Duke Cogema Stone & Webster

MOX Project

Quality Assurance Plan

Docket Number 070-03098

Revision 4

Prepared by

Duke Cogema Stone & Webster

Under

U. S. Department of Energy

Contract DE-AC02-99-CH10888

Duke COGEMA Stone & Webster, LLC
QUALITY ASSURANCE PROGRAM
POLICY STATEMENT
15 December 2005

Duke COGEMA Stone & Webster (DCS) has developed a comprehensive quality assurance program that establishes the quality assurance requirements and applicable management measures to control DCS design, construction, and operations phase (Base Contract, Option 1, and Option 2) activities for the U.S. Department of Energy (DOE) MOX Fuel Project. The DCS Quality Assurance (QA) Program applies to quality-affecting activities on the MOX Fuel Project. The QA Program is a living program that will be revised prior to deactivation of the MOX Fuel Fabrication Facility. This program consists of this policy statement, MOX Project Quality Assurance Plan (MPQAP), and QA procedures. The basis of the MPQAP is 10CFR50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants* (as required by 10CFR70); Parts I and II of ASME NQA-1-1994, *Quality Assurance Program Requirements for Nuclear Facilities* as revised by the ASME NQA-1a-1995 Addenda; and U.S. Nuclear Regulatory Commission Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction).*

The MPQAP and its QA procedures define the actions taken by DCS management and personnel during the performance of quality-affecting activities on the project to ensure QA requirements are consistently met. This QA Program is based on line and staff organizations being responsible and held accountable for the quality of their assigned work. The Quality Assurance organization verifies the achievement of quality through audits, assessments, and reviews.

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 DCS QA Program described in the MPQAP and QA procedures is assigned to the DCS Quality Assurance Manager who reports directly to me.

Functional Area Managers are responsible for the QA procedures required by this program.

DCS personnel are given authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. Stop-work authority, including investigation, resolution, completion of corrective actions and authorization for resumption of work, is to be exercised in accordance with approved procedures.

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

L. R. Barnes
President & MOX Project Manager

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Revision 4 Change 1 was initiated to update the organization description in Section 1.2, remove additional historical background information from the Introduction, incorporate the current QA Policy Statement, and make minor corrections. Non-editorial changes are described in the following table along with identification of the pages containing those changes. The changes from Revision 4 are indicated with a sidebar and Change 1 in the margin. Change indication relative to Revision 3 has been retained.

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 4 CHANGE 1
QA Policy Statement	**Replaced with policy statement from the current DCS President.**
General Editorial Corrections	• **Spelled out quality assurance where the reference is to functions or responsibilities of the organization. The acronym "QA" is used to identify criteria, requirements, and program content.** • **Spelled out acronyms at the first occurrence in the document.** • **Corrections to punctuation and notes.**
Introduction **Affected Pages ix, xi, xiii, xiv, and xv.**	• **Expanded description of Management Measure 15.2, *Configuration Management,* to include criteria 8 and 15.** • **Removed DOE Contract information under *Provisions for Continuing QA*.** • **Clarified *Use of Subcontractor QA Programs* to identify cross reference to Sections 4 and 7 for the flow-down of QA Controls to subcontractors.**
Section 1 **Affected Pages 1 through 5, 8**	• **Entire sub-section 1.2 replaced with current organization description.** • **Figure 1-1 updated to match the organization description.**
Section 2 **Affected Pages 13, 18, 19**	• **Clarified in Sub-section 2.2.3A that QA grading evaluations are reviewed by Regulatory Affairs (which includes the Licensing and Safety Analysis functions) and Quality Assurance.** • **Sub-section 2.2.7A revised to clarify the requirement for annual evaluation of quality-affecting activities.** • **Sub-section 2.2.8A revised to clarify the requirement for a periodic evaluation and report to DCS Management on the status of the QA Program.**
Section 3 **Affected Pages 25**	• **Sub-section 3.2.4I revised to reflect content from NQA-1 1994.**
Section 4 **Affected Pages 37**	• **Added "as applicable" to end of sentence relative to invoking 10CFR21 on IROFS procurements, recognizing that the procurement of "Commercial Grade Items" does not include invoking of 10CFR21 on the supplier.**
Section 5 **Affected Pages 40**	• **Replaced "QA Manager" with "Quality Assurance" in the second paragraph of sub-section 5.1 reflecting the review is required to be performed by the quality assurance function.**
Section 6 **Affected Pages 42**	• **Removed the word "format" from sub-section 6.2.3 to ensure the focus is placed on the content of the documents.**
Section 16 **Affected Pages 74**	• **Revised sub-section 16.2.1B3) for consistency with notification and reporting requirements.**

MPQAP SECTION	DESCRIPTION OF CHANGE IN REVISION 4 CHANGE 1
Section 18 **Affected Pages 85, 86, 90, 91**	• **Removed the reference to the DCS QA Manager from the third paragraph in sub-section 18.1, sub-section 18.2.9D, sub-section 18.2.10, and sub-section 18.2.11E. The requirements for the activities to be performed remain.** • **Clarified sub-section 18.2.1A to clearly identify the two year frequency for Internal Audits only applies to the operations phase of the project.**

