document Preparation

Procurement documents issued for SSCs or services shall include the following provisions, as applicable to the procured material, equipment or service:

A. A statement of the scope of work to be performed by the supplier.

B. Technical requirements including:

1) Design bases, identified or referenced in the procurement documents;

2) Specific documents (such as specifications, drawings, codes, standards, regulations, procedures or instructions) describing the technical requirements of the material, equipment or services to be furnished, shall be specified along with their revision level or change status; and

3) Tests, inspections or acceptance requirements that MOX Services will use to monitor and evaluate the performance of the supplier shall be specified; or

4) Identification of Commercial Grade Items for procurement.

C. Applicable Quality Assurance Program Requirements.

1) A requirement for the supplier/subcontractor to have a documented quality assurance program that implements applicable requirements of 10 CFR 50 Appendix B as implemented through the development and implementation of an NQA-1 1994/1995 addenda compliant QA Program in place before the initiation of work. The extent of the quality assurance program shall depend on the scope, nature or complexity of the material, equipment or service to be procured.

2) A requirement for the supplier/subcontractor to incorporate the appropriate requirements into any subtier procurement documents.

3) A requirement for reporting a defect or non-compliance determined to be a substantial safety hazard in accordance with 10CFR21 for IROFS procurements of non-commercial grade items only. If the supplier/subcontractor is unable to determine if the defect/non-compliance is a substantial safety hazard then the supplier/subcontractor has the option to report the item to MOX Services for determination of reportability.

D. Identification of right of access to supplier/subcontractor, including their subtier suppliers, facilities and records for inspection or audit by MOX Services, or other designee authorized by MOX Services.

E. Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier/subcontractor without MOX Services authorization.

F. Identification of documentation required to be submitted to MOX Services for information, review, acceptance, or approval shall be identified along with a document submittal schedule. Record retention times, disposition requirements and record maintenance responsibilities shall be identified for documentation that will become quality assurance records. MOX Services shall require supplier/subcontractors to submit those records being temporarily stored by them that are subject to records turnover requirements. The timing of the submittal shall be prescribed by procurement documents.

NOTE: *Once accepted by MOX Services, records are controlled and submitted to the records management system in accordance with QA procedures.*

G. Requirements for the supplier/subcontractor to report to MOX Services in writing adverse quality conditions resulting in work stoppages and nonconformances. These documents shall identify when MOX Services approval of partial and full work releases and disposition of nonconformances is required.

H. Requirement for the identification of recommended spare parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies. This is typically addressed in the procurement specifications.

I. Commercial Grade procurements shall also be identified in procurement documents.

J. Exceptions and clarifications for QL-1LR procurement requirements are defined in Attachment B.

4.2.2 Procurement Document Review and Approval

A. Procurement document reviews shall be performed and documented before issuing the procurement documents to the supplier/subcontractor. A review of the procurement documents and any changes thereto shall be made to verify that documents include applicable technical and quality assurance program requirements and contain appropriate provisions to ensure that

material, equipment or services will meet the governing requirements.

B. Personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement shall perform reviews of the procurement documents. Reviewers shall include representatives from the technical and quality assurance organizations.

4.2.3 Procurement Document Change

A. Changes to the scope of work, technical requirements, quality assurance program requirements, right of access, documentation requirements, work stoppage and nonconformance, hold points and lists of spare parts delineated in procurement documents, shall be subject to the same degree of control as used in the preparation of the original procurement document.

B. Changes resulting from proposal/offer evaluations or pre-contract negotiations shall be incorporated into procurement documents. The evaluation of these changes and the resulting impact shall be completed before the subcontract is awarded. This evaluation shall consider any additional or modified design criteria, inclusion of appropriate requirements as specified by this section and the analysis of exceptions or changes requested or specified by the supplier/subcontractor. The analysis will identify any impact these changes might have on the procurement

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5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 5 Instructions, Drawings, and Procedures of 10CFR50, Appendix B; and Basic Requirement 5 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)***.** During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Quality-affecting activities are prescribed by and performed in accordance with documented, approved QA procedures and other approved implementing documents (drawings, specifications, etc.) appropriate to the MOX Project work scope. Procedures are reviewed by affected managers for definition of work controlling processes. Documents that directly implement the requirements of the MPQAP are reviewed by MOX Services Quality Assurance to ensure the process provides implementation for QA Program requirements and commitments. MOX Project Procedures are approved by the MOX Services Project Manager. Functional Area managers may use supplementary workplace instructions to provide additional guidance for quality-affecting activities. These controlled workplace instructions are reviewed to ensure they do not conflict with this document or the project procedures. Use of approved procedures for quality-affecting activities is an important management measure implemented to ensure consistent application of requirements.

5.2 REQUIREMENTS

5.2.1 Types of Implementing Documents

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Implementing documents include QA procedures and specifications. In some instances QA Program requirements may be included in individual examples of other documents, such as drawings. Work controlling procedures may use approved checklists, travelers or other means to assure process requirements are met including prerequisite requirements prior to starting work. Procedures provide a consistent method for process performance and documentation of completion as well as ensure specified safety and environmental conditions are maintained.

5.2.2 Content of Implementing Documents

Implementing documents shall include the following information as appropriate to the work to be performed:

A. Responsibilities of the organizations affected by the document,

B. Technical and regulatory requirements,

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

D. Quantitative or qualitative acceptance criteria sufficient for determining activities were satisfactorily accomplished,

E. Prerequisites, limits, precautions, process parameters and environmental conditions,

F. Quality verification points and hold points,

G. Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, checklists or signoff blocks),

H. Identification of the lifetime or nonpermanent quality assurance records generated by the implementing document, and

I. Identification of associated quality-affecting items and activities.

5.2.3 Review and Approval of Implementing Documents

Implementing documents shall be reviewed, approved and controlled according to the requirements of Section 6, *Document Control*.

5.2.4 Compliance with Implementing Documents

A. When work cannot be accomplished as described in the implementing document or accomplishment of such work would result in an undesirable situation, the work shall be stopped.

B. Work shall not resume until the implementing document is changed (according to Section 6) to reflect the correct work practices or otherwise controlled through an approved process (e.g., approved corrective action specified as a result of the Corrective Action Process- see Section 16).

6 DOCUMENT CONTROL

6.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 6 Document Control of 10CFR50, Appendix B; and Basic Requirement 6 and Supplement 6S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Document Control is defined as the act of assuring the documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. Applicable QA procedures provide controls over MOX Services generated QA documents as well as QA documents received from supplier/subcontractors. QA procedures describe methods for preparing, reviewing, approving, controlling distribution of, changing, correcting, and deleting documents. Documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel in accordance with the applicable QA procedures.

6.2 REQUIREMENTS

6.2.1 The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. These documents include project procedures, Design Requirements Document, Basis of Design documents, Engineering Design Specifications, Design drawings, as-built drawings, engineering calculations, procurement documents, purchase orders and related documents, vendor-supplied documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, inspection and test reports and all such documents made electronically available.

6.2.2 Documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel. The reviewing organization has access to pertinent background data or information necessary to base their approval.

6.2.3 The responsibility for preparing and maintaining documents shall be assigned to the appropriate MOX Services functional area. The applicable QA procedures shall establish controls for the content of documents.

6.2.4 Documents shall be reviewed in accordance with applicable QA procedures for adequacy, correctness and completeness prior to approval and issuance.

6.2.5 The organizational position responsible for approving the document for release shall be identified in applicable QA procedures.

6.2.6 The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled to ensure:

A. Documents, in either hard copy or electronic media, used to perform work are distributed to, or made available to, the work location.

1) Controlled distributions shall be made to work locations not having access to the Electronic Data Management System (EDMS).

2) The transmittal for controlled distributions shall require receipt acknowledgement.

3) Identification of documents with controlled distribution and the distribution list shall be maintained.

B. Effective dates are established for approved documents. If an effective date is not documented on the coversheet then the document is assumed to be effective on the date approved.

C. The disposition of obsolete or superseded documents is controlled. Controlling instructions are contained in the applicable project procedures for document control and records management.

D. A system is established to identify the current status, including the current revision approved for use, of each document.

6.2.7 Changes to documents shall be reviewed for adequacy, correctness and completeness, prior to approval and issuance.

A. Changes shall be reviewed by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable. The reviewing organization has access to pertinent background data or information necessary to base their approval.

B. The quality assurance organization shall review changes to documents if the changes directly implement the requirements of the MPQAP.

C. Changes shall be approved for release by the designated organizational position that is responsible for the document.

D. QA procedures shall define the method used to incorporate changes. If the defined method is other than reissue of the entire document, the procedure shall define the maximum number of changes permitted prior to requiring reissue of the entire document.

E. QA procedures shall require that a history of changes to quality-affecting documents, including the reasons for the changes, be documented and maintained. For QA procedures this document history shall be reviewed each time changes to the procedures are proposed.

6.2.8 QA procedures may provide for expedited changes to implementing documents. If permitted, the expedited change shall include:

A. Identification of conditions necessary for use of an expedited change, such as unreasonable delay to the safe completion of the controlled activity;

B. Identification of necessary reviews for implementation of the expedited change;

C. Identification of the approval required for the expedited change;

D. Provisions for processing the change through the normal change process including establishment of time limits consistent with the type and nature of the document being changed.

6.2.9 Editorial corrections may be made to documents without being subject to review requirements. The applicable QA procedure shall define the organizational positions authorized to make editorial corrections. The following items are considered editorial corrections:

- Correcting grammar or spelling
- Renumbering sections or attachments
- Changing the title or number of the document
- Updating organizational titles.

NOTE: *A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.*

6.2.10 Procedure Use

Procedures used during the operational phase are reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every 2 years to determine if changes are necessary or desirable. The 2 year review is not required provided that all of the following are met:

A. Applicable procedures are reviewed following any modification to a system.

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

C. Procedures are updated during use when discrepancies are found.

D. Procedures are reviewed prior to use if not used in the previous 2 years.

E. A QA program audit of procedures is conducted every 2 years.

6.2.11 Temporary Procedures (during Operations Phase)

A. Temporary procedures include designation of the period of time during which it is valid to use them.

B. Temporary procedure changes which clearly do not change the intent of the approved procedure are approved by two members of the staff knowledgeable in the areas affected by the procedures.

6.2.12 Provisions are in place to continually improve work instructions through reviews and incorporation of feedback from users.

7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 7 Control of Purchased Material, Equipment and Services of 10CFR50, Appendix B; and Basic Requirement 7 and Supplement 7S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3). During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

MOX Services procurement of Quality Level 1 and Quality Level 2 material, equipment and services is controlled to assure conformance with specified technical and QA requirements. These controls include requirements for pre-award evaluations of supplier/subcontractors' QA Programs, annual evaluations, periodic audits/source inspections and surveillance. Supplier/subcontractors with an approved QA Program are placed on the MOX Services Approved Suppliers List prior to award of subcontract. Source inspections and surveillances, as well as, evaluations of received items and services are performed, as necessary, upon delivery or completion to ensure requirements specified in procurement documents are met. Supplier/subcontractor evaluations, annual evaluations, audits, surveillances, source inspections and receipt inspections are documented.

NOTE: *This section does not apply to direct-support services used for staff augmentation.*

7.2 REQUIREMENTS

7.2.1 Procurement Planning

MOX Services procurements shall be planned and documented. Procurement planning shall:

A. Identify procurement methods and organizational responsibilities, including what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.

B. Identify and document the sequence of actions and milestones necessary for completion of the procurement.

C. Provide for the integration of:

1) Procurement document preparation, review and change control according to the requirements of Section 4, *Procurement Document Control*;

2) Selection of procurement sources, proposal/offer evaluation and award;

3) Evaluation of supplier/subcontractor performance;

4) Verifications including any hold and witness point notifications;

5) Control of nonconformances;

6) Corrective action;

7) Acceptance of the material, equipment or service; and

8) Identification of quality assurance records to be provided to MOX Services.

D. Be accomplished as early as is practicable and no later than at the start of those procurement activities.

E. Be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier/subcontractor's quality performance.

F. Include the involvement of affected organizations.

7.2.2 Source Evaluation and Selection

A. Supplier/subcontractor selection shall be based on an evaluation, performed before the subcontract and/or purchase order is awarded, of the supplier/subcontractor's capability to provide items or services in accordance with procurement document (technical and quality) requirements.

Audits are not necessary for procuring the following items:

1) Those that are relatively simple and standard in design, manufacturing, and testing;

2) Those that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.

B. The functional area needing the procurement shall request that Quality Assurance evaluate the potential supplier/subcontractor's QA Program for placement on the MOX Services approved supplier list.

C. Measures for evaluating and selecting procurement sources shall be specified in QA procedures and include one or more of the following methods:

1) Evaluation of the supplier/subcontractor's history for providing an identical or similar product which performs satisfactorily in actual use.

2) Evaluation of supplier/subcontractor's current quality assurance records supported by any documented qualitative and quantitative information.

3) Evaluation of the supplier/subcontractor's technical and quality capability based on an evaluation of supplier/subcontractor facilities, personnel and quality assurance program implementation.

4) Verification that suppliers of calibration services have accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), the American Association for Laboratory Accreditation (A2LA) or other accreditation agencies accepted as signatories to the International Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA). The following additional requirements shall be noted in procurement documents;

- Purchase document impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements,
- Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance,
- Purchase documents require identification of the laboratory equipment/standards used.
- The alternative method is limited to the domestic calibration service suppliers.

D. The results of procurement source evaluation and selection shall be documented in accordance with the applicable QA procedure.

E. Exceptions and clarifications for QL-1LR suppliers are defined in Attachment B.

7.2.3 Proposal/Offer Evaluation

A. Technically qualified personnel from the QA, procurement, and responsible organizations shall perform an evaluation to determine if the proposal/offer meets procurement document requirements. As a minimum, this evaluation shall review the following subjects consistent with the importance, complexity and quantity of items or services being procured:

1) Technical considerations

2) QA Program requirements

3) Supplier/subcontractor personnel qualifications

4) Supplier/subcontractor production capability and past performance

5) Safety program requirements

6) Alternatives and exceptions.

B. Before the subcontract is awarded, MOX Services shall resolve or obtain commitments to resolve unacceptable quality conditions identified during the proposal/offer evaluation.