MPQAP REV. 4 SECTION	DESCRIPTION OF CHANGE FROM REVISION 3
QA Policy Statement	Revised Policy Statement for brevity. QA Policy is now stated in terms of activities instead of contract phases.
Table of Contents	Added page numbers for the Table of Contents and removed the Section Revision column, since revisions will be controlled for the entire document.
General Changes	1. Broadened the application of the QA Program to include activities related to the start-up and operation as well as design and construction of the MOX Fuel Fabrication Facility. 2. Revised document to reference activities and phases of the project instead of referencing to the DOE Contract phases. 3. General revision of document to clearly delineate requirements and align with the supplemental requirements of NQA-1. 4. Replaced Duke Engineering & Services (DE&S) with Duke Project Services Group, Inc. throughout the document, reflecting the change in Duke Energy equity partner in DCS.
Introduction	This entire section was revised to clearly indicate this section does not contain requirements and commitments. Change bars are not included in this section. The Introduction provides background material on the QA Program development and implementation philosophy, cross reference information relative to NUREG 1718 identified Management Measures, and material related to the project history. Descriptions from Rev. 3 Paragraph 2.1.2 *Use of Subcontractor QA Programs* and Paragraph 2.2 *Graded Quality Assurance* were added to the Introduction. Requirements for continuing QA were moved from the Introduction in Rev. 3 to Paragraph 1.3.6.
1.0 Organization	This entire section was revised and reformatted. Change bars are not included in this section. Paragraph 1.2 was revised to identify functional responsibilities and interfaces. The position identified in Revision 3 as the Project Manager is replaced with the DCS President/Chief Executive Officer. The Engineering and Construction functions were separated to provide appropriate focus on responsibilities as DCS progresses toward initiation of construction. Paragraph 1.3 of Rev. 4 contains the requirements from Rev.3 Paragraphs 1.3, 1.4, 1.5, and 1.6 and the requirements for continuing QA from the Rev. 3 Introduction.

MPQAP REV. 4 SECTION	DESCRIPTION OF CHANGE FROM REVISION 3
2.0 Quality Assurance Program	This entire section was revised and reformatted to clearly identify the requirements and remove background information. Change bars are not included in this section. The table of NQA-1 Part II Subparts in Paragraph 2.1 of Rev. 3 has been deleted. Subpart 2.7 is specifically addressed in Paragraph 3.2.7 of Rev. 4. The guidance of the remaining Subparts is used by DCS in the development of implementing documents for the related activities. Paragraph 2.1.1 *Program Basis* was revised to broaden the definition of quality-affecting and application of the QA Program to include activities related to start-up and operation. Paragraph 2.1.2 *Use of Subcontractor QA Programs* in Rev. 3 was moved to the Introduction as it contained descriptions and reference information. The first paragraph from 2.2 of Rev. 3 was condensed into Rev. 4 Paragraph 2.1.2 *Graded Quality Assurance*, with the specific requirements from the balance of Revision 3 Paragraph 2.2 being captured in Paragraph 2.2 Rev. 4 described below. The description and philosophy of graded QA in Rev. 3 Paragraph 2.2 is addressed in the revised Introduction. Rev. 4 Paragraph 2.2 contains the requirements from Section 2 of Rev. 3 as follows: • Paragraph 2.2.1 is a new section addressing the *Application of QA Controls for Product*. • Paragraph 2.2.2 addresses *Categorization of SSCs for MFFF*, including the definition of Quality Levels. The definitions for QL-1a and QL-1b have been revised for clarity of application, but all IROFS remain Quality Level 1. • Paragraph 2.2.3 addresses *Identification of QA Controls for MFFF*, providing the requirements for QA grading in Rev. 3 Paragraph 2.2.2. • Paragraph 2.2.4 addresses the requirements for the *Application of Graded QA Controls* previously in Rev. 3 Paragraph 2.2.3. • Paragraph 2.2.5 addresses *Feedback Mechanisms and Reassessing Safety Significance*, providing the requirements in Rev. 3 Paragraph 2.2.4. • Paragraph 2.2.6 addresses *Personnel Indoctrination, Training, and Qualification*, expanding the requirements from Rev. 3 Paragraphs 2.3, 2.5, and 2.6. • Paragraph 2.2.7 addresses *Management Assessments*, replaces Rev. 3 Paragraph 2.4. This revision expands the requirements implementing criteria addressed in NUREG 1718 Section 15.6 and providing a linkage between the audit and assessment activities. • Paragraph 2.2.8, *Quality Assurance Program Status Reporting*, addresses the requirements from Rev. 3 Paragraph 2.7.
3.0 Design Control	Change bars are included in this section to identify where changes were made for editorial clarifications. In addition, the following are identified by change bars: • Divided Rev. 3 Paragraph 3.2.2H. into 3.2.2H. and I. to emphasize these as two distinct requirements. • Moved and revised Rev. 3 Paragraph 3.2.4G.3 to 3.2.2J. clarifying the requirement and ensuring it applies to more than QL-1 SSCs. • Revised Paragraph 3.2.3D. to more clearly reflect the requirements of NQA-1. • Revised Paragraph 3.2.7 to more clearly reflect the requirements of NQA-1 Subpart 2.7.

MPQAP REV. 4 SECTION	DESCRIPTION OF CHANGE FROM REVISION 3
4.0 Procurement Document Control	Change bars are included in this section to identify where changes were made for editorial corrections. In addition, the following are identified by change bars: • Added requirement 4.2.1B.4). • Revised 4.2.1C. to clarify that flowdown of 10CFR50 Appendix B requirements applies to QL-1 procurements and to clarify the defect reporting requirements in accordance with 10CFR21 for IROFS. • Deleted final sentence from Rev. 3 Paragraph 4.2.2B. because compliance with QA Requirements is the line organization's responsibility.
5.0 Instructions, Procedures, and Drawings	Change bars are included in this section to identify where changes were made for editorial corrections.
6.0 Document Control	This entire section was revised and reformatted to clearly identify the requirements. Change bars are not included in this section. Paragraph 6.2.6 addresses the requirements from Paragraph 6.2.5 of Rev. 3, adding clarification of specific requirements for controlled distribution where access to the Electronic Data Management System is not available.
7.0 Control of Purchased Material, Equipment and Services	This entire section was revised and reformatted to clearly identify the requirements. Change bars are not included in this section. The following specific changes are noted: • The term 'supplier' has been replaced with 'supplier/subcontractor' throughout the document. This change is extensive in Section 7 negating the usefulness of change bars. • Rev. 3 Paragraph 7.2.2E. was deleted. DE&S no longer exists and Duke Energy ASL is not applicable to a fuel fabrication facility. • Paragraph 7.2.11 revised to reflect NQA-1 requirements. • Paragraph 7.2.13 added to address the process for procuring QL-2 SSCs, analogous to the process for Commercial Grade Items for IROFS. • Paragraph 7.2.14 address requirements from Rev. 3 Paragraph 7.3
8.0 Identification and Control of Materials, Parts and Components	Change bars are included in this section to identify where changes were made for editorial corrections. In addition the detailed requirements of Paragraph 8.2 are identified for QL-1 only. The general requirements in the second paragraph of 8.1 apply to both QL-1 and QL-2 items.
9.0 Control of Special Processes	Change bars are included in this section to identify where changes were made for editorial corrections.
10.0 Inspection	Change bars are included in this section to identify where changes were made for editorial corrections.
11.0 Test Control	Change bars are included in this section to identify where changes were made for editorial corrections. In addition to the editorial corrections, Paragraph 11.2.6 was revised to define the requirements for qualification of test personnel.
12.0 Control of Measuring and Test Equipment	Change bars are included in this section to identify where changes were made for editorial corrections. In addition to the editorial corrections, Paragraph 12.2.4 was revised to include damaged M&TE and reference Section 15 for the evaluation.
13.0 Handling, Storage and Shipping	Change bars are included in this section to identify where changes were made for editorial corrections.
14.0 Inspection, Test, and Operating Status	Change bars are included in this section to identify where changes were made for editorial corrections.
15.0 Nonconforming Materials, Parts and Components	Change bars are included in this section to identify where changes were made for editorial corrections.