C. Supplier/subcontractor quality assurance programs shall be evaluated for acceptable implementation of identified Quality Assurance Program requirements before subcontract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to these requirements.

D. Supplier/subcontractor quality assurance programs shall be accepted by Quality Assurance for the scope of services provided before the supplier/subcontractor performs quality-affecting activities.

7.2.4 Supplier/Subcontractor Performance Evaluation

A. MOX Services shall establish measures to interface with the supplier/subcontractor and to verify supplier/subcontractor performance. The measures shall include:

1) Establishing an understanding between MOX Services and the supplier/subcontractor of the requirements and specifications identified in procurement documents.

2) Requiring the supplier/subcontractor to identify planning techniques and processes to be used in fulfilling procurement document requirements.

3) Reviewing supplier/subcontractor documents that are prepared or processed during work performed to fulfill procurement requirements.

4) Identifying and processing necessary change information.

5) Establishing a process for document information exchanges between MOX Services and supplier/subcontractor.

6) Establishing the extent of source surveillance and inspection.

B. The extent of MOX Services verifications shall be a function of the relative importance, complexity/quantity of items or services being procured and the supplier/subcontractor's quality performance.

C. MOX Services verifications shall be conducted as early as practical and shall not relieve the supplier/subcontractor of the responsibility for the verification of quality achievement. Verifications include supplier audits, surveillances or source inspections (or combinations) used as a method of evaluating the supplier/subcontractor's performance, and evaluation of MOX Services' documentation to aid in the determination of the effectiveness of the supplier/subcontractor's quality assurance program.

7.2.5 Control of Supplier/Subcontractor Generated Documents

A. Supplier/subcontractor generated documents shall be controlled, processed and accepted by MOX Services in accordance with the requirements established in the applicable QA procedures.

B. Measures shall be implemented to ensure that the submittal of supplier/subcontractor generated documents is accomplished in accordance with the procurement document requirements. These measures shall also provide for the acquisition, processing and recorded evaluation of technical, inspection and test data compared against the acceptance criteria.

7.2.6 Acceptance of Items or Services

7.2.6.1 General

A. Methods for accepting supplier/subcontractor furnished material or equipment shall include one or more of the following, as appropriate to the items being procured:

1) Evaluating the supplier/subcontractor certificate of conformance;

2) Performing one or a combination of source verification, receiving inspection or post-installation test;

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

1) Technical verification of the product produced;

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

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

C. The supplier/subcontractor shall verify that furnished material, equipment, or services comply with procurement requirements before offering the material, equipment, or services for acceptance and shall provide objective evidence that material, equipment, or services conform to procurement documents.

7.2.6.2 Certificate of Conformance

When a certificate of conformance is used to accept material, equipment, or service:

A. The certificate shall identify the purchased material, equipment or service to the specific procurement document/purchase order number.

B. The certificate shall identify the specific procurement requirements met by the purchased material, equipment or service (such as codes, standards, pre-installation tests, and other specifications). This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall

include any approved changes, waivers or deviations applicable to the material, equipment or service.

C. The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving nonconformances.

D. The certificate shall be signed and dated or otherwise authenticated by an individual who is responsible for the supplier/subcontractor's quality assurance function and whose responsibilities and position are described in the supplier/subcontractor's quality assurance program.

E. The certification process, including the documents to be followed in filling out a certificate and the administrative documents for review and approval of the certificates, shall be described in the supplier/subcontractor's quality assurance program.

F. Measures shall be identified to verify the validity of supplier/subcontractor certificates and the effectiveness of the certification process (such as by audit of the supplier/subcontractor or by an independent inspection or test of the item). Verifications shall be conducted by MOX Services at intervals commensurate with the past quality performance of the supplier/subcontractor.

Additionally, when design and/or procurement requirements necessitate the need, a Certified Material Test Report (CMTR/MTR) shall be provided. The report shall contain sufficient data and information to verify the actual properties of the items and the actual results of required tests. In cases where the CMTR/MTR is provided from an unqualified source, additional testing (chemical, physical, Positive Material Identification, etc.) shall be necessary, as required, to provide reasonable assurance that the CMTR/MTR accurately matches the supplied material. For QL-1LR procurements, a commercial CMTR/MTR is acceptable.

7.2.6.3 Source Verification

MOX Services may accept material, equipment or service by monitoring, witnessing or observing activities performed by the supplier/subcontractor. This method of acceptance is called source verification.

A. Source verification shall be implemented at predetermined points consistent with the supplier/subcontractor's planned inspections, examinations, or tests and performed at intervals consistent with the importance and complexity of the item.

B. Upon MOX Services acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item and to the Supplier/subcontractor, with MOX Services maintaining the records of acceptance.

C. Personnel shall be qualified in accordance with the applicable requirements for the type of verification performed.

7.2.6.4 Receiving Inspection

When receiving inspection is used to accept an item:

A. The inspection shall consider any source verifications/audits and the demonstrated quality performance of the supplier/subcontractor.

B. The inspection shall be performed in accordance with established inspection QA procedures.

C. The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness.

D. The inspection shall be planned and executed according to the requirements of Section 10, *Inspection*.

E. Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier/subcontractor documentation submittals.

F. Evaluations of suppliers are documented and take into account the following, where applicable:

Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available. The results of the review are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve months, the annual evaluation shall be performed as follows:

1) review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions;

2) results of previous source verifications, audits, and receiving inspections;

3) operating experience of identical or similar products furnished by the same supplier;

4) results of audits from other sources (e.g., customer or NRC audits).

7.2.6.5 Post-Installation Testing

When using post-installation testing as a method of acceptance, MOX Services and the supplier/subcontractor shall mutually establish test requirements and acceptance documentation based on the MOX Services established performance requirements.

7.2.7 Control of Supplier/Subcontractor Nonconformance

MOX Services and the supplier/subcontractor shall establish and document the process for disposition of items that do not meet procurement document requirements according to the following requirements.

A. The supplier/subcontractor shall be required to evaluate nonconforming items according to the applicable requirements of Section 15, *Nonconforming Materials, Parts, or Components*.

B. The supplier/subcontractor shall be required to submit reports of nonconformance to MOX Services identifying supplier/subcontractor disposition, technical justification, and verification of implementation of the disposition.

C. Reports of nonconformance to procurement document requirements, or documents approved by MOX Services, shall be submitted to MOX Services for approval of the recommended disposition, if other than “reject”, whenever one of the following conditions exists:

1) Technical or material requirements are violated

2) A requirement in supplier/subcontractor documents, which have been approved by MOX Services, is violated

3) The nonconformance cannot be corrected by continuation of the original manufacturing process or by re-work

4) The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

D. For reports of nonconformance identified in Paragraph C above, MOX Services shall disposition the supplier/subcontractor's recommendation and verify implementation of the disposition.

7.2.8 Commercial Grade Items

A. Commercial grade item means a structure, system, or component, or part thereof that affects its items relied on for safety (IROFS) function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

The following terms are defined consistent with their application to the MFFF:

1) Basic Component – When applied to MOX Services MFFF licensed under 10 CFR 70, basic component means a structure, system, or component, or part thereof that affects their IROFS function, that is directly procured by the licensee or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (i.e., exceed performance requirements of 10 CFR 70.61).

In all cases, basic components includes IROFS related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

2) Critical Characteristics – When applied to MOX Services MFFF licensed pursuant to 10 CFR 70, critical characteristics are those important design, material, and

performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended IROFS function.

3) Dedicating Entity - When applied to MOX Services MFFF licensed pursuant to 10 CFR 70, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where MOX Services applies the commercial grade item procurement strategy and performs the dedication process, MOX Services would assume full responsibility as the dedicating entity.

4) Dedication - When applied to MOX Services MFFF licensed pursuant to 10 CFR 70, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

B. Critical characteristics for commercial grade items shall be determined and approved by the manager responsible for the procurement based on the performance requirements for the item including the intended IROFS safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will

meet their catalog or manufacturer specifications and perform the specified functions as intended.

C. Where the design utilizes commercial grade items in Quality Level 1 applications, the following requirements are an acceptable alternate to other requirements of Paragraph 7.2 except as noted in 2) below:

1) The commercial grade material/equipment is identified in an approved design output document. An alternate commercial grade material/ equipment may be applied, provided there is verification that the alternate commercial grade material/equipment will perform the intended function and will meet design requirements applicable to both the replaced material/equipment and its application.

2) Supplier evaluation and selection, where determined necessary by the purchaser based on the complexity and importance to safety, shall be in accordance with Paragraph 7.2.2.

3) Commercial grade items shall be identified in the subcontract/purchase order by the manufacturer's published product description.

4) One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance:

   i. Special test(s) or inspection(s) or both;
   ii. Commercial grade survey of the supplier;
   iii. Source verification;
   iv. Acceptable supplier/item performance records.

5) Prior to release of a commercial grade item, MOX Services shall determine that:

   i. Damage was not sustained during shipment;
   ii. The item received was the item ordered;
   iii. Inspection and/or testing is accomplished, as required, to assure conformance with critical characteristics; and
   iv. Documentation, as applicable to the item, was received and is acceptable.

D. For specific QL-1LR dedication applications see Attachment B.

7.2.9 Approved Supplier List

A. Quality Assurance shall develop and maintain the Approved Suppliers List. The approved supplier list contains those supplier/subcontractors whose Quality Assurance Programs have been evaluated and accepted by MOX Services Quality Assurance in accordance with approved procedures.

B. Quality Assurance shall perform and document an evaluation of each supplier/subcontractor every 12 months. Satisfactory results will maintain the supplier/subcontractor on the approved supplier list.

C. Supplier/subcontractors shall be evaluated by means of an audit at least triennially.

D. Supplier/subcontractors that have unacceptable evaluations shall have appropriate restrictions identified on the approved suppliers list.

7.2.10 Approved Commercial Grade Item List

A. Quality Assurance shall develop and maintain the Commercial Grade Item Approved Suppliers List. The approved supplier list contains those supplier/subcontractors whose Quality Assurance Programs have been evaluated and accepted by MOX Services Quality Assurance for the items to be procured in accordance with approved procedures.

B. Quality Assurance shall perform and document an evaluation of each supplier/subcontractor every 12 months. Satisfactory results will maintain the supplier/subcontractor on the approved supplier list.

C. Supplier/subcontractors that have unacceptable evaluations shall have appropriate restrictions identified on the approved suppliers list.

8 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS

8.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 8 Identification and Control of Materials, Parts, and Components of 10CFR50, Appendix B; and Basic Requirement 8 and Supplement 8S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

The MOX Services QA Program procedures establish the necessary controls to assure that only correct and accepted material, parts and components including the use of consumables and items with limited shelf life and partially fabricated assemblies are used or installed. In addition, procedures require that identification is maintained on the items or in documents traceable to the items in a manner that assures that adequate identification and controls are established and maintained.

8.2 REQUIREMENTS

8.2.1 Identification

A. Identification on the items shall be established and maintained.

B. Items of production (batch, lot, component, part) shall be identified from the time of initial receipt and/or fabrication, up to and including installation or end use. The identification shall relate the item to an applicable design or other pertinent specifying documents.

8.2.2 Physical Markings

B. Item identification methods shall include use of physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels or tags attached to containers or procedural control).

C. Physical markings, when used, shall:

1) Be applied using materials and methods that provide a clear and legible identification,

2) Not detrimentally affect the function or service life of the item,

3) Be transferred to each part of an identified item when the item is subdivided, and

4) Not be obliterated or hidden by surface treatments or coatings, or after installation unless other means of identification are substituted.

8.2.3 Traceability

A. Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents.

B. Item traceability documentation shall ensure that the item can be traced from its source through installation or end use.

8.2.4 Other Requirements

The controls for items shall address the following requirements, as applicable:

A. If codes, standards or specifications include specific identification or traceability requirements (i.e., identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records), then identification and traceability methods shall implement the requirements specified.

B. If items have a limited operating or shelf life specified, then methods shall be established that preclude using the item beyond the shelf or operating life.

C. If item storage is required, then methods shall be established for the control of item identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

1) Maintenance or replacement of markings and identification tags damaged during handling or aging,

2) Protection of identification markings subject to excessive deterioration resulting from environmental exposure, and/or

3) Updating related documentation.

9 CONTROL OF SPECIAL PROCESSES

9.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 9 Control of Special Processes of 10CFR50, Appendix B, and Basic Requirement 9 and Supplement 9S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Processes other than "special processes" such as "work control" are controlled by written procedures using drawings, checklists, travelers or other appropriate means to control the work. The requirements for the content and generation of the procedures controlling these processes are addressed in Section 5, *Instructions, Procedures, and Drawings*. MOX Services QA Program procedures establish the necessary requirements for the control of special processes, such as welding, heat treating, chemical cleaning and nondestructive examination. These requirements include personnel qualification and certification, acceptable equipment, environmental conditions and applicable codes, design specifications and other established standards.

9.2 REQUIREMENTS

9.2.1 Special Processes

A. Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards.

B. Processes to be controlled as special processes shall meet the following criteria:

1) The results are highly dependent on the control of the process; or

2) The results are highly dependent on the skill of the operator; and

3) Inspection or test of the product cannot readily determine quality of the results.

C. Based on the above criteria, a list of the special processes that each participating MOX Services organization will perform, or be responsible for performing, shall be established and maintained.

9.2.2 Personnel, Implementing Documents, and Equipment Qualifications

Implementing MOX Services documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Special process implementing documents shall include or reference:

A. Qualification requirements for personnel, implementing documents and equipment,

B. Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process and calibration requirements, and/or

C. Requirements of applicable codes and standards, including acceptance criteria for the special process.

9.2.3 Qualification of Nondestructive Examination Personnel

Nondestructive examinations (radiography, magnetic particle, ultrasonic, liquid penetrant, electromagnetic, visual testing and leak testing) required to be used for the MOX Fuel Project shall be performed by personnel who have been qualified and certified in accordance with Paragraph 2.2.6G of this document.

10 INSPECTION

10.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 10 Inspection of 10CFR50, Appendix B; and Basic Requirement 10 and Supplement 10S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Inspections verifying conformance of an item or activity to specified requirements are planned and executed. Characteristics for inspection and inspection methods employed are specified in QA procedures. The inspection program establishes the inspections to be performed (source, in-process, final, receipt, maintenance, modification, in-service, and operations). Inspection results are documented. Persons, independent of those who performed and who directly supervised the work, perform inspection for acceptance. The inspection program may be implemented by or for MOX Services.

10.2 REQUIREMENTS

Inspection requirements and acceptance criteria are contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. Inspection activities, associated with QL-1 and QL-2 items, require qualified inspection personnel, are documented, and controlled by instructions, procedures, drawings, checklists, travelers or other appropriate means.

10.2.1 Inspection Planning

Documented Inspection planning shall include:

A. Identification of each work operation where inspection is necessary to ensure quality;

B. Identification of documents that shall be used to perform the inspections;

C. Identification of the characteristics for inspection and the identification of when, during the work process, inspections are to be performed for those characteristics;

D. Identification of inspection or process monitoring methods employed;

E. Sufficient information for the final inspection to provide a conclusion regarding conformance of the item to specified requirements;

F. Identification of the functional qualification level (category or class) of personnel performing inspections;

G. Identification of acceptance criteria;

H. Identification of sampling requirements;

I. Methods to record inspection results; and

J. Selection and identification of the measuring and test equipment to be used to perform the inspection to ensure that the equipment is calibrated and is of the proper type, range, accuracy and tolerance to accomplish the intended function.

K. Organization responsible for performing the inspection.

10.2.2 Selecting Inspection Personnel to Perform Inspections

A. The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements of Paragraph 2.2.6H.

B. Data recorders, equipment operators or other inspection team members who are supervised by a qualified inspector shall not be required to be a qualified inspector.

C. Inspections shall be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection personnel shall not report directly to the immediate supervisor responsible for the work being inspected.

D. Attachment B contains exceptions and clarifications for selecting personnel to perform inspections for QL-1LR installations.

10.2.3 Inspection Hold Points

A. When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization placing the hold point, the specific hold points shall be indicated in documents.

B. Consent to waive specified hold points shall be documented and approved before continuing work beyond the designated hold point.

10.2.4 Statistical Sampling

When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method used shall be based on recognized standard practices and these practices shall be implemented through applicable approved procedures.

10.2.5 In-Process Inspections and Monitoring

A. Items shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment and personnel shall be provided.

B. Inspection and process monitoring shall be conducted when control is inadequate with only one method.

C. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process.

D. Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process.

10.2.6 Final Inspection

A. Finished items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required in order to verify the quality and conformance of the item to specified requirements.

B. Documentation not previously examined shall be examined for adequacy and completeness.

C. Final inspections shall include a review of the results and resolution of nonconformances identified by earlier inspections.

D. Modifications, repairs or replacements of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.

10.2.7 Accepting Items

The acceptance of an item shall be documented and reviewed and approved by qualified and authorized personnel to evaluate the technical

adequacy of the inspection results. The inspection status of an item shall be identified according to Section 14, *Inspection, Test, and Operating Status*.

10.2.8 Inspection documentation shall identify:

A. The item inspected, date of inspection, the name of the inspector or the inspector's unique identifier, who documented, evaluated and determined acceptability;

B. Name of data recorder, as applicable and type of observation or method of inspection;

C. The inspection criteria, sampling plan or reference documents (including revision levels) used to determine acceptance;

D. Results indicating acceptability of characteristics inspected;

E. Measuring and test equipment used during the inspection including the identification number and the most recent calibration date; and

F. Reference to information on actions taken in connection with nonconformance, as applicable.

11 TEST CONTROL

11.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 11 Test Control of 10CFR50, Appendix B, and Basic Requirement 11 and Supplement 11S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)***.** During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*. The requirements in Supplement 11S-2 for computer program testing are addressed in Paragraph 3.2.7.

Tests required to verify conformance of an item to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. The test control program includes various types of testing such as proof tests before installation preoperational tests, post maintenance tests, post modification tests and operational tests. Test results are documented and their conformance with acceptance criteria is evaluated.

11.2 REQUIREMENTS

11.2.1 Test Planning

Test planning shall include:

A. Identification of the documents to be developed to control and perform tests;

B. Identification of items to be tested, test requirements and acceptance limits, including required levels of precision and accuracy;

C. Identification of test methods to be employed and instructions for performing the test;

D. Identification of test prerequisites addressing calibration for instrumentation, adequacy of test equipment and instrumentation, qualifications of personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions, and provisions for data acquisition;

E. Identification of mandatory hold points and methods to record data and results;

F. Provisions for ensuring that prerequisites for the given test have been met;

G. Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function; and

H. Identification of the functional qualification of personnel performing tests.

11.2.2 Performing Tests

Tests shall be performed in accordance with QA procedures addressing, as applicable:

A. Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.

B. Test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and used, necessary monitoring is performed, and suitable environmental conditions are maintained.

C. Test requirements and acceptance criteria provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated.

D. Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.

E. Potential sources of uncertainty and error. Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.

11.2.3 Use of Other Testing Documents

A. Other testing documents [i.e., American Society for Testing and Materials (ASTM) specifications, vendor manuals or other related documents containing acceptance criteria] may be used instead of preparing special test procedures. If used, then they shall incorporate the information directly into the approved test procedure or shall be incorporated by reference in the approved test procedure.

B. Documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.

11.2.4 Test Results

A. Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that test requirements have been satisfied.

B. The test status of an item shall be identified in accordance with Section 14, *Inspection, Test, and Operating Status*.

11.2.5 Test Documentation

Test documentation shall identify the:

A. Item or work product tested, date of test, names of tester and data recorders, type of observation and method of testing;

B. Test criteria or reference documents used to determine acceptance;

C. Results and acceptability of the test;

D. Actions taken in connection with any nonconformances noted;

E. Name of the person evaluating the test results; and

F. Measuring and test equipment (M&TE) used during the test including the identification number and the most recent calibrated date.

11.2.6 Qualification of Test Personnel

A. The individual who directs a test to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements of Paragraph 2.2.6H.

B. Data recorders, equipment operators, or other test team members performing under the direction of a qualified test director shall not be required to be qualified under Paragraph 2.2.6H.

C. Tests shall be directed by personnel other than those who performed or directly supervised the work being tested. Test directors shall not report directly to the immediate supervisor responsible for the work being tested.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 12 Control of Measuring and Test Equipment (M&TE) of 10CFR50, Appendix B; and Basic Requirement 12 and Supplement 12S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)***.** During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

This section establishes MOX Services control for tools, gages, instruments reference standards, nondestructive examination equipment, and other M&TE used for quality-affecting activities. M&TE is controlled, at specified periods calibrated, and adjusted to maintain accuracy within necessary limits.

12.2 REQUIREMENTS

12.2.1 Calibration

A. M&TE shall be calibrated, adjusted and maintained at prescribed intervals or, prior to use, against certified reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented.

B. Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated.

1) If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used, provided they are shown to be adequate for the requirements.

2) The basis for the calibration acceptance shall be documented and authorized by responsible management as defined in applicable QA procedures. The level of management authorized to perform this function shall be identified.

C. The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting measurement control. For M&TE used in one-time-only applications,

the calibration shall be performed both before and after use, when practicable.

D. A calibration shall be performed when the accuracy of calibrated M&TE is suspect.

E. Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration and uniquely identified to provide traceability to its calibration data.

12.2.2 Documenting Use of M&TE

The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected or items inspected or tested since the last calibration.

12.2.3 Out of Calibration M&TE

A. M&TE shall be considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist:

1) The calibration due date or interval has passed without re-calibration.

2) The device produces results known or suspected to be in error.

B. Out-of-calibration M&TE shall be controlled. The controls shall include the following requirements:

1) Out-of-calibration M&TE shall be tagged, segregated or otherwise controlled to prevent use until they have been recalibrated.

2) When M&TE is found out-of-calibration during re-calibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to determine acceptability of previously collected data, processes monitored, or items previously inspected or tested. The evaluation shall be documented.

C. If any M&TE is consistently found out-of-calibration during the re-calibration process, it shall be repaired, replaced, or the calibration interval shortened.

12.2.4 Lost or Damaged M&TE

If M&TE is lost or damaged, it shall be documented as a nonconforming item in accordance with Section 15, *Nonconforming Materials, Parts, or Components*. The evaluation of the nonconformance must address the validity of results obtained using that equipment since its last valid calibration to determine acceptability of previously collected data, processes monitored or items previously inspected or tested.

12.2.5 Handling and Storage

M&TE shall be properly handled and stored to maintain accuracy.

12.2.6 Commercial Devices

Calibration and control shall not be required for rulers, tape measures, levels and other normal commercial equipment that provides adequate accuracy.

12.2.7 M&TE Documentation

Records of calibration status and the capability of M&TE to perform its intended function are maintained. M&TE calibration documentation shall include the following information:

A. Identification of the measuring or test equipment calibrated;

B. Traceability to the calibration standard used for calibration;

C. Calibration data;

D. Identification of the individual performing the calibration;

E. Identification of the date of calibration and the re-calibration due date or interval, as appropriate;

F. Results of the calibration and statement of acceptability;

G. Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE including evaluation results, as appropriate; and

H. Identification of the document (including revision level) used in performing the calibration.

13 HANDLING, STORAGE, AND SHIPPING

13.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 13 Handling, Storage, and Shipping of 10CFR50, Appendix B, and Basic Requirement 13 and Supplement 13S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Handling, storage, cleaning, packaging, shipping and preservation of items are controlled in accordance with requirements of this section to prevent damage or loss and to minimize deterioration.

13.2 REQUIREMENTS

13.2.1 Controls

A. Handling, storage, cleaning, packaging, shipping and preservation of items shall be conducted in accordance with established work and inspection procedures, shipping instructions or other specified documents.

B. For critical, sensitive, perishable or high-value articles, specific implementing documents for handling, storage, cleaning, packaging, shipping and preservation shall be prepared and used.

13.2.2 Special Equipment Tools and Environments

A. If required for particular items, special equipment (i.e., containers, shock absorbers and accelerometers) and special protective environments (i.e., inert gas and specific moisture/temperature levels) shall be specified and provided.

B. If special equipment and environments are used, provisions shall be made for their verification.

C. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.

D. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained.

E. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

13.2.3 Marking and Labeling

A. Measures shall be established for marking and labeling for the packaging, shipping, handling and storage of items as necessary to adequately identify, maintain and preserve the item.

B. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

13.2.4 During Operations, the following additional provisions apply:

A. Controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could affect their function.

B. Controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes are followed.

C. Cleanliness controls for work on IROFS and non IROFS risk-significant equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure.

14 INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 14 Inspection, Test, and Operating Status of 10CFR50, Appendix B, and Basic Requirement 14 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3). During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

This section establishes requirements for MOX Services to identify the status of inspection and test activities. Status is indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status is maintained through indicators (i.e., physical location and tags, markings, shop travelers, stamps, inspection records, computerized logs, or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified. Status indicators provide for indicating the operating status of systems and components of the nuclear facility (i.e., tagging valves and switches) to prevent inadvertent operation.

14.2 REQUIREMENTS

14.2.1 Identifying Items

A. Items that have satisfactorily passed required inspections and tests shall be identified.

B. The identification methods shall preclude the inadvertent installation, use or operation of items that have not passed required inspections and tests.

14.2.2 Indicating Status

A. The status of required inspection and tests of items shall be indicated when necessary to preclude inadvertent bypassing of such inspections and tests.

B. The status of inspections and tests shall be identified either on the items or in documents traceable to the items.

C. Status shall be maintained through the use of status indicators (i.e., tags, markings, labels and stamps), or other means (i.e., travelers, logs, inspection or test records).

D. The authority for applying and removing status indicators shall be specified.

E. Status indicators shall be used to provide an indication of the test or operating status of items or facilities to prevent inadvertent changes in operating status.

F. During Operations Phase, procedures require independent verifications, where appropriate, to ensure that necessary measures such as tagging equipment, have been implemented correctly.

G. During Operations Phase, temporary modifications, such as temporary bypass lines, electrical jumpers, lifted leads, and temporary trip point setting, are controlled by approved procedures which include a requirement for independent verification.

15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

15.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 15 Nonconforming Materials, Parts or Components of 10CFR50, Appendix B, and Basic Requirement 15 and Supplement 15S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

This section provides the process for controlling items that do not conform to specified requirements. These items are controlled to prevent inadvertent installation or use. The controls provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations.

15.2 REQUIREMENTS

15.2.1 Documenting and Evaluating Nonconforming Items

A. A nonconforming item (a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate) is properly controlled to prevent its inadvertent test, installation, or use.

B. Procedures are used for the identification, documentation, segregation, disposition and notification of the nonconforming items to the affected organization.

C. Procedures are used for documenting the reviews, acceptance, rejection, repair or reworked nonconforming items.

D. Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

E. Nonconformance documentation shall be reviewed and recommended dispositions of nonconforming items shall be proposed. The review shall include determining the need for additional corrective actions according to the requirements of Section 16, *Corrective Action*. In addition, organizations affected by the nonconformance shall be notified.

F. Recommended dispositions shall be evaluated and approved.

G. Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements and access to pertinent background information.

H. The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be specified.

I. Further processing, delivery, installation or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition.

15.2.2 Identifying Nonconforming Items

A. Nonconforming items shall be identified by marking, tagging or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable.

B. If the identification of a nonconforming item is not practical, the container, package or segregated storage area, as appropriate, shall be identified.

15.2.3 Segregating Nonconforming Items

A. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

B. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

15.2.4 Disposition of Nonconforming Items

A. The disposition of “use-as-is,” “reject,” “repair,” or “rework” for nonconforming items shall be identified and documented.

B. The technical justification for the acceptability of a nonconforming item that has been dispositioned “repair” or “use-as-is” shall be documented.

C. Items that do not meet original design requirements that are dispositioned “use-as-is” or “repair” shall be subject to design control measures commensurate with those applied to the original design.

1) If changes to the specifying document are required to reflect the as-built condition, the disposition shall require action to change the specifying document to reflect the accepted nonconformance.

2) Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation.

D. The disposition of an item to be reworked, or repaired shall contain a requirement to reexamine (inspect, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

16 CORRECTIVE ACTION

16.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 16 Corrective Action of 10CFR50, Appendix B, and Basic Requirement 16 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

Conditions adverse to quality are promptly identified, documented, classified and corrected as soon as practical. Such conditions are tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken. Provisions are in place to ensure corrective actions are not inadvertently nullified by subsequent actions.