MPQAP REV. 4 SECTION	DESCRIPTION OF CHANGE FROM REVISION 3
16.0 Corrective Action	Change bars are included in this section to identify where changes (other than paragraph renumbering) were made for editorial corrections. In addition, the 10CFR21 reporting considerations (Rev. 3 Paragraphs 16.2.1.2 C. and D.) are revised in Paragraphs 16.2.1B.3), 4), and 5).
17.0 Quality Assurance Records	This entire section was revised and reformatted to clearly identify the requirements. Change bars are not included in this section. In addition to the reformatting, the following specific changes were made: • Retention requirements from Rev. 3 Paragraph 17.2.2.1 were consolidated in Paragraph 17.2.6, *Retention of Records*. • Rev. 3 Paragraph 17.2.2.2E. was deleted. This requirement was already addressed in Section 4. See Paragraph 4.2.1F. • Removed the Rev. 3 Paragraph 17.2.4.1 and 17.2.5 references to the Duke Energy Records Center and the Duke Engineering & Services records storage area. Paragraph 17.2.4A. (both Rev. 3 and Rev. 4) requires this level of detail to be addressed in an approved QA procedure. It is not appropriate for this level document.
18.0 Audits	This entire section was revised and reformatted to clearly identify the requirements. Change bars are not included in this section. In addition to the reformatting, the following specific changes were made: • Paragraph 18.2 lead in revised to provide linkage between the audit and assessment activities. • Paragraph 18.2.1 revised the frequency for internal audits to be based on performance and extend the periodicity to two years. This approach involves the use of Management Assessments to supplement the audit process and requires annual evaluation of quality affecting activities in conjunction with Paragraph 2.2.7. • Paragraphs 18.2.7, 18.2.8, and 18.2.9 were revised to reference Section 16 *Corrective Action* rather than repeat the requirements for addressing conditions adverse to quality. • Moved technical specialist qualifications to the end of Paragraph 18.2.9. • Combined and revised Rev. 3 Paragraphs 18.2.9 A. through E with Paragraph 18.2.9.2 C to reflect NQA-1. • Rev. 3 Paragraph 18.2.10 was converted to Figure 18-1.

Change 1

INTRODUCTION

This Introduction identifies the basis of the Duke Cogema Stone & Webster (DCS) Quality Assurance (QA) Program and includes background information relative to the DCS QA Program and its application to the overall project. The Introduction does not contain requirements or commitments for DCS implementation of QA requirements. The requirements and commitments are contained in Sections 1 through 18 of this document.

The consortium of Duke Project Services Group, Inc., COGEMA Inc., and Stone & Webster, Inc., has formed a Limited Liability Company called Duke Cogema Stone & Webster (DCS) to assist the U.S. Department of Energy (DOE) Chicago Office in their mission of disposing of US owned, surplus, weapons-usable plutonium in accordance with DOE Contract No. DE-AC02-99CH10888. DCS 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. Change 1
"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 and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*, were used in conjunction with 10CFR50, Appendix B to develop the quality assurance requirements for the DCS QA Program. This MOX Project Quality Assurance Plan describes DCS' 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 DCS QA Program. DCS 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 DCS 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 DCS 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 DCS 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 18 of this document describe the quality assurance requirements for quality-affecting activities on the project and 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.

NUREG 1718 SRP Section 15 Management Measures

This document describes the QA requirements, implementing procedural controls and documentation requirements that apply to the NUREG 1718 Standard Review Plan Section 15 Management Measures: 15.1, Quality Assurance; 15.2, Configuration Management; 15.3, Maintenance; 15.4, Training and Qualification of Plant Personnel; 15.5, Plant Procedures; 15.6, Audits and Assessments; 15.7, Incident Investigations; and 15.8, Records Management, as they pertain to Design, Construction, and Operations phases quality-affecting activities. The continued application of the management measures for these important program elements are focused on ensuring that principal SSCs (before completion of the ISA) and IROFS are available and reliable in performing their designed function. The MPQAP details the DCS QA Program requirements. Correlation of the applicable sections of this document with the management measures of NUREG 1718 are in Table I-1.

[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.

Table I-1: NUREG 1718 Management Measures

Management Measure	Applicable MPQAP Sections
15.1 Quality Assurance	Policy Statement, Sections 1-18
15.2 Configuration Management	Sections 2, 3, 5, 6, 8, 15, 17
15.3 Maintenance	Sections 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17
15.4 Training and Qualification of Plant Personnel	Sections 2, 5, 17
15.5 Plant Procedures	Sections 2, 5, 17
15.6 Audits and Assessments	Sections 2, 17, 18
15.7 Incident Investigations	Sections 2, 15, 16, 17
15.8 Records Management	Sections 1-18

Change 1

The following summarizes how DCS utilizes the applicable sections of this document to ensure compliant application of these management measures:

Management measure 15.1, "Quality Assurance," is implemented through the controls established in this document.

Management measure 15.2, "Configuration Management," is implemented as an essential part of the design control process meeting the requirements of Section 3, *Design Control*. Engineering generates design output documents according to approved procedures that meet the requirements of Section 5, *Instructions, Procedures, and Drawings*, and Section 3, *Design Control*, requirements for specific design procedure content. Design output documents are distributed for use according to the requirements of Section 6, *Document Control*. Section 8, *Identification and Control of Materials, Parts, and Components*, and Section 15, *Nonconforming Materials, Parts, or Components*, are integral to ensuring that physical configuration matches the documented configuration of the facility. Completed design documents are maintained in the Records management system according to the requirements of Section 17, *Quality Assurance Records*. Configuration management during design through construction, testing, operations and deactivation is essential in maintaining the design basis documentation and the facility to the as-designed and evaluated for safety condition.

Change 1

Management measure 15.3, "Maintenance," maintenance personnel will be trained in accordance with Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*. Procedures used to perform maintenance utilize the applicable requirements of the design documents and meet the requirements of Section 5, *Instructions, Procedures, and Drawings*. Where applicable, grading of QA controls is performed in accordance with requirements of Paragraphs 2.2.2, 2.2.3, 2.2.4, and 2.2.5. Spare and replacement parts will be procured, received, accepted, stored and issued according to the requirements of Section 4, *Procurement Document Control*, Section 7, *Control of Purchased Material*, Section 8, *Identification and Control of Materials, Parts, and Components*, and Section 13, *Handling, Storage, and Shipping*. Any required special processes are performed meeting the requirements of Section 9, *Control of Special Processes*. Equipment used to perform maintenance and inspections is calibrated in accordance with the requirements of

Section 12, *Control of Measuring and Test Equipment*. Nondestructive Examination personnel and inspection and test personnel are certified in accordance with Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*. Inspections are performed meeting the requirements of Section 10, *Inspection*, and testing after maintenance meets the requirements of Section 11, *Test Control*. Maintenance activities follow the requirements of Section 14, *Inspection, Test, and Operating Status*. Completed records of maintenance are maintained in the records management system meeting the requirements of Section 17, *Quality Assurance Records*.

Management measure 15.4, "Training and Qualification of Plant Personnel," is essential to the safe and successful design, construction, testing and operation of the MOX Fuel Fabrication Facility (MFFF). Training of plant personnel is commensurate with the complexity of assigned tasks. Personnel are trained in the specific project and plant procedures identified by their supervisors as being needed for their assigned tasks. These procedures are generated and approved meeting the requirements of Section 5, *Instructions, Procedures, and Drawings*. Training during design, construction and operations meets the requirements of Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*. Training records are maintained in the records management system in accordance with the requirements of Section 17, *Quality Assurance Records*. Retraining, when applicable, to maintain proficiency or when changes to work methods, technology, or job responsibilities occur meets the requirements of Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*.

Management measure 15.5, "Plant Procedures," is implemented by personnel that are appropriately trained to the applicable procedures according to requirements of Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*. The plant maintenance, testing, and operating procedures meets the requirements of Section 5, *Instructions, Procedures, and Drawings*. Plant procedures are distributed according to the requirements of Section 6, *Document Control*. When completed the procedure results are maintained in the records management system in accordance with the requirements of Section 17, *Quality Assurance Records*.

Management measure 15.6, "Audits and Assessments," is used to inform management of the effectiveness of the implementation of the DCS QA Program. Personnel who perform audits and assessments are trained according to the requirements of Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification.* Audits are performed to the applicable project procedure that meets the requirements of Section 18, *Audits*, and Section 5, *Instructions, Procedures, and Drawings*. Assessments are performed to the applicable project procedure that meets the requirements of Paragraph 2.2.7, *Management Assessments*, and Section 5, *Instructions, Procedures, and Drawings*. Completed assessments and audits results are reported to management for program improvements and maintained in the records management system in accordance with the requirements of Section 17, *Quality Assurance Records*.

Management measure 15.7, "Incident Investigations," is implemented by personnel trained in accordance with the requirements of Paragraph 2.2.6, *Personnel Indoctrination, Training, and Qualification*. The applicable procedures used to identify, investigate,

report and trend conditions adverse to quality implement the requirements for non-conforming items in Section 15, *Nonconforming Materials, Parts, or Components*, and the corrective action process in Section 16, *Corrective Action*. Investigations and corrective actions are documented and retained in the records management system meeting the requirements of Section 17, *Quality Assurance Records*.

Management measure 15.8, "Records Management," is implemented by utilizing records management procedures meeting the requirements of Section 5, *Instructions, Procedures, and Drawings*. Completed QA records are maintained by the project meeting the requirements of Section 17, *Quality Assurance Records*. This management measure is used to maintain records generated by implementation of this document.

Provisions for Continuing QA

Change 1

This document is a living, controlled document that controls the DCS QA Program. DCS maintains and updates the MPQAP as necessary to support ongoing DCS activities. Prior to Deactivation, the MPQAP will be revised as necessary to identify the QA controls applicable for deactivation activities. See Paragraph 1.3.6, *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:

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 DCS 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).

Duke Project Services Group, COGEMA, Inc., and Stone & Webster Inc. are the equity owners of DCS LLC. Subcontracted to DCS are three major subcontractors with the following specific elements of the DOE Contract DE-AC02-99CH10888 Statement of Work:

- Framatome ANP, Inc. for the design and qualification of the fuel;
- Nuclear Fuel Services (NFS) for design input for safeguards and security functions requisite for Category I Special Nuclear Material; and
- Duke Power for support of the fuel qualification program and irradiation of the MOX fuel in the mission reactors.