Significant conditions adverse to quality are evaluated for reportability and reported if conditions meet the Title 10 of the Code of Federal Regulations, Part 21, "Reporting of Defects and Noncompliance" (10CFR21) reporting criteria. Regardless of the reportability determination, the cause of the significant condition is determined and corrective action taken. The identification, cause, and corrective actions are documented and reported to appropriate levels of management. Follow-up action is taken to verify implementation of this corrective action.

MOX Services QA procedures provide requirements and processes for the following activities:

- Prompt identification, correction and trending of conditions adverse to quality;
- Evaluating significant conditions adverse to quality for reportability to the NRC under 10 CFR 21 requirements and reporting such conditions when warranted;
- Stopping work, if applicable;
- Determining root cause and preventive actions for significant conditions adverse to quality; and
- Verifying implementation of corrective actions.

16.2 REQUIREMENTS

16.2.1 Identifying and Classifying Conditions Adverse to Quality

A condition adverse to quality shall be identified when an implementing document requirement is not met. Conditions adverse to quality shall be classified based on their significance, and corrective actions shall be taken accordingly. The categories of significance shall include: Conditions adverse to quality and Significant conditions adverse to quality.

A. Conditions Adverse to Quality

1) Conditions adverse to quality are defined as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances.

2) Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the MOX Services Quality Assurance organization for tracking and trending.

3) Responsible management shall investigate and fully identify the condition and document the results.

4) Responsible management shall utilize the investigation results to determine and document planned corrective actions (including remedial action and if appropriate, actions to prevent recurrence). Concurrence from the MOX Services Quality Assurance organization is obtained for planned corrective actions on significant conditions adverse to quality.

5) Responsible management shall complete corrective actions and document completion of actions in a timely manner.

B. Significant Conditions Adverse to Quality

1) Significant conditions adverse to quality are defined as:

i. A deficiency that would seriously impact an item from performing its intended function of assuring compliance to 10CFR70.61 performance requirements;
ii. A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;
iii. A deficiency in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in

order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;

iv. A deviation from performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;

v. A significant error in a computer program used to support activities affecting quality after it has been released for use;

vi. Loss of essential data required for activities or items subject to the MOX Services QA Program;

vii. A deficiency, repetitive in nature, related to an activity or item subject to the MOX Services QA Program; and

viii. A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to MOX Services QA Program.

2) Significant conditions adverse to quality shall be documented and reported to the management responsible for the condition, their upper management, and to the MOX Services Quality Assurance organization for tracking.

3) Significant conditions adverse to quality related to QL-1 SSCs shall be evaluated for reportability under 10CFR21 to determine if the defects or noncompliances are reportable to the NRC. If found to be reportable, the responsible management shall immediately inform MOX Services Licensing, MOX Services Quality Assurance, MOX Services President and other appropriate management within the organization to ensure the condition is reported to the NRC in accordance with established requirements.

4) If a supplier/subcontractor reports a defect or noncompliance related to QL-1 SSC which the supplier/subcontractor evaluates as a substantial safety hazard, MOX Services shall determine if the identified condition affects any products received by MOX Services for QL-1 application and identify and control any such products as nonconforming items under Section 15, *Nonconforming Materials, Parts, or Components.*

5) If the supplier/subcontractor identifies a defect or noncompliance but is unable to determine if the defect or noncompliance is a substantial safety hazard then upon notification from the supplier/subcontractor MOX Services shall determine if the condition is reportable to the NRC. If found to be reportable, the responsible management shall immediately inform MOX Services Licensing, MOX Services Quality Assurance, MOX Services

President and other appropriate management within the organization, and report the condition to the NRC in accordance with established requirements.

6) Significant conditions adverse to quality shall be evaluated for a stop work condition to determine if stopping work is warranted. If a stop work condition is identified, management shall issue stop work in accordance with the applicable QA procedure. Upon resolution of the related significant condition adverse to quality, management shall take appropriate action to lift and close (in part or total) the stop work order.

7) Responsible management shall investigate and determine the extent of the condition and document the results.

8) Responsible management shall then determine the root cause, and corrective action (including remedial action and actions to prevent recurrence) based on investigation results. Concurrence from MOX Services Quality Assurance organization shall be obtained to ensure that QA requirements are satisfied.

9) Responsible management shall complete remedial action and document completion of actions in a timely manner.

16.2.2 Follow-Up and Closure Action

MOX Services shall verify implementation of corrective actions taken for reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete. For significant conditions adverse to quality, MOX Services Quality Assurance organization will verify implementation of corrective actions.

16.2.3 Trending of MOX Services Deficiencies

The MOX Services Quality Assurance organization shall establish criteria for determining nonconformance trends. Reports of conditions adverse to quality and significant conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends shall be reported to the appropriate management within the organization for corrective action.

16.2.4 Incident Investigations (during Operations Phase)

Incident investigations are used for investigating abnormal events, other than those that involve Conditions Adverse to Quality. 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 shall be procedurally documented.

17 QUALITY ASSURANCE RECORDS

17.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 17 Quality Assurance Records of 10CFR50, Appendix B, and Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

A QA record is any completed document that furnishes evidence of the quality of items and/or activities affecting quality. Records may include specially processed records such as radiographs, photographs, negatives, microforms and magnetic/electronic media.

17.2 REQUIREMENTS

17.2.1 Record Management System

A. MOX Services shall establish a record management system and Records Center at the earliest practicable time consistent with the schedule for accomplishing work activities.

B. The record management system and associated Records Center shall be defined, implemented and enforced in accordance with written procedures, instructions or other documentation.

C. Procedures describing the record management system shall include methods for controlling records withdrawn from storage that are required for the completion of work activities.

D. Provisions shall be made for the capability to retrieve information stored on magnetic or optical media.

17.2.2 Generation of Records

A. Implementing documents shall specify the records to be generated, supplied, and maintained.

B. Documents that are designated to become records shall be legible, accurate and completed appropriate to the work accomplished.

C. Training is provided for individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/regeneration, and recovery.

D. Classifications of Records

MOX Services records shall be classified for retention purposes as lifetime records or nonpermanent records in accordance with the criteria in this section.

1) Lifetime Records

Lifetime records are those that meet one or more of the following criteria:

i. Those of significant value in demonstrating capability for safe operation;
ii. Those of significant value in maintaining, reworking, repairing, replacing or modifying an item;
iii. Those of significant value in determining the cause of an accident or malfunction of an item; and/or
iv. Those providing required baseline data for in-service inspections.

Lifetime records are required to be maintained for the life of the particular item while it is installed in the facility or stored for future use. Examples of typical lifetime QA records are shown in Figure 17-1.

2) Nonpermanent Records

Nonpermanent records are those providing evidence an activity was performed in accordance with the applicable requirements of the MOX Services QA Program but need not be retained for the life of the item because they do not meet the criteria for lifetime records. The retention period for nonpermanent records shall be documented in the applicable implementing QA procedure and the QA Records Retention Index. QA audit, surveillance and assessment reports are examples of nonpermanent records.

E. Producing Valid Records

1) The individual using the procedure is responsible for ensuring the records required by the procedure are submitted to the permanent record storage facility.

2) Documents that may become records shall be maintained and processed in a prudent manner to avoid unnecessary delay and/or expense in retrieving the record when the record is needed to support other work.

3) Individuals creating records shall ensure the records are legible, accurate and complete, and shall protect them from damage, deterioration or loss until the records are submitted to the Records Center.

4) Documents shall be considered valid records only if authenticated (i.e., stamped, initialed or signed and dated complete by authorized personnel). If the nature of the record (i.e., magnetic or optical media) precludes stamping or signing, then other means of authentication by authorized personnel is permitted. Handwritten signatures are not required if the document is clearly identified as a statement by the responsible individual or organization. Transfer of authentication authority is documented and controlled in accordance with written procedures.

5) Records may be originals or copies, including electronic images.

6) Provisions shall be made for the capability to retrieve information stored on magnetic or optical media. Compatible processing systems shall be available, or information shall be transferred to other readable media that supports MOX Services workscope.

17.2.3 Receiving Records

A. A process shall be established for the submittal of records to the Records Center. The process shall identify the permissible time, after authentication of records, for submission and provide for identification of records being submitted.

B. A receipt control system shall be established for temporary and permanent storage of records in the Records Center.

C. The receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process. As a minimum, the receipt control system shall include the following:

1) A method for identifying records received and verifying they are the records identified for submittal;

2) Procedures for receipt and inspection of records including verification of legibility and completeness of the records during and after processing for storage;

3) A method for submittal of completed records to the storage facility without unnecessary delay;

D. For electronic records, the Records Center is also responsible for organizing and implementing an inventory of system applications, record formats, and programs required to process and retrieve electronic records.

E. The Records Center shall protect the records from damage, deterioration or loss when received.

F. Records shall be indexed to ensure retrievability. Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies. The indexing system shall include:

1) The location of the records within the records management system; and

2) The retention classification of the record.

3) For electronic records, in addition to the minimum indexing information requirements, the software name, version, and equipment (hardware) used to produce and maintain the electronic media must be provided.

17.2.4 Storing and Preserving Records

A. Records shall be stored and preserved in the Records Center in accordance with an approved QA procedure that provides:

1) A description of the storage facility;

2) A description of the filing system to be used;

3) A method for verifying that the records received are in agreement with the transmittal document;

4) A method for verifying that the records are those designated and the records are legible and complete;

5) A description of rules governing control of the records, including access, retrieval and removal;

6) A method for maintaining control of and accountability for records removed from the storage facility;

7) A method for filing supplemental information and disposition of superseded records;

8) A method for precluding entry of unauthorized personnel into the storage area to guard against larceny and vandalism;

9) A method for providing for replacement, restoration or substitution of lost or damaged records; and

10) A method to safeguard records against equipment malfunction or human error.

B. Storage methods shall be developed to preclude deterioration of records in accordance with the following:

1) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature and pressure.

2) For hardcopy records, approved filing methods shall require records to be:

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

3) 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.

4) Electronic media should be stored in dust-free environment, away from electronic devices and demagnetizing equipment. Media should be maintained at the constant temperature of 40 to 80 degrees Fahrenheit, with a constant relative humidity of 30 to 50 percent. Magnetic and optical media should be tested periodically to identify any loss of data, to ensure that they are free of permanent errors, and that the record system hardware/software still supports the retrieval of the records.

C. Record Repositories

Documents used for acceptance or rejection (examples are, but not limited to, Work Plans and Test Procedures), which remain in use for more than one shift, shall be placed in temporary storage by the originating organization until completion. After completion of all required activities, the records shall be transmitted to permanent storage in accordance with the requirements of this Section and associated QA procedures.

Other records may be stored on the MOX computer system which is backed up at established intervals.

Temporary storage requirements do not apply to engineering output documents. When used in the performance of activities, these documents shall be retrieved from the electronic records storage.

1) Temporary Storage

i. Records shall be temporarily stored on project computer shared drives or in a container or facility with a fire rating of one (1) hour, the data on the project computer shared drives shall be backed up on a frequency specified in project procedures. The backup of the shared drives shall be stored in a one hour fire rated container or facility. The temporary storage container or facility shall bear an Underwriters' Laboratories label (UL) (or equivalent) certifying one (1) hour fire protection, or be certified by a person competent in the technical field of fire protection.

ii. The maximum time limit for keeping records in temporary storage shall be specified by QA procedures consistent with the nature or scope of work.

2) Permanent Storage

MOX Services records permanent storage shall either invoke the alternate single facilities provision of section 4.4.2 or the dual facilities provision of section 4.4.4 of Supplement 17S-1 of NQA-1-1994. With either provision used, the Records Center shall be constructed in a manner that minimizes the risk of damage or destruction from the following:

i. Natural disasters (i.e., winds, floods or fires);
ii. Environmental conditions (i.e., high and low temperatures and humidity); and
iii. Infestation of insects, mold or rodents.

Where the alternate single facilities provision is used, then records shall be stored in the Records Center in two hour fire rated Class B file containers meeting the requirements of National Fire Protection Association (NFPA) 232-1986 or NFPA 232AM-1986.

Where the dual storage facilities provision is used the two facilities shall be sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

If the dual storage facilities provision is used via scanned documents into an electronic records management system, then a back-up tape shall be periodically made of the electronic records management system and its contents and the tape shall be stored in temporary storage device in a fire-proof safe. Monthly, a tape of the entire records management system shall be placed in the fire proof safe. This process invokes the dual storage provision as one copy resides on the records management system computer and a second copy of the total records system resides in a remote location with temporary storage being used for records entered in the interim.

17.2.5 Retrieving Records

A. When an Electronic Data Management System is used for records storage, write access to the records shall be controlled. Read only access shall be provided to MOX Services personnel when necessary for retrieval of record information.

B. For those records not included in an Electronic Data Management System, the records management system shall provide for retrieval of records in accordance with planned retrieval times based upon the designated record type.

C. Access to records storage facilities shall be controlled, by designating personnel who are permitted access to the records, including those with write access to the Electronic Data Management System.

D. Authorized personnel with access to electronic records and information systems will have a unique user ID/password for access.

17.2.6 Retention of Records

A. Lifetime records shall be retained and preserved for the operating life of the item or facility. Lifetime records shall be maintained for the life of the particular item while it is installed in the facility or stored for future use.

B. Records designated as nonpermanent shall be maintained as follows unless required by other regulatory requirements:

1) Three (3) years for programmatic records

2) Ten (10) years or as specified by procurement documents for product records.

3) Nonpermanent records shall not be disposed of until the following conditions are met:

i. DEAR 970.5204-79 and other regulatory requirements are satisfied;
ii. Facility status allows document disposal; and
iii. MOX Project Quality Assurance Plan requirements are satisfied.

C. Electronic records classified as lifetime or nonpermanent are required to meet the same retention requirements prescribed for paper records/hardcopies. Retention requirements for electronic records also identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces.

D. An electronic record migration/regeneration program is implemented for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. This program is implemented in accordance with documented procedures that provide for appropriate record authentication, quality verification of the completion, and accuracy of the data transferred.