Additional technical support to the MOX Fuel Project activities is provided through subcontracts with COGEMA, Inc. to:

- Electricite de France (EDF) for MOX fuel operating experience;
- Belgonucleaire (BN) for MOX fuel process and facility design experience;
- COGEMA Group, including SGN for process design;
- Packaging Technology, Inc. (PacTec) and Transnuclear, Inc. (TN) for fuel transportation package design and transportation integration.

Subcontractors for quality-affecting activities are evaluated under the controls of the DCS QA Program. Change 1

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

[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.

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 DCS 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. Change 1

Quality-affecting transportation activities during Design, Construction, and Operations involves transportation interfaces with MFFF design and the mission reactors. COGEMA, Inc. subcontracts this activity to Transnuclear and PacTec. This activity is performed under the Transnuclear/PacTec QA Plan. DCS maintains PacTec on the Approved Suppliers List in accordance with Section 7 of this document.

Fuel design and qualification is assigned to Framatome ANP, formerly Framatome Cogema Fuels (FCF). Quality-affecting Design activities, including Design activities that extend into and through Construction, for Framatome's assigned workscope is controlled by the Framatome ANP Fuel Sector Quality Management Manual and associated implementing QA procedures. DCS QA provides oversight of Framatome's quality-affecting activities and maintains Framatome ANP on the Approved Suppliers List.

Design, Construction, and Operations phases of a fuel fabrication facility workscope assigned to Duke Power to identify and implement needed modifications for future irradiation services by nature of having existing U.S. Nuclear Regulatory Commission (NRC) licenses for operation are required to be performed under the direction of Duke Power's QA Program. Oversight of these activities will also be provided under the Duke Power QA Program. Since these activities are performed under the Duke Power QA Program for those NRC Licensed facilities and are not linked to the design, construction, or operation of the MFFF, DCS does not maintain Duke Power on the Approved Supplier List for these activities. Change 1

1. ORGANIZATION

1.1 GENERAL

The Duke Cogema Stone & Webster (DCS) 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).

The DCS 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. Change 1

DCS 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 the design phase concludes and construction begins, the organizational structure will shift with an increased work scope and resources for the Construction and a decrease in work scope for Facilities Design and Process Design.

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

1.2 ORGANIZATION RESPONSIBILITIES

The Duke Cogema Stone & Webster (DCS) 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. Change 1

DCS 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 DCS President

The DCS President is responsible for MOX fuel project activities and is accountable to the DCS Board of Governors. The members of the Board of Governors are corporate executives of the three corporate owners of DCS (Duke Project Services Group, Inc.; COGEMA Inc.; and Stone & Webster, Inc.). The DCS President is the highest level of

management responsible for the DCS safety program and establishing DCS 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 is responsible for project management, including integrating the functional areas discussed in the paragraphs below. Change 1

1.2.2 Quality Assurance

The DCS Quality Assurance Manager reports directly to the DCS President and is responsible for maintaining the MOX Project Quality Assurance (QA) Plan and verifying its effective implementation at applicable DCS work locations. This position is independent of the managers responsible for performing quality-affecting work and is independent of cost and schedule considerations. QA procedures are approved by the manager responsible for the performance of the activities being controlled with the concurrence of the quality assurance organization. DCS Quality Assurance will witness specified testing and inspections of IROFS.

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

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

1.2.3 Construction Services[4]

The Construction Services function 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 subcontractors and vendors that are subcontracted to execute specific construction work scopes. The Construction Manager reports to the DCS President.

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,

[4] This position will be eliminated upon completion of construction.

and issued for construction under the controls of the DCS 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. Change 1

Construction acceptance testing (CAT) is performed in accordance with the terms and conditions of the construction subcontract. The purpose of the CAT is to confirm proper installation of components and readiness for startup testing prior to construction acceptance from the subcontractor.

1.2.4 Engineering Services

This function provides the design for the process, facilities, equipment, and software for the MFFF. The engineering function also provides technical assistance to Regulatory Affairs. The Engineering Manager reports to the DCS President during design and construction. During the operations phase, this function transitions to become a part of Plant Operations.

During the design phase, Process Design 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 startup testing and the development of operating and maintenance procedures.

Facilities Design 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.

Software Design 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 startup tests. This function also supports the performance of equipment acceptance and startup testing. In the operations phase, this function transitions to Plant Operations to support maintenance and maintain configuration control of the operations software.

Equipment Design performs design of the MOX process and aqueous polishing gloveboxes, including internal equipment and other mechanical units. This function is also responsible for developing glovebox and equipment technical specifications for detailed design and procurement. This function coordinates with Procurement and QA to ensure engineering 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 startup tests. This function also supports the performance of equipment acceptance and startup testing. In the operations phase, this function transitions to Plant Operations. Change 1

Systems Engineering 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.

1.2.5 Regulatory Affairs

The Regulatory Affairs Manager reports to the DCS President. Regulatory Affairs provides planning and execution of MFFF licensing, safety analysis, nuclear criticality safety, and compliance activities, including interfaces with regulatory agencies, and managing the preparation and maintenance of the MFFF license application and the Integrated Safety Analysis Summary. 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. This function is also responsible for Environment, Safety, and Health (ES&H) requirements, to ensure consistent interpretations of ES&H requirements, support licensing, perform design reviews, and manage development of the Environmental Report. During construction, this function manages field ES&H activities and in operations, 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.

1.2.6 Business Management

The Business Manager reports to the DCS President. Business Management provides document control, records management, training, finance and accounting, contract administration, human resources, facilities management, project security control and technology control programs, information technology, project controls, process unit assembly, and procurement. This function includes the functions of Corporate Secretary, Treasurer, and Facility Security Officer.