17.2.7 Correcting Information in Records

A. Corrections shall include the identification of the person authorized to make the correction and the date the correction was made. Additional relevant information associated with the correction may also be added (e.g., corrective action tracking number, audit number).

B. Corrections to records shall be performed in accordance with QA procedures, which provide for appropriate review or approval of the corrections, by the originating organization.

C. Obliteration of information contained on a record is not permitted. If a record is discovered with obliterated information, corrective action shall be initiated in accordance with the provisions of Section 16, *Corrective Action.*

D. For records stored in electronic media, a new record is to be generated when substantial corrections or changes to previous electronic records are required.

17.2.8 Replacing Records

Replacement, restoration or substitution of lost or damaged records shall be performed in accordance with QA procedures, which provide for appropriate review or approval by the originating organization and any additional information associated with the replacement.

ATTACHMENTS:

Figure 17-1: Example of Typical Lifetime QA Records

Figure 17-1: Examples of Typical Lifetime QA Records

Design Records

- Applicable codes and standards used in design
- Computer programs or corresponding mathematical model
- System process flow diagrams or charts
- Design drawings
- Design calculations and record of verification
- Approved design change requests
- Design deviations
- Design reports
- Design verification data
- Design specifications and amendments
- License Application
- Systems descriptions
- Systems process and instrumentation diagrams
- Technical analysis, evaluations and reports
- Safety Ranking Evaluation Reports

Procurement Records

- Procurement specification
- Subcontract/purchase order including amendments

Contractor Records

- As-built drawings and records
- Certificate of compliance
- Heat treatment records
- Major defect repair records
- Nonconformance reports
- Performance test procedure and results records
- Pressure test results (hydrostatic or pneumatic)
- Welding procedures
- NDE procedures & results of examination

Installation Construction Records Reports

Receiving and Storage—Nonconformance

Welding
- Heat treatment records
- Major weld repair procedures and results
- Weld procedures
- NDE results

Mechanical
- Cleaning procedures and results
- Installed lifting and handling equipment procedures, inspection and test data
- Lubrication procedures
- Pressure test results (hydrostatic or pneumatic)

Electrical and I & C

- Cable pulling tension data
- Cable separation data
- Cable splicing procedures
- Cable terminating procedures
- Certified cable test reports
- Relay test procedures
- Voltage breakdown test results on liquid insulation

General

- As-built drawings and records
- Final inspection reports and releases
- Nonconformance reports
- Specifications and drawings

Figure 17-1: Examples of Typical Lifetime QA Records (Continued)

Pre-Operational and Start-Up Test Records

- Automatic emergency power source transfer procedures and results
- Final system adjustment data
- Pressure test results (hydrostatic or pneumatic)
- Instrument AC system and inverter test procedures and reports
- Main and auxiliary power transformer test procedures and results
- On-site emergency power source energizing procedures and test reports
- Pre-operational test procedures and results
- Primary and secondary auxiliary power test procedures and results
- Station battery and DC power distribution test procedures and reports

Operation Records

- Records and drawings changes identifying facility design modifications made to systems and equipment described in the license application
- Off-site environmental monitoring survey records
- Facility radiation and contamination survey records
- Radiation exposure records for individuals entering radiation control areas
- Records of gaseous and liquid radioactive material released to the environment
- Training and qualification records for current members of the plant operating staff
- Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments
- Changes made to operating procedures

Operation Records (Cont.)

- Low level radioactive waste records
- Sealed source leak test results
- Records of annual physical inventory of all sealed source material
- Records and logs of maintenance activities, inspections, repair and replacement of items of structures, systems and components
- Fire protection records
- Nonconformance reports
- Plant equipment operations instructions
- Security plan and procedures
- Emergency plan and procedures
- Quality Assurance and Quality Control Manuals
- Records of activities required by the security plan and procedures
- Records of activities required by the emergency plan and procedures
- Applicable records noted in other sections of this document for any modifications or new construction applicable to structures, systems or components
- Evaluation of results of reportable safety concerns as required by regulations
- Annual environmental operating report
- Annual plant operating report
- Records to support licensing conditions such as safeguards and special nuclear material accountability
- Reportable events

Maintenance Records

- Preventive Maintenance (PM)
- Corrective Maintenance (CM)
- Surveillance / monitoring
- Functional Test (including Post Maintenance / Post Modification Test)

18 AUDITS

18.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of Criterion 18 Audits of 10CFR50, Appendix B; the Basic Requirement 18 and Supplements 18S-1 and 2S-3 of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*. During Operations the project will transition from Regulatory Guide 1.28 (Rev.3) to Regulatory Guide 1.33 (Rev 2), *Quality Assurance Program Requirements (Operation)*.

QA verifies MOX Services compliance with this document and determines QA Program effectiveness by performing planned and periodic internal audits. External audits are used as one of the processes to evaluate suppliers as addressed in Section 7, *Control of Purchased Material, Equipment, and Services*. Elements that have been selected for audit are evaluated against specified requirements. Objective evidence is examined to the depth necessary to determine if these elements are being implemented effectively. QA audits are performed in accordance with written procedures or checklists by appropriately trained and qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and provided to the appropriate management for review and corrective action as applicable. Follow-up actions are taken where indicated.

The auditing organization has the organizational independence and authority to execute an effective audit system to meet requirements of this document.

18.2 REQUIREMENTS

MOX Services utilizes two distinct levels of activities 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. Those levels of evaluation are:

- Audits, which provide a comprehensive independent evaluation of activities and procedures are planned, documented, and performed by the Quality Assurance organization. Audits evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of quality-affecting activities; and

- Assessments, which 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 (reference Paragraph 2.2.7, Management Assessments).

18.2.1 Internal Audit Schedules

A. Internal audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work, and performance history. During the Design and Construction phases regularly scheduled internal audits of each MOX Services functional area quality-affecting activities shall be performed annually. The frequency for audits of operational phase IROFS related activities will be based on the safety significance of the activity and performance history so that each area is evaluated annually (Assessment or Audit) and audited at least once every two years. A grace period of 90 days may be applied for those activities required to be performed on a periodic basis unless otherwise noted. The grace period does not allow the clock for a particular activity to be reset forward. The clock for an activity is reset backwards by performing the activity early.

B. Regularly scheduled internal audits shall be supplemented by additional audits or assessments of specific subjects, operational safety parameters, work products, or functional areas when necessary to provide an adequate assessment of compliance or effectiveness, or there is an indication of performance degradation.

C. The audit schedule shall ensure that coverage is maintained current for the applicable and active elements of this document, consistent with the performance history. The evaluation of previous audit results, Management Assessments, corrective actions, nonconformance reports, identified trends adverse to quality, and the impact of significant changes in personnel, organization, or this document is used to establish and maintain the audit schedule.

D. Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.

E. Nuclear Criticality Safety (NCS) audits are conducted and documented such that aspects of the Nuclear Criticality Safety Program will be audited at least every two years.

F. During Operations, the functional areas of the MOX Services organization for auditing include at a minimum, verification of compliance and effectiveness of implementation of internal rules, procedures. The functional areas include:

- Engineering, Configuration and Modification Control
- Operations
- Maintenance
- Radiation Protection/Radwaste Management
- Chemical/Radiochemical Control
- Nuclear Safety
- Environmental Control
- Operating Limits Manual Compliance
- Performance, Training & Qualification
- Corrective Action

G. When any work is performed under the requirement of the QA program and is delegated to others, the work being performed will be audited as part of the QA program audits.

18.2.2 External Audit Schedules

A. Audits are conducted as follows for procurement of items:

1) The supplier's QA program is audited on a triennial basis.

2) The triennial period begins when the first audit is performed.

3) A grace period of 90 days may be applied for those activities required to be performed on a periodic basis unless otherwise noted. The grace period does not allow the clock for a particular activity to be reset forward. The

clock for an activity is reset backwards by performing the activity early.

4) An audit is initially performed prior to the supplier starting work.

5) If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier (with respect to the scope of the original audit), an audit of the modified requirements is conducted, thus starting a new triennial period.

6) If the supplier is implementing the same QA program for other customers that is proposed for use on the auditing party's contract, the preaward survey may serve as the first triennial audit. Therefore, when such preaward surveys are employed as the first triennial audits, they must satisfy the same audit elements and criteria as those used on other triennial audits.

7) If more than one purchaser (MOX Services, subsuppliers & other Licensees) buys from a single supplier, MOX Services may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit will be verified to satisfy the requirements of the MOX MPQAP, and the audit report will be maintained by MOX Services as a record. MOX Services remains individually responsible for the adequacy of the audit even when performed by others.

18.2.3 Audit Plans

A. An audit plan shall be developed for each scheduled audit.

B. This plan shall identify the audit scope, requirements to be audited, type of audit personnel needed, activities to be audited, organizations to be notified, applicable documents, audit schedule, and procedures or checklists to be used.

C. Audits shall include evaluations of the applicable procedures, instructions, activities.

D. The audit plan shall ensure the audit samples are focused on high importance to safety IROFS, when practical.

18.2.4 Audit Teams

A. Auditors shall be independent of any direct responsibility for performing the work being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

B. An audit team shall be identified before beginning each audit. The audit team shall include representatives from QA and any applicable organizations. In the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team.

C. A lead auditor shall be appointed to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report and evaluate responses. Technical specialists may be used to assist in assessing the adequacy of technical processes.

D. Before commencing the audit, the lead auditor shall ensure audit team has the experience or training needed for the scope, complexity, and nature of the work to be audited. Lead auditors, auditors and technical specialists shall be qualified according to the requirements of Paragraphs 18.2.10 and 18.2.12.

18.2.5 Performing Audits

Written notification of a planned audit shall be provided to the involved organizations at a reasonable time before the audit is to be performed. The notification includes relevant information pertaining to the audit, such as schedule, scope and names of audit lead and team members, if known. Unannounced audits do not require prior written notification; however, prior agreement should be obtained by the parties involved. In addition, the audit team leader shall ensure the following is performed:

A. The audit team shall be adequately prepared before starting the audit;

B. Audits shall be performed in accordance with written procedures or checklists;

C. Elements that have been selected for the audit shall be evaluated against specified requirements;

D. Objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively;

E. Audit results shall be documented by auditing personnel, and reported to/reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization; and

F. Identified audit findings (conditions adverse to quality) shall be documented according to the requirements of Section 16, *Corrective Action*. Minor audit findings, if corrected during the audit, shall be documented and verified by the audit process.

18.2.6 Reporting Audit Results

The audit report shall be prepared and signed by the audit team leader, and issued to the management of the audited organization and participating organizations within thirty days of the audit exit. The audit report shall include the following information:

A. A description of the audit scope.

B. Identification of the auditors.

C. Identification of persons contacted during the audit.

D. A summary of the audit results.

E. Statement as to the effectiveness of the implementation of the elements audited.

F. A description of each reported condition adverse to quality in sufficient detail to enable corrective action by the audited organization according to the requirements of Section 16, *Corrective Action*.

G. A description of minor adverse conditions corrected during the audit, including identification of the actions taken and verification of completion of those actions.

H. A requested date for response by the audited organization.

18.2.7 Responding to Audits

Management of the audited organization shall respond to conditions adverse to quality according to the requirements of Section 16, *Corrective Action*.

18.2.8 Evaluating Audit Responses

The adequacy of corrective actions for adverse audit findings (conditions adverse to quality) shall be evaluated according to the requirements of Section 16, *Corrective Action*.

18.2.9 Closing an Audit

Follow-up action shall be taken to verify corrective actions are accomplished according to the requirements of Section 16, *Corrective Action*. Written notification of audit closure shall be provided for external audits upon verification that corrective actions have been satisfactorily completed. Internal audits are considered closed when the audit report is distributed and conditions adverse to quality (if any) have been identified for corrective action in accordance with Section 16.

18.2.10 Audit Team Qualification Requirements

A. Auditors shall have appropriate orientation, current applicable training and demonstrated competency. One or a combination of the following methods shall be used to develop competence of personnel performing various audit functions:

1) MOX Services QA indoctrination to provide a working knowledge and understanding of this document, general structure of the QA Program, and other nuclear-related codes, standards, regulations, regulatory guides and procedures and other documents used to plan, perform, report, and close audits;

2) Training programs to provide general and specialized training in audit performance;

i. General training shall include the fundamentals, objectives and techniques of planning and performing audits;
ii. Specialized training shall include methods of examining, questioning, evaluating and documenting specific audit items and methods of closing out adverse audit findings (conditions adverse to quality).

3) On-the-job training, guidance and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting and follow-up action involved in conducting audits.

B. Auditor Qualifications

1) Auditors shall be indoctrinated and trained as appropriate and shall have the experience or education commensurate with the scope, complexity or special nature of the activities to be audited. An auditor should possess good communication skills, general knowledge of the audit process and skills in the audit techniques of examining, questioning and evaluating.

2) Auditors shall have verifiable evidence that the requirements for education and experience have been met as provided in Figure 18-1 (minimum of eight credits).

C. Lead Auditor Qualifications

1) Lead auditors shall be capable of organizing and directing audits, reporting audit findings, evaluating corrective actions and closing out audit findings. Lead auditors shall be current with auditor training and lead auditor requirements.

2) Lead auditors shall have verifiable evidence that the requirements for education and experience have been met as provided in Figure 18-1 (minimum of ten credits).

3) Lead auditors shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the candidate's management.

4) A lead auditor shall have participated in a minimum of five quality assurance audits or equivalent verifications within a period of time not to exceed three years prior to the date of certification. Equivalent verifications include management assessments, pre-award evaluations or other monitoring activities, providing the parameters of the audit process are met. One audit shall be a nuclear-related quality assurance audit or equivalent verification within the year prior to certification.

5) A lead auditor shall have demonstrated knowledge and understanding of audit planning in IROF functions for designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, operating, maintaining, repairing, refueling, modifying, and safety of the facility.

6) Lead auditors shall have passed an examination that evaluates the comprehension of and ability to apply the audit knowledge described in this section. The test shall be oral, written, practical or any combination.

7) Upon satisfaction of the above requirements, lead auditors shall be certified as being qualified to lead audits

8) Lead auditors shall maintain their proficiency through one or a combination of the following:

   i. Regular and active participation in the audit process.
   ii. Review and study of codes, standards, procedures, instructions and other documents related to the MOX Services QA Program and program auditing.
   iii. Participation in training programs.

9) MOX Services Quality Assurance shall evaluate and document the proficiency of lead auditors annually. Based on the evaluation, management may choose to extend the qualification, require re-training or require re-qualification.

10) Personnel previously certified as lead auditors who have not maintained their proficiency for a two-year period shall require re-qualification prior to performance as a lead auditor. This re-qualification shall consist of retraining based upon management evaluation of the candidate's knowledge, including; understanding of referenced codes and standards, general structuring of QA Programs, auditing techniques and on the job training as deemed necessary. In addition, the candidate must be re-examined and participate as an auditor in at least one nuclear audit.

D. Acceptance of Auditor/Lead Auditor Qualifications

Auditors and lead auditors certified under other programs may be accepted by MOX Services provided compliance with requirements of item A and either B or C above are documented and the individual has been certified in accordance with the QA procedure on auditor qualification and certification.

E. Technical Specialist Qualifications

1) Technical specialists selected for auditing assignments shall be indoctrinated and trained as appropriate and shall have the level of experience or training commensurate with the scope, complexity or special nature of the work being audited.

2) Technical specialists shall also have verifiable evidence as meeting the requirements for education and experience as provided in Figure 18-1 (minimum of five credits).

18.2.11 Lead Auditor Examination

The test may be oral, written, practical or any combination. Quality Assurance shall:

A. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations.

B. Develop and maintain objective evidence regarding the type and content of the examination.

18.2.12 Lead Auditor Certification

Each lead auditor shall be certified as being qualified to lead audits. This certification shall document:

A. MOX Services Lead Auditor Certification.

B. Name of the lead auditor.

C. Dates of certification or re-certification.

D. Basis of qualification (i.e., education, experience, communication skills, training and examination as applicable).

E. Signature approval of the designated representative who is responsible for such certification.

ATTACHMENT

Figure 18-1: Qualification Point Values for Audit Team Members

Figure 18-1

Qualification Point Values for Audit Team Members

The following credits are assigned to audit team members in evaluating and determining qualification and certification level for performing audits:	**Credits**
Education Requirements (Four credits maximum)	
An associate degree from an accredited institution:	1
If the degree is in engineering, physical sciences, mathematics or quality assurance:	2
A bachelor degree from an accredited institution:	2
If the degree is in engineering, physical sciences, mathematics or quality assurance:	3
In addition, for a master degree in engineering, physical sciences, business management or quality assurance from an accredited institution:	1
Experience Requirements (Nine credits maximum)	
Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility:	1 per Year (5 Max)
Additionally up to four credits maximum for the following:	
If two years of this experience have been in the nuclear-related field:	1
If two years of this experience have been in quality assurance:	2
If two years of this experience have been in auditing:	3
If two years of this experience have been in nuclear-related quality assurance:	3
If two years of this experience have been in nuclear-related quality assurance auditing:	4
Professional Competence (Two credits maximum)	
For certification of competency in engineering, science or quality assurance specialties, issued and approved by a state agency or national professional or technical society:	2
Rights of Management (Two credits maximum)	
When determined appropriate by management, up to two credits may be granted for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance and completed quality assurance training courses).	2

19 MAINTENANCE

19.1 GENERAL

The MOX Services QA Program described in this section and associated QA procedures implement the committed requirements of 10CFR50, Appendix B; NQA-1-1994 as revised by NQA-1a-1995 addenda; including Subpart 2.18 applicable to Option 2 (Operations) and Regulatory Guide 1.33 (Rev.2), *Quality Assurance Program Requirements (Operation)*.

19.2 REQUIREMENTS

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

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

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

Maintenance for IROFS is developed and conducted to maximize availability and reliability for assurance that the designed safety functions and ISA requirements

will be achieved, when needed. This maintenance is performed under strict procedural controls and the resultant records are maintained as proof of compliance to safety requirements.

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

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

19.2.1 Maintenance Categories

Maintenance activities generally fall into the following categories:

- Surveillance/Monitoring
- Preventive Maintenance
- Corrective Maintenance

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.

19.2.2 Surveillance / Monitoring

Surveillance/monitoring is utilized to detect degradation and adverse trends of IROFS so that action may be taken prior to component failure. The monitored parameters are selected based upon their ability to detect the predominate failure modes of the critical components. Data sources include; surveillance, periodic and diagnostic test results, plant computer information, operator rounds, walk downs, as-found conditions, failure trending, and predictive maintenance. Surveillance/monitoring and reporting is required for IROFS and any administrative controls that could impact the functions of an IROFS.

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

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

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

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

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

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

19.2.3 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) enable the facility personnel to calibrate equipment and monitoring devices important to plant safety and safeguards. Testing performed on IROFS that are not redundant will provide for compensatory measures to be put into place to ensure that the IROFS function is performed until it is put back into service.

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

After conducting preventive maintenance on IROFS, and before returning an IROFS to operational status, functional testing of the IROFS, if necessary, is performed to ensure the IROFS performs its intended safety function. Functional testing is described in detail in Section 11 and 11.3.3, Functional Tests.

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

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

19.2.4 Corrective Maintenance

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

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

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

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

COMMITMENT TO QUALITY ASSURANCE STANDARDS

NQA-1-1994 / NQA-1-1995a, Quality Assurance Requirements for Nuclear Facility Applications, Part I, Basic Requirements and Supplementary Requirements for Nuclear Facilities.

The MPQAP follows Part I.

NQA-1-1994 / NQA-1-1995a, Part 1I, Quality Assurance Requirements for Nuclear Facility Applications.

The MPQAP follows Part II with the following alternatives to the Subparts as noted:

SUBPART 2.1 Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants

The MPQAP follows this Subpart with the following alternatives:

1. Section 2.1, Planning: This is considered a clarification.

   The required planning is frequently performed on a generic basis for application to many systems and component installations. This results in standard procedures for cleaning, inspection, and testing which meet the requirements of the standard. Individual plans for each item or system are not normally prepared unless the work operations are unique; however, standard procedures are reviewed for applicability in each case. Cleaning procedures are limited in scope to those actions or activities which are essential to maintain or achieve required quality.

2. Section 10, POST OPERATIONAL REPAIRS AND MODIFICATIONS: This section does not apply during the construction phase. It will be addressed in the Operations QA Pan.

SUBPART 2.2 Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants

The MPQAP follows this Subpart during Construction with the following alternatives: This Subpart is not applicable during Operations.

Section 4.5.2, Inspections at Point of Shipment and Section 4.5.3, Inspection at Port of Entry.

COMMITMENT TO QUALITY ASSURANCE STANDARDS

In the aftermath of the September 11, 2001 terrorist attacks, on board point of shipment and port of entry inspections are no longer allowed. To assure acceptable items are received, packaging inspections prior to shipment and at receipt of the item will be performed.

SUBPART 2.3 Quality Assurance Requirements for Housekeeping for Nuclear Power Plants

The MPQAP follows this Subpart.

SUBPART 2.4 Installation, Inspection, and Testing Requirements for Power Instrumentation, and Control Equipment at Nuclear Facilities.

The MPQAP follows this Subpart.

SUBPART 2.5 Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants

The MPQAP follows this Subpart with the following alternatives:

1. Section 4.2, Materials Suitability:

   ASME Section III does not apply. The MOX facility is not an ASME Section III facility. We are committed to ACI-315 and ACI-349.

2. Section 6, INSPECTION OF FOUNDATION PILE AND CAISSON CONSTRUCTION:

   This section does not apply as there are no pilings or caissons used for the construction of the project.

3. Section 7.11, In-Process Tests on Concrete and Reinforcing and Prestressing Steel:

   ASME Section III does not apply. The MOX facility is not an ASME Section III facility. We are committed to ACI-315 and ACI-349.

4. Section 7.13, Welded Reinforcing Bar Splices:

   ASME Section III does not apply. The MOX facility is not an ASME Section III facility. We are committed to ACI-315 and ACI-349.

5. Section 5.2 (c), Materials:

   Exception: To the maximum and minimum index density of soils using ASTM D 4253 and D 4254. MOX Services will use ASTM D1557, Standard Test Methods

for Laboratory Compaction Characteristics of Soil Using Modified Effort (56,000 ft-lbf/ft^3 (2,700 kN-m/m^3)) for determining maximum dry density. If MOX Services uses soils for backfilling operations that are cohesionless, free-draining soils with fines less than 15%, such as pure sand, then the referenced standards of ASTM D4253 and D4254 will be used.

6. Section 5.3 Placing and Compacting Equipment & Section 5.5 (e), Soils Compaction

Clarification of "Backfilling activities for Utility Trenches": Construction will specify and document the number of passes, overlap of passes and compacting equipment used, Engineering will specify the lift thickness and material to be used. This methodology will be validated by compaction testing for the first segment of backfilling, including bedding, haunching and initial fill. Field Engineers will verify the adequacy of compacting equipment.

SUBPART 2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications

The MPQAP follows this Subpart.

SUBPART 2.8 Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants

The MPQAP follows this Subpart.

SUBPART 2.15 Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants

The MPQAP follows this Subpart during construction. This Subpart is not applicable during Operations.

SUBPART 2.16 Requirements for the Calibration and Control of Measuring Test Equipment Used in Nuclear Facilities

The MPQAP follows this Subpart.

SUBPART 2.18 Quality Assurance Requirements for Maintenance of Nuclear Facilities

This Subpart does not apply during the construction phase.

COMMITMENT TO QUALITY ASSURANCE STANDARDS

SUBPART 2.20 Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants

The MPQAP follows this Subpart.

SUBPART 2.21 Quality Assurance Guidelines for Decommissioning Nuclear Facilities

This Subpart does not apply to the MPQAP during the construction phase. It will be addressed in a separate QA Plan for Decommissioning.

NQA-1-1994 / NQA-1-1995a, Part 1II, Nonmandatory Appendices

SUBPART 3.1 Nonmandatory Guidance on Quality Assurance Programs for Nuclear Applications

The MPQAP follows Part III, Subpart 3.1, Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel."

The remaining Appendices are not applicable to the MPQAP.

SUBPART 3.2 Nonmandatory Guidance on Quality Assurance Programs for Nuclear Facility Applications

This Subpart is not applicable.

SUBPART 3.3 Nonmandatory Guidance on Quality Assurance Program Requirements for Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories

This Subpart is not applicable.

NRC REGULATORY GUIDE 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3, August 1985.

The MPQAP follows this Regulatory Guide during Design and Construction with the following alternative:

MOX Services elects to use NQA-1-1994 as revised by NQA-1-1995 addenda instead of NQA-1-1983.

COMMITMENT TO QUALITY ASSURANCE STANDARDS

NRC REGULATORY GUIDE 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2, February 1978.

The MPQAP allows transition from RG 1.28 to RG 1.33 for Operations.

GENERIC LETTER (GL) 88-18, "Plant Record Storage on Optical Disks."

The MPQAP follows this Generic Letter.

Augmented QA Program for IROFS
(Low Importance to Safety)

1.0 Introduction

MOX Services has developed a process for determining the importance to safety of IROFS. While all IROFS are important to safety, the relative importance varies from low to high. The IROFS Ranking Process identifies the IROFS relative importance to safety (high or low). This augmented program describes the application of QA controls to IROFS whose relative importance to safety is low. This is consistent with 10CFR50 Appendix B, Criterion II, QA Program and NQA-1 1994/1995a, Basic Requirement 2, QA Program, which require that QA controls be applied to IROFS to an extent consistent with their importance to safety. The controls identified in this augmented program are considered to be the minimum acceptable QA controls. Additional QA controls may be applied when determined to be required by MOX Services.

2.0 Scope

The augmented QA program is applicable to IROFS whose importance to safety is determined to be low based on a documented evaluation.

3.0 IROFS Importance to Safety Ranking Process (IROFS Ranking Process)

The purpose of this process is to define the relative importance of IROFS to the overall safety criteria for the application of graded QA controls. IROFS ranking shall consider the likelihood of failure and the consequence of that failure. IROFS whose importance to safety is high will be maintained as QL-1 IROFS with all required QA controls as defined in the MPQAP. Those whose importance to safety is low will be identified as QL-1LR and QA controls will be applied commensurate with the IROFS relative importance to safety.

IROFS ranking evaluations are performed by Nuclear Safety. The evaluation is documented, reviewed, approved and maintained as a QA record. Design changes subsequent to the evaluation are reviewed by nuclear safety to determine the impact on the importance to safety evaluation results.

The IROFS Ranking Process criterion is based on consideration of the relative likelihood and consequences of IROFS failure.

The likelihood criteria are:

- frequency of the initiating event
- reliability of the IROFS
- surveillance of the IROFS
- the safety margin from normal operations to the safety limit

Augmented QA Program for IROFS
(Low Importance to Safety)

The consequence criteria are:

- monitoring versus controlling function of the IROFS
- the consequences associated with the IROFS safety function failure
- the safety margin from the safety limit to the event consequences
- the additional protection features

An overall importance to safety ranking for an IROFS is assigned based on consideration of the likelihood and consequence criteria described above for each IROFS safety function.

This process is an acceptable method for determining relative importance to safety in the context of 10CFR50 Appendix B and is consistent with NQA-1.

4.0 The provisions of sections 1, 2, 3, 5, 6, 8, 9, 11, 12, 13, 14, 15, 16 and 18 of this QA Plan apply without exception. The provisions of sections 4, 7, 10 and 17 of this QA plan apply with exceptions and clarifications as discussed in sections 4.1 thru 4.3. See "Table QL-1LR Applicability" for specific MPQAP applicability.

4.1 Procurement Document Control/Control of Purchased Items and Services

A. **IROFS** may be procured directly from suppliers based on nationally/internationally recognized independent accreditation from Underwriters Laboratory or Factory Mutual subject to the following. MOX Services will perform a surveillance of UL or FM prior to using UL or FM as the basis for supplier selection. This surveillance is a onetime requirement.

- The supplier shall submit the UL or FM qualification report for the item to be procured, the UL or FM process evaluations report for the supplier, the supplier's quality assurance manual and the supplier's UL or FM accreditation certificate.
- The accreditation organizations test/qualification report for the item to be procured in conjunction with normal construction/preoperational/start-up testing is reviewed by MOX Services and has been determined to be sufficient to demonstrate that the item will perform its safety function.
- The accreditation organizations evaluation of the technical and quality capability of the suppliers' process controls is reviewed by MOX

Services and has been determined to be sufficient to provide reasonable assurance that the manufactured items are representative of the item tested.