1.2.7 Fuel Services

The Fuel Services Manager reports to the DCS President. A portion of Fuel Services is Irradiation Services, to provide 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 DCS. This function also includes Packaging & Transportation, providing 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 DCS and the mission reactors, providing the transportation and logistics support necessary to deliver the MOX fresh fuel assemblies to the mission reactors for irradiation. Change 1

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 DCS 10 CFR 70 MFFF License.*

1.2.8 Plant Operations

The Operations Manager reports to the Manager of Fuel Services. During the design phase, 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 identification of functional testing in preparation for startup testing and transition to operations. This function is responsible for the conduct of the startup testing and the acceptance of turnover of the facility for operations. During operations, this function is responsible for operation and maintenance of the facility, including configuration management. For the operations phase, this function is expected to become a direct report to the President.

1.3 REQUIREMENTS

1.3.1 Organizational Interfaces

The organizational interfaces between DCS, 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

DCS 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 DCS team locations and subcontractors is identified in applicable plans, work task agreements, basic ordering agreements, subcontracts, and procedures. In cases of delegation, DCS retains the overall responsibility for work performed under the direction of DCS.

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 Quality Assurance Manager.

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

1.3.5 Stop Work Authority

Stop work authority within DCS 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 DCS QA Program.

1.3.6 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. Changes that lessen DCS QA Program approved requirements shall be submitted with written justification to the NRC for approval prior to implementation.

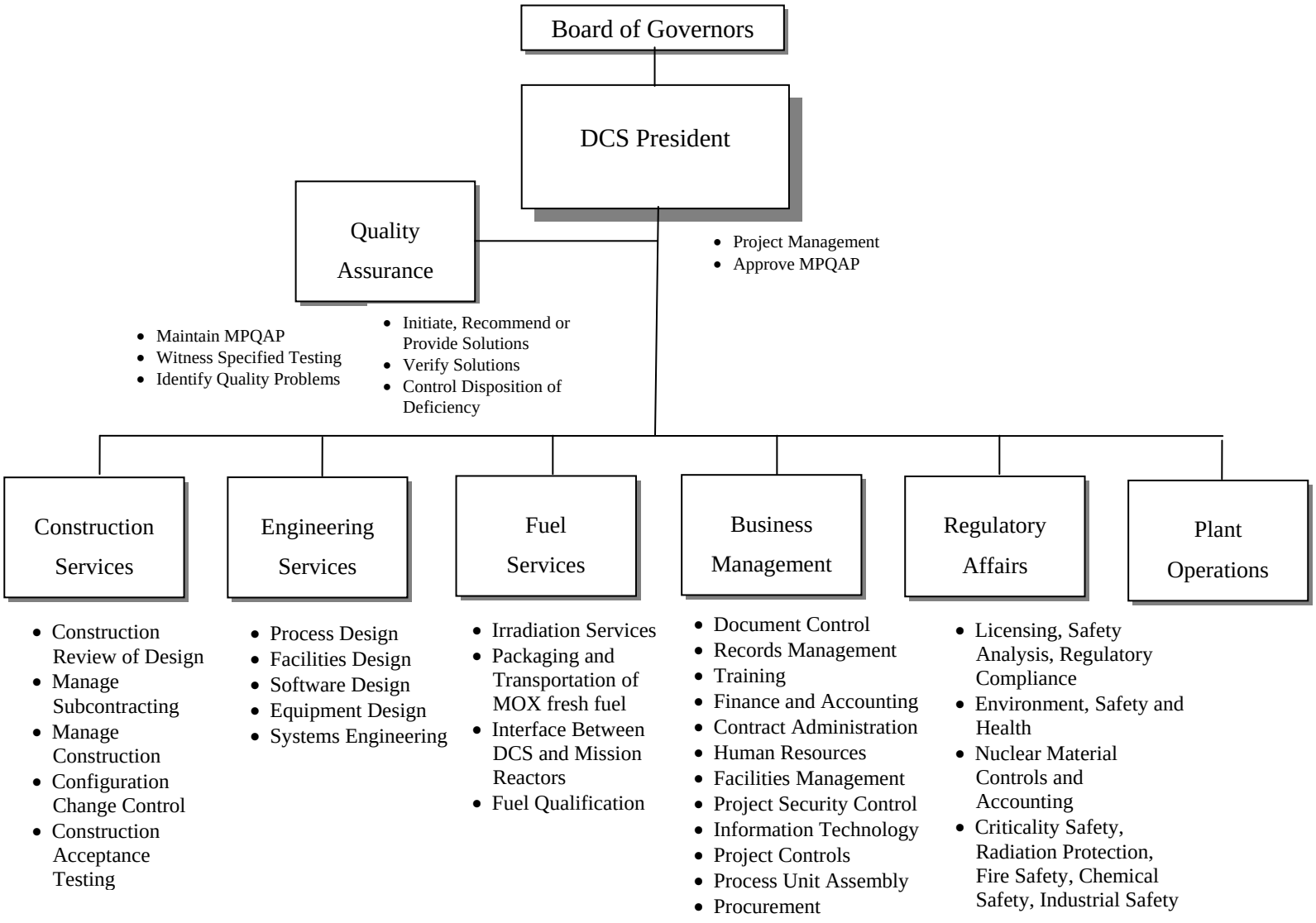
C. Prior to Deactivation this document will be revised as necessary to detail the QA controls appropriate for deactivation activities.

ATTACHMENTS:

Figure 1-1: DCS Functional Organization

Figure 1-1: DCS Functional Organization

Change 1



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2. QUALITY ASSURANCE PROGRAM

2.1 GENERAL

The DCS 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[5] of NQA-1-1994 Part I as revised by NQA-1a-1995 addenda; and Regulatory Guide 1.28 (Rev.3).

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 DCS, 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 Subpart 2.7 of Part II of ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications*, as revised by NQA-1a-1995 Addenda and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction)*, were used to provide detailed implementing guidance for 10CFR50, Appendix B quality assurance requirements for the DCS QA Program.

Specific processes and controls, implementing these requirements, are specified in QA project procedures and detailed work place procedures. 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 DCS QA Program provides for any special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality.

[5] Regulatory Guide 1.28 (Rev.3) provides for the use of the NQA-1-1983 version of this appendix. DCS 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.