- If either of the conditions above cannot be met, MOX Services shall identify supplemental controls that are required to be established, consistent with section 7 of the MPQAP and documented in the purchase order per section 4 of the MPQAP. The supplemental requirements will be implemented by MOX Services or a MOX Services approved NQA-1 supplier.
- The supplier provides to MOX Services a current certificate of accreditation, or equivalent, from the accreditation organization. This will be identified during MOX Services receipt inspection as part of item acceptance.
- For the items procured the supplier shall provide a certificate of conformance. MOX Services quality control shall perform a receipt inspection and, where appropriate, MOX Services shall perform functional testing during start-up as a minimum.
- The items will be designated as basic components upon acceptance. This will normally occur at QC receipt inspection.

Factory Mutual and Underwriters Laboratories recalls will be reviewed as a part of the MOX Services Lessons Learned process. The recall list will be reviewed quarterly as a minimum.

B. Laboratory materials testing and calibration services associated with foreign procurements may be procured from laboratories accredited by COFRAC, and Swiss Accreditation Services subject to the following:

- A COFRAC/SAS certificate of accreditation to ANSI/ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories shall be provided by the supplier that is current and covers the analysis scope as described in the purchase order. MOX Services shall verify the certificate during receipt inspection
- For calibration suppliers the requirements of section 7.2.2.C.(4) of the MPQAP are met except that use of specified foreign suppliers is authorized. For laboratory materials testing the purchase document shall impose additional technical and administrative requirements to satisfy MPQAP and technical requirements and, where applicable, require identification of standards used.

- For laboratory materials testing, MOX Services will use blind testing for initial qualification, quarterly for the first year and annually thereafter.

C. Suppliers that have an ASME NCA-3800 certified program may be added to the Approved Commercial Grade Vendor List based on the accreditation subject to the following clarifications:

- Small item exclusion per NCA-3810 does not apply,
- NCA-3855.5 upgrade must be accompanied by analysis to demonstrate the upgrade satisfies critical characteristics,
- Supplier evaluation (audit or surveillance) after work commencement is required
- Supplier must submit a certificate of accreditation, or equivalent

D. When the procurement specification is used in lieu of a separate commercial grade dedication package, MOX Services shall document the safety function, critical characteristics, verification method, acceptance criteria, and basis for selection in the procurement specification and will use the normal receipt inspection as the means to confirm/document completion of the verification requirements and the designation of the item as a basic component.

4.2 Inspection

Inspections may be performed by MOX Services qualified Construction or Assembly personnel in lieu of quality control inspectors. Personnel will receive same training and qualification as a Level II QC inspector in accordance with MPQAP section 2.2.6.H, but will not be certified as a level II inspector. While these qualified personnel shall be independent of the work as defined in MPQAP section 10.2.2.C, they may not report through the QA/QC organization.

4.3 Records

IROFS ranking evaluations shall be maintained as lifetime records.

Augmented QA Program for IROFS
(Low Importance to Safety)

QL-1LR Applicability			
1	Organization	Yes	
2	Quality Assurance Program	Yes	
3	Design Control	Yes	
4	Procurement Document Control	Partial	
	4.2.1.A	Yes	
	4.2.1.B	Yes	Supplemented by Attachment B 4.1.D
	4.2.1.C	N/A	Replaced by Attachment B Section 4.1A
	4.2.1.D	Yes	
	4.2.1.E	Yes	
	4.2.1.F	Yes	
	4.2.1.G	No	
	4.2.1.H	Yes	
	4.2.1.I	Yes	
	4.2.1.J	Yes	Invokes Attachment B for QL-1LR
	4.2.2	Yes	
	4.2.3	Yes	
5	Instructions, Procedures, and Drawings	Yes	
6	Document Control	Yes	
7	Control of Purchased Material, Equipment, and Services	Partial	
	7.2.1	Yes	
	7.2.2	No	Replaced by Attachment B 4.1.A, B, C
	7.2.3	Yes	
	7.2.4	Yes	
	7.2.5	Yes	
	7.2.6	Yes	
	7.2.7	Yes	
	7.2.8	Yes	
	7.2.9	N/A	
	7.2.10	Yes	

Augmented QA Program for IROFS
(Low Importance to Safety)

8	Identification and Control of Material, Parts, and Components	Yes	
9	Control of Special Processes	Yes	
10	Inspection	Partial	
	10.2.1	Yes	
	10.2.2	Yes	Supplemented by Attachment B 4.2
	10.2.3	Yes	
	10.2.4	Yes	
	10.2.5	Yes	
	10.2.6	Yes	
	10.2.7	Yes	
	10.2.8	Yes	
11	Test Control	Yes	
12	Control of Measuring and Test Equipment	Yes	
13	Handling, Storage, and Shipping	Yes	
14	Inspection, Test, and Operating Status	Yes	
15	Nonconforming Materials, Parts, or Components	Yes	
16	Corrective Action	Yes	
17	Quality Assurance Records	Yes	Supplemented by Attachment B 4.3
18	Audits	Yes	
19	Maintenance	Yes	

Enclosure 2

MOX Services Response to Second Request for Additional Information Related to the MOX Project Quality Assurance Plan Revision 11 Dated March 11, 2013

NRC RAI 1.a (1) *- Please include in the MPQAP a description of (1) any technical and quality requirements that will be imposed on the supplier in the purchase order;*

MOX Services RAI Response

Technical Requirements:

MPQAP Revision 11, Change 1 does not require a change to the MPQAP requirement to specify these technical requirements in purchase orders. Consistent with current requirements (i.e., no change as a result of application of augmented QA program), technical requirements will continue to be identified in procurement documents consistent with *MPQAP Section 4.2.1 B*.

> *"4.2.1 Procurement documents issued for SSCs or services shall include the following provisions, as applicable to the procured material, equipment or service:*
>
> *B. Technical requirements including:*
>
> *1) Design bases, identified or referenced in the procurement documents; and*
>
> *2) Specific documents (such as specifications, drawings, codes, standards, regulations, procedures or instructions) describing the technical requirements of the material, equipment or services to be furnished, shall be specified along with their revision level or change status; and*
>
> 3) *Tests, inspections or acceptance requirements that MOX Services will use to monitor and evaluate the performance of the supplier shall be specified; "*

Quality Requirements:

No change to the MPQAP is required since the MPQAP requirements themselves do not change, however, the means to accomplish these requirements do change. The following quality requirements will be specified in the procurement document:

1. The supplier will be required to submit certification documentation demonstrating that they hold a current FM or UL certification for the product to be procured. (Unique to augmented QA Program approach using UL or FM)

2. The supplier will be required to notify MOX Services if there are any changes in the FM or UL certification status. (Unique to augmented QA Program approach using UL or FM

3. The supplier will be required to perform activities in accordance with their QA program/process as evaluated by UL or FM and any special provision that may be imposed by MOX Services. The supplier will be required, at the time of delivery, to

provide a certificate of conformance (COC) to the requirements of the purchase order certifying that the work was performed in accordance with the QA program as evaluated by UL or FM. (Unique to augmented QA Program approach using UL or FM

4. The purchase order will impose provisions for access to the supplier's facility for audit/surveillance activities. Access shall include MOX Services or others as authorized by MOX Services. (Not unique to augmented QA Program approach using UL or FM)

5. Any nonconforming conditions that arise during the fabrication of products and their resolution for MOX Services shall be provided to MOX Services for review and, where appropriate, approval. (Not unique to augmented QA Program approach using UL or FM)

Note: During the purchase requisition/bid evaluation phase the supplier will be required to submit their QA Program, the FM or UL product qualification test report and process evaluation report. Based on the documented evaluation of these documents additional QA controls may be specified. (Not unique to augmented QA Program approach using UL or FM)

NRC RAI 1.a (2) *– The criteria MOX Services will apply to review UL/FM test/qualification reports to determine if testing is sufficient to demonstrate the item will perform its safety function;*

MOX Services RAI Response

The MOX Services engineer shall determine the safety function(s) of the item to be procured. For each safety function the engineer shall review the testing performed by FM/UL and determine whether the characteristics verified during the test and the method of testing is appropriate to demonstrate the safety function. This approach is similar to that used during commercial grade dedication (*Reference MPQAP Section 7.2.8.B*).

> *"Critical characteristics for commercial grade items shall be determined and approved by the manager responsible for the procurement based on the performance requirements for the item including the intended IROFS safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will meet their catalog or manufacturer specifications and perform the specified functions as intended."*

If the testing is not sufficient to demonstrate the safety function, then another supplier will be selected or supplemental testing/verification will be specified. When supplemental provisions are specified, these provisions will be evaluated to determine if additional QA controls are required. The QA controls will be commensurate with MPQAP controls normally applied for the verification method.

NRC RAI 1.a (3) – *The criteria that MOX Services will apply to review the UL/FM evaluation report for QL-1LR suppliers to determine whether the suppliers' process controls are sufficient to provide reasonable assurance that manufactured items are representative of items tested;*

MOX Services Response

MOX Services criteria for review will be to assure that the UL/FM evaluation report demonstrates the suppliers' capability to provide items or services in accordance with the procurement document requirements (*Reference MPQAP section 7.2.2.A*).

> *"Supplier/subcontractor selection shall be based on an evaluation, performed before the subcontract and/or purchase order is awarded, of the supplier/subcontractor's capability to provide items or services in accordance with procurement document (technical and quality) requirements".*

Specifically MOX Services will utilize the guidance provided in the MPQAP and NQA-1 to an extent consistent with the relative importance, complexity/quantity of items being procured (*Reference MPQAP section 7.2.4.B*).

> *"The extent of MOX Services verifications shall be a function of the relative importance, complexity/quantity of items or services being procured and the supplier/subcontractor's quality performance".*

If the evaluation is not sufficient to demonstrate the proper QA controls, then another supplier will be selected or supplemental QA controls will be specified in the procurement document. MOX verification of these supplemental QA controls will be commensurate with MPQAP verification methods normally applied for that type of control.

NRC RAI 1.a (4) – *How certificates of conformance will be used to demonstrate compliance with Appendix B:*

MOX Services Response

As noted in the response to RAI 1.a (1) above, the supplier will be required to provide a COC confirming that the work has been performed in accordance with the technical and quality requirements of the purchase order and the Supplier's QA Program as evaluated by UL or FM. Accompanying the COC will be inspection reports, test reports and/or other documentation demonstrating compliance with the acceptance requirements specified by engineering in the purchase order. Clarifying text has been included in Section 4.1.A of Attachment B of the MPQAP.

RAI 1.a (5) – *Information that will be documented by MOX Services to show that the UL or FM process is adequate for the category of item being procured;*

MOX Services RAI Response

The following documentation will be required by MOX Services procedures and is applicable to QL-1LR procurements:

1. The UL and/or FM qualification report and process evaluation will be required to be submitted as part of the Bid package by the perspective supplier. As part of the supplier evaluation and selection process, PP3-12, *Supplier Evaluation,* a vendor surveillance report will be prepared documenting the technical evaluation of the UL or FM qualification testing and QA evaluation of the UL or FM Process evaluation. If successful, this evaluation will be the basis for adding the supplier to the approved commercial grade vendors' list.
2. The COC and documentation provided by the supplier to establish the acceptance of material in accordance with the purchase order shall be provided with the shipment and will receive a documented Receipt Inspection by MOX Services Quality Control receipt inspection staff (*Reference MPQAP section 7.2.6.4*)

   "7.2.6.4 Receiving Inspection

   When receiving inspection is used to accept an item:

   A. The inspection shall consider any source verifications/audits and the demonstrated quality performance of the supplier/subcontractor.

   B. The inspection shall be performed in accordance with established inspection QA procedures.

   C. The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness.

   D. The inspection shall be planned and executed according to the requirements of Section 10, Inspection.

   E. Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier/subcontractor documentation submittals."

3. If supplemental QA controls are required the verification method (e.g., Audit, Surveillance, Survey, and/or Source Verification) shall be documented in accordance with existing procedures.

NRC RAI 1.b – *Please describe how MOX Services will determine if functional testing is sufficient for product acceptance and verification of critical characteristics or, if further testing is required.*

MOX Services RAI Response

MOX Services considers that functional testing by itself is not normally an acceptable basis for acceptance of a commercial item as a basic component. As discussed in RAI 1.a (2) MOX Service will determine the critical characteristics based on the safety function of the item to be procured. Appropriate verifications and verification methods will be required for each critical characteristic. The reference to functional testing was to indicate that if functional testing is

required and the testing by the UL or FM is not sufficient to satisfy the critical characteristics, then MOX Services may rely on planned functional testing, if that will resolve the shortcoming of the UL or FM testing. Such functional testing is performed during Construction or Start-Up and, when appropriate, will be used as part of the basis for acceptance as opposed to imposing additional requirements on the supplier.

No MPQAP change is required since the basic requirement is already established in MPQAP Attachment B and the detailed requirements will be established in MOX Project Procedures prior to use.

NRC RAI 1.c – *Please specify in the MPQAP the frequency upon which recalls will be reviewed as part of the MOX Services lessons learned process*.

MOX Services RAI Response

MOX Services will act immediately whenever a potential recall for items used in a QL-1 (including QL-1LR) application come to MOX Services attention. The lessons learned process and, when appropriate the corrective action process will be used. As a minimum, MOX Services will use PP1-7, *MFFF Lessons Learned Procedure,* to require the review of UL and FM recalls at least quarterly for recalls that could potentially affect the MOX facility safety functions. MOX Services will revise the MPQAP, Attachment B, section 4.1.B to incorporate the quarterly review requirement. If recall results indicate an adverse trend with UL or FM products, a reevaluation of UL or FM as a basis for supplier selection shall be performed.