2.1.2 Graded Quality Assurance

DCS is implementing a graded QA Program 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. A graded QA Program provides a safety benefit by allowing preferential allocation of resources based on the safety significance of SSCs. In this context grading refers to the selection of QA controls to be applied to SSCs and their related activities.

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 DCS 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 DCS. 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 this 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 includes Items Relied on For Safety (IROFS) and SSCs designated as “defense-in-depth” IROFS.

1) Quality Level 1a (QL-1a) 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-1a 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.

2) Quality Level 1b (QL-1b) are SSCs identified as "defense-in-depth" IROFS. These SSCs are not credited in the Integrated Safety Analysis to meet 10CFR70.61 performance requirements.

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) Protecting QL-1 SSCs from physical interactions; 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. Controls are applied to these SSCs using the DCS 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 equivalent to "non-QA" and 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.

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 selection 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. The grading process reflects the criteria used for determining which QA requirements are not necessary to support reasonable assurance of the performance of specific IROFS and QL-2 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 Regulatory Affairs and Quality Assurance functions; and Change 1

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

B. Grading Criteria

The evaluation of SSCs for selection of QA controls shall provide the basis for graded application, considering the following criteria:

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;

10) Program risk; and

11) Other relevant factors.

C. QL-1a SSCs and their associated activities (to prevent or mitigate a postulated confinement or criticality accident) are subject to the requirements in Sections 1 through 18 of this document. Grading of QA controls for QL-1a SSCs, if justified, shall be on a case-by-case basis in discrete analyses.

D. QL-1b SSCs and their associated activities are subject to the requirements in Sections 1 through 18 of this document unless non-application is justified through a grading analysis.

E. QL-2 SSCs and their associated activities are subject to the requirements in Sections 1 through 18 of this document except where non-application is specifically identified (e.g. Paragraph 3.2.4 *Design Verification*, Paragraph 4.2.1C for QA Program requirements including applicability of 10CFR21 to Procurements, Paragraph 7.2.13 for Procurement of QL-2 SSCs), unless non-application is justified through a grading analysis. This evaluation shall identify and justify which, if any, QA controls are not necessary to ensure these SSCs meet their intended functions. The evaluation may be documented for specific SSCs or for categories or groupings of SSCs by function. (This evaluation may include nuclear industry precedent in the application of augmented QA requirements.)

F. QL-3 and QL-4 SSCs and their associated activities may be voluntarily included under the controls of the DCS QA Program by management direction. Since those controls are voluntary for these items and activities, no justification is required for application or non-application of DCS QA Program requirements.

2.2.4 Application of Graded QA Controls

QA grading analyses for QL-1a, QL-1b and QL-2 SSCs are used to 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

DCS 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 DCS 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) Training logs;

3) Personnel training records.

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*, December 1988 Edition.

H. Require procedures for certification of inspection and test personnel[6] to identify:

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

[6] 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 Supplement 2S-1 of NQA-1-1983. See footnote 5 for justification for using NQA-1-1994 version instead of NQA-1-1983.

training, with emphasis on first-hand experience gained through actual performance of inspections and tests.

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;

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.

6) Qualification (or certification) records including:

   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 :
      (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. 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. DCS shall establish in written procedures for the control and administration of training and qualification of Audit and Lead Audit personnel; see Paragraphs 18.2.9, 18.2.10, and 18.2.11 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

DCS 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. 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. | Change 1

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 DCS Management, addressing pertinent information from audit reports, corrective actions, nonconformances, management assessments, etc. | Change 1

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

3. DESIGN CONTROL

3.1 GENERAL

The DCS 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). The DCS 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 DCS QA procedures to assure that applicable requirements are correctly translated by DCS 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 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. DCS 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. Design documents 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.

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.

3.2.3 Design Analysis

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

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

C. 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.

D. 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.

E. 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

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. Change 1

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

Development of software must address each of the seven phases of the software life cycle- Requirements, Design, Implementation, Test, Installation and Checkout, Operation and Maintenance, and Retirement. The following paragraphs address each phase along with a description of the phase, activities involved and documentation that is required for that phase.

1) Requirements Phase

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 phase 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 Phase

During the Design Phase, 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 Phase 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 Phase

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

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

4) Testing Phase

During the Testing Phase, 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 Phase

i. During the Installation and Checkout phase, 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 Phase 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 Phase

i. Prior to the Operations and Maintenance Phase 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 Phase

During the Retirement Phase, 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 defined at the completion of each major phase of software development. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.
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 DCS 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 DCS.

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 DCS organizations.

G. Access Control

DCS 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 DCS Approved QA Programs

   i. Individuals or organizations developing and supplying QA software under subcontract to DCS 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 DCS. Applicable requirements of this section shall become the responsibility of the DCS upon receipt of software. Typically this software enters the process at the start of the Installation and Checkout Phase.

iii. Procurement documents shall require the supplier to report software errors or failures to DCS. DCS 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 DCS 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 DCS 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).

Applicable design bases and other requirements necessary to assure adequate quality are included or referenced in DCS procurement documents for procurement of QL-1 and QL-2 material, equipment and services. DCS 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.

DCS 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. Change 1

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 DCS 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. For QL-1 procurements these include:

1) A requirement for the supplier/subcontractor to have a documented quality assurance program that implements applicable requirements of 10CFR50, Appendix B 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 DCS 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 DCS, or other designee authorized by DCS.

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

F. Identification of documentation required to be submitted to DCS 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. DCS 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 DCS, records are controlled and submitted to the records management system in accordance with QA procedures.*

G. Requirements for the supplier/subcontractor to report to DCS in writing adverse quality conditions resulting in work stoppages and nonconformances. These documents shall identify when DCS 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.

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.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 GENERAL

The DCS 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-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 workscope. Procedures are reviewed by affected managers for definition of work controlling processes. QA procedures are reviewed by DCS Quality Assurance to ensure the process provides implementation for QA Program requirements and commitments and approved by the DCS Manager responsible for the activity. 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. Change 1

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, drawings, and specifications. 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. 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 DCS 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).