NRC RAI 2 – *Please describe the basis for MOX Services' Determination that the scope of onsite inspections conducted by UL and FM for certifying suppliers are of sufficient frequency and breadth of program areas to ensure that the QA controls implemented by the suppliers are adequate and effective and that manufactured items are representative of the items tested during the certification process.*

MOX Services RAI Response

The MPQAP section 7.2.2.A requires for supplier selection an evaluation of the supplier/subcontractor's capability to provide items or services in accordance with the procurement document. Since UL or FM will have completed a detailed review and testing of the product they are in a good position to understand the QA controls necessary to assure future products are representative of the product evaluated and tested. Any changes to the product design must also be submitted to and approved by UL or FM. MOX services review of this documentation will determine whether additional controls are required. MOX Services uses the guidance of the MPQAP and NQA-1 in their review of the process control evaluation by UL or FM. If additional controls are determined to be necessary, they will be included in the purchase order and verified by MOX Services. The UL or FM evaluations are typically done at least annually. MOX Services will review QL-1LR suppliers annually in accordance with PP3-12, *Supplier Evaluation,* and as part of that review will confirm that UL or FM follow-up reviews have been performed.

Additionally, as discussed in RAI 1 above the MOX services purchase order will specify the tests, inspections and/or acceptance requirements required from the supplier. Appropriate documentation will be required to be provided with the COC demonstrating compliance with the purchase order requirements in accordance with the QA Program as evaluated by UL or FM. During receiving inspection MOX Services quality control will verify receipt of this documentation and that the documentation demonstrates compliance to MOX purchase order requirements. An MPQAP applicability matrix has been included in Attachment B to provide additional clarification.

NRC RAI 3.a – *Please clarify the wording in the excerpted text "These are reviewed by UL or FM and appropriate is determined by their respective Engineering departments." It does not read logically.*

MOX Services RAI Response

MOX Services agrees with the comment. The sentence is incomplete. It should read "These are reviewed by UL or FM and appropriate **testing** is determined by the respective UL or FM Engineering departments."

NRC RAI 3.b – *Please describe the basis for the MOX Services determination that UL or FM accreditation and testing services meet the graded QL-1LR QA program requirements (i.e., graded Appendix B).*

MOX Services RAI Response

Suppliers that manufacture and supply UL of FM listed components are subject to UL or FM surveillance to establish their continued commitment to quality and consistency of supply. Subsequent to initial evaluation and certification, UL certified manufacturers submit their factories to periodic, unannounced inspections by representatives of UL or FM who audits production to determine the manufacturer's continued compliance to UL or FM's requirements. Furthermore, components manufactured by these suppliers are periodically tested to verify their design features and ensure their capability to meet their performance requirements. The UL process for supplier evaluation, certification and oversight is credited as the part of the MOX Services basis for evaluation and supplier selection. In addition MOX Services applies its QL-1LR program to the items received, independently verifies the products acceptability (through technical review, receipt inspection and other suitable measures, as required) and periodically monitors information sources to ensure product performance is maintained and there have been no recalls associated with procured SSCs.

NRC RAI 3.c –*Please clarify if the UL or FM certification programs allow for the manufacturers to outsource the manufacture/production of certified items to another company or another facility location. If yes what controls are in place to confirm that the other company/location is manufacturing these items properly?*

MOX Services RAI Response

UL or FM requires their surveillances be performed at the point of manufacture/production. MOX will place a restriction in the terms and conditions of the contract indicating that any

outsourcing or work performance at a location other than that evaluated by UL or FM requires MOX Services Approval. MOX Services approval will require verification of program implementation at the remote location by MOX Services, UL or FM. The MPQAP has been revised to require performance of a surveillance on UL or FM prior to use.

NRC RAI 4 – *The statement "MOX Services may document…" is unclear. Please revise the statement to show the commitment that MOX Services will document the QL-1LR items safety function, critical characteristics, verification method, acceptance criteria and basis for selection in the procurement specification (or, if preferred, in a separate commercial grade dedication package) or provide information on why they would not document these items.*

MOX Services RAI Response

MOX agrees with the comment and the wording in the MPQAP has been clarified to state MOX Services shall either prepare a separate commercial grade dedication package or shall document…" The original intent of the statement was to recognize that MOX Services currently uses separate commercial grade dedication packages but may alternatively provide this information in the purchase specification.

NRC RAI 5 – *MOX Services justification for UL or FM approach to accreditation included a discussion of what was done at the AREVA LaHague and Melox facilities. Please provide details regarding the use of accredited suppliers at those facilities. The additional details should include:*

a. A discussion of why performance history of two years of INES Reportable events is sufficient to support MOX Services assumption regarding performance of accredited items.

b. A description of the types of components that were procured for the French facilities using the accreditation supplier process. Additionally, provide a comparison of the types that were purchased for the French facilities using an accreditation process to those that may be procured under the QL-1LR program using UL/FM.

c. A description of the qualification processes or the accreditation entities that were used at the French facilities and a discussion of how they are comparable to what UL/FM does as part of their accreditation processes.

MOX Services RAI Response

MOX Services provided the information in response to an NRC comment during the initial stages of our discussions regarding QL-1LR IROFS. The intent of including this information was simply to demonstrate that a similar approach has been used in France and has been successful. This was intended to be used in conjunction with the remaining elements of the discussion.

Since this information was provided as supplemental information two years was consider to be sufficient. However, we have reviewed the past 9 years of performance and have found that there were no events above a level 2 that involved hardware failures. A level 2 involves exposure to a worker with no acute health effects.

The types of components that were procured commercial included manometers, valves, HVAC, sensors, indicators, switches and internal components to electrical panels. MOX Services intends its use to be similar to the French application. This process will not be used on items that are subject to design or specifications unique to the nuclear application, and products typically include those that are used in applications other than nuclear facilities and are procured principally based on manufacturers' product description.

NRC RAI 6.a - *Please revise the MPQAP and supporting documents related to international calibration to (1) reflect the limitation that accreditation can only be used in lieu of a commercial grade survey (not to add suppliers to the approved suppliers list) and (2) describe the complementary controls/actions, such as independent sampling, that will be used to dedicate international calibration services. For the use of independent sampling, please specify the periodicity in the MPQAP (i.e., "not to exceed yearly, if active") and identify if sampling will be done for each supplier or only a sample of all the accredited suppliers used.*

MOX Services RAI Response

MOX Services will revise the MPQAP to change the words "…on the approved suppliers list based on…" to read "…on the approved commercial grade vendors List…" The approved commercial grade vendors list is MOX's listing of commercial grade suppliers that required evaluation.

MOX Services will submit any prospective laboratory to blind sample testing as part of the initial supplier selection basis and at least annually thereafter. The sample and basis will be documented in MOX Services procedures. The MPQAP will be revised to reflect this approach in Attachment B, section 4.1.B.

NRC RAI 6.b - *Please revise the MPQAP and supporting documents related to international testing to (1) describe the basis for international testing lab capabilities. Because the NRC has not yet provided direct review of international testing supplier performance or compliance with ILAC and SAS/COFRAC requirements and oversight, further justification is needed by MOX Services to describe the basis for supplier performance beyond their accreditation status. This justification can include the results of MOX Services audits and surveys of international testing suppliers, their demonstrated performance history, or a commitment to perform more rigorous sampling of testing services during initial use of suppliers to establish performance capability, and (2) describe the complementary controls/actions, such as independent sampling, that will be used to dedicate international testing services. For the use of independent sampling, please specify in the MPQAP the initial and subsequent periodicity and sample size for testing services, or describe how MOX Services will determine the initial and subsequent periodicity and sample size. Please ensure that, whether documented in the MPQAP or an alternate QA Record, the basis for selection of initial and subsequent sample size and periodicity for testing suppliers is documented.*

MOX Services RAI Response

MOX Services has already provided this explanation in the justification document provided along with the MPQAP R11 Change Notice 1 and does not believe a change to the MPQAP is

warranted. To reiterate, the key elements of the justification for use of international laboratories is:

a. The laboratories shall only be used on IROFS whose relative importance to safety has been determined to be low.
b. The NRC has already accepted the ILAC process domestically for calibrations. The ILAC process domestically and internationally for calibration and laboratory services verifies the adequacy of applicable QA program controls including compliance to ISO 17025 regarding laboratory process controls. In addition, the verification process verifies capability and process control for each analytical method approved for use and the analytical methods approved are documented in the COFRAC/SAS certification certificates.
c. MOX has evaluated Lab Pourquery a French laboratory certified by COFRAC and found them to meet the elements of the commercial grade dedication. MOX Services performed a survey on Lab Pourquery which addressed the following: (1) verified the following elements: Organization, QA Program; Procurement Document Control; Instructions, Procedures and Drawings; Control of Purchased Materials; Equipment and Services Handling, Storage and Shipping; Inspection, Test and Operating Status; Control of Measuring and Test Equipment; Nonconforming Material Parts or Components; Corrective Action, Records; and Audits.; (2) the QA Manual (Laboratoire Pourquery Quality Management Plan); (3) Lab Pourquery's ability to comply with with technical documents DCS01-ZMJ-SPE-M-19114-4, *Process Equipment fabrication Inspection and Test Requirements* and DCS-ZMJ-DS-NTE-N-65107-3, *Technical Engineering Information for Material Testing*; (4) Program review, personnel qualification, documentation, supplier qualifications and interviews; and (5) COFRAC Laboratory accreditation.
d. MOX Services as part of a corrective action was required to recertify 99 commercial certified material test reports (CMTRs). During this review there were no unsatisfactory CMTRs identified. Laboratories, such as MECASEM Group (COFRAC), Laboratoire Pourquery (COFRAC) and Laboratoire d'essais Metullurgiques (SAS) are certified and this certification is verified during supplier selection and included on the approved list for Commercial Grade vendors.
e. Blind samples will be submitted to the laboratory initially, then quarterly for the 1st year and annually thereafter. Blind sampling will be five (5) known samples sent to laboratory for testing. The laboratory test results will be verified to the known samples.

NRC RAI 6.c - *Please describe how MOX Services will adjust the periodicity and sample size of independent sampling for international calibration and testing suppliers based on supplier performance.*

MOX Services RAI Response

MOX Services monitors the performance of all of our IROFS suppliers. Whenever, unsatisfactory conditions are identified the adverse condition is evaluated by MOX Services in accordance with the MOX Services corrective action program. Unsatisfactory performance can lead to termination of services or remedial action. For those adverse conditions that affect the adequacy of the testing, remedial action will require independent monitoring of laboratory results until confidence has been re-established. The extent of monitoring to re-establish

confidence is a function of the severity of the adverse conditions observed and will be documented in the respective corrective action plan.

NRC RAI-7.a - *Please confirm that the scope and frequency of these on site evaluations at both levels (ILAC evaluations of SAS/COFRAC and SAS/COFRAC evaluations of suppliers) meet minimum ILAC standards.*

MOX Services RAI Response

The European Cooperation for Accreditation (EA), an ILAC recognized Regional Cooperation Body and signatory to the Mutual Recognition Agreement (MRA), perform on site (COFRAC or SAS headquarters) evaluations of COFRAC and SAS upon initial certification and at least annually thereafter. The EA on site (headquarters) evaluation includes oversight of a COFAC or SAS certification evaluation at a material supplier. ILAC and ILAC Regional Cooperation Bodies are bound by the signed Mutual Recognition Agreement (MRA) to abide by the procedures defined in the ILAC requirements document.

NRC RAI 7.b - *Please confirm that the requirements for initial accreditation for SAS/COFRAC are comparable to those applied by ILAC to domestic calibration suppliers.*

MOX Services RAI Response

ILAC and ILAC Regional Cooperation Bodies are bound by the signed Mutual Recognition Agreement (MRA) to abide by the procedures defined in the ILAC requirements document. MOX Services has performed a commercial grade survey of Laboratories Pourquery and found the controls to be adequate and the laboratory certification to be the same format and equivalent content to domestic calibration laboratory certificates. The certificates of accreditation indicate that the supplier is accredited to ISO 17025 and specifically the analytical techniques, including limitations where applicable, that were accredited. In addition to a program review, Lab Pourquery was required to demonstrate to COFRAC reviewers proficiency for each technique identified on the accreditation certificate for example: Test of Metallic Materials – Mechanical Tests (29-1), Test of Metallic Materials – Determination of the Chemical Composition of Ferrous Metals (29-2), Test of Metallic Materials - Physical and Physico-Chemical Tests (29-4) and Test of Metallic Materials – Tests on Welded Assemblies (29-5).

NRC RAI 8 - *Please clarify what is meant by "other laboratory services"*

MOX Services RAI Response

MOX Services agrees the word "other" makes the statement confusing. MOX Services has deleted this sentence from the MPQAP, Attachment B, section 4.1.B. as it is already stated as a requirements in *MPQAP section Paragraph 7.2.2.C.4* which is invoked in Attachment B section 4.1.B (second bullet)with the exception of the domestic supplier limitation.

"7.2.2.C.4 Verification that suppliers of calibration services have accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), the American Association for Laboratory Accreditation (A2LA) or other accreditation agencies accepted as signatories to the International Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA). The following additional requirements shall be noted in procurement documents;

- *Purchase document impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements,*
- *Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance,*
- *Purchase documents require identification of the laboratory equipment/standards used.*
- *The alternative method is limited to the domestic calibration service suppliers."*

NRC RAI 9 - *Please revise Section 16.2.1 of the MPQAP to include references to QL-1LR, in addition to QL-1, in the discussion of invoking of the requirements of 10 CFR Part 21 for the reporting of defects and non-compliances. Please include in your response a discussion of the measures that will be used, if any, to ensure that MOX Services is notified of defects and deviations associated with QL-1LR calibration and testing services (including any measures imposed on sub-suppliers who provide calibration services to a MOX approved supplier)?*

MOX Services Response

Section 16.2.1 does not require a revision as QL-1LR is a subset of QL-1 and consequently 10CFR21 is applicable to QL-1LR products at the point of acceptance by MOX Services.

MOX Services contractually requires our suppliers to notify us of any nonconformances. For these procurements this condition of the contract will be modified to note that any nonconformances or failures to comply that affect the products delivered must be reported to MOX Services. We will also indicate that the end date of this condition of the contract is with the deactivation of the MOX Facility.

In addition, MOX Services has included an applicability matrix in Attachment B for clarity.

Additional MPQAP Change

The requirement to submit a list of IROFS subject to an augmented QA program has been removed from section 2.2.3.C. The requirement was removed since as description of the augmented QA program including the criteria for determining QL-1LR IROFS is provided as Attachment B to the MPQAP. The application of the augmented QA program and the determination of QL-1LR is subject to NRC inspection. Consequently, the submitting of a list of QL-1LR IROFS is redundant.