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 DCS 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 Specifications, drawings, calculations, and procurement documents.

6.2.2 Documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

6.2.3 The responsibility for preparing and maintaining documents shall be assigned to the appropriate DCS functional area. The applicable QA procedures shall establish controls for the content of documents. Change 1

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 organizations or disciplines affected by the change.

B. The quality assurance organization shall review changes if the quality assurance organization was involved in the review of the previous version or the new changes affect quality requirements.

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.*

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 GENERAL

The DCS 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).

DCS 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 DCS 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

DCS 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 DCS.

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.

B. Except when purchasing commercial grade items under Paragraph 7.2.12 or QL-2 SSCs under Paragraph 7.2.13, the functional area needing the procurement shall request that Quality Assurance evaluate the potential supplier/subcontractor's QA Program for placement on the DCS 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.

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

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, DCS 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. DCS shall establish measures to interface with the supplier/subcontractor and to verify supplier/subcontractor performance. The measures shall include:

1) Establishing an understanding between DCS 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 DCS and supplier/subcontractor.

6) Establishing the extent of source surveillance and inspection.

B. The extent of DCS 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. DCS 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 DCS's 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 DCS 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

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

3) Technical verification of the product produced;

4) Surveillance or audit of the work;

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

B. 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.

7.2.7 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.

B. The certificate shall identify the specific procurement requirements met by the purchased material, equipment or service. 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 DCS at intervals

commensurate with the past quality performance of the supplier/subcontractor.

7.2.8 Source Verification

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

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

7.2.9 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.

7.2.10 Post-Installation Testing

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

7.2.11 Control of Supplier/Subcontractor Nonconformance

DCS 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 DCS 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 DCS, shall be submitted to DCS 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 DCS, 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, DCS shall disposition the supplier/subcontractor's recommendation and verify implementation of the disposition.

7.2.12 Commercial Grade Items

A. Commercial grade items are items that are:

1) Not subject to design or specification requirements that are unique to nuclear facilities or activities;

2) Used in applications other than nuclear facilities or activities; and

3) To be ordered on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog)

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 will 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:

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 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 (e.g., catalog number).

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, DCS 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.

7.2.13 Procurement of Quality Level 2 SSCs

A. Characteristics for Quality Level 2 SSCs shall be determined and approved by the manager responsible for the procurement based on the

performance requirements for the item. Specific characteristics used for acceptance of the item are selected based on providing reasonable assurance that the item will meet the specifications and will perform the specified functions as intended.

B. For Quality Level 2 SSCs the following requirements are an acceptable alternate to other requirements of Paragraph 7.2:

1) The material/equipment is identified in an approved design output document. An alternate material/equipment may be applied, provided there is verification that the alternate 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 DCS based on complexity, shall be in accordance with Paragraph 7.2.2.

3) The requirements for the items shall be identified in the subcontract/purchase order by the manufacturer's published product description (e.g., catalog number) or through detailed procurement documents.

4) Prior to release of a the item, DCS 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 characteristics identified in 7.2.13A; and
iv. Documentation, as applicable to the item, was received and is acceptable.

7.2.14 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 DCS 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.

8. IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS

8.1 GENERAL

The DCS 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).

The DCS QA Program procedures establish the necessary controls for QL-1 and QL-2 to assure that only correct and accepted material, parts and components are used or installed. In addition for QL-1, 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 FOR QL-1 ONLY

8.2.1 Identification

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

B. Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use. The identification shall relate the item to the pertinent specifying document.

8.2.2 Physical Markings

A. 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).

B. 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 are 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 DCS 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).

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*. DCS 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 DCS organization will perform, or be responsible for performing, shall be established and maintained.

9.2.2 Personnel, Implementing Documents, and Equipment Qualifications

Implementing DCS 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, neutron radiography 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 DCS 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).

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. Inspection results are documented. Persons, independent of those who performed and who directly supervised the work, perform inspection for acceptance.

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 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.

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.

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 approved by qualified and authorized personnel. 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 DCS 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). 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. 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 DCS 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).

This section establishes DCS control for tools, gages, instruments 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 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

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 DCS 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).

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.

14. INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL

The DCS 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).

This section establishes requirements for DCS 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.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

15.1 GENERAL

The DCS 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).

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

B. 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.

C. Recommended dispositions shall be evaluated and approved.

D. 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.

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

F. 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.

15.2.5 Trending

Nonconformance documentation shall be periodically analyzed by the quality assurance organization to identify quality trends in accordance with Section 16, *Corrective Action*.

16. CORRECTIVE ACTION

16.1 GENERAL

The DCS 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).

Conditions adverse to quality are promptly identified 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.

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.

DCS 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 DCS 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 DCS Quality Assurance organization shall be obtained for planned corrective actions to ensure that QA requirements are satisfied.

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 public health and safety;
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 DCS QA Program;
vii. A deficiency, repetitive in nature, related to an activity or item subject to the DCS 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 DCS 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 DCS 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 DCS Regulatory Affairs, DCS Quality Assurance, DCS President and other appropriate management within the organization to ensure the condition is reported to the NRC in accordance with established requirements. Change 1

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, DCS shall determine if the identified condition affects any products received by DCS 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 DCS shall determine if the condition is reportable to the NRC. If found to be reportable, the responsible management shall immediately inform DCS Regulatory Affairs, DCS Quality Assurance, DCS 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 DCS 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

The DCS Quality Assurance organization 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.

16.2.3 Trending of DCS Deficiencies

The DCS 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.

17. QUALITY ASSURANCE RECORDS

17.1 GENERAL

The DCS 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).

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. DCS 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. Classifications of Records

DCS 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.

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 DCS QA Program but need not be retained for the life of the item because they do not meet the criteria for lifetime records. QA audit, surveillance and assessment reports are examples of nonpermanent records.

D. 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.

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

E. 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.

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; and

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

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.

C. Record Repositories

1) Temporary Storage

i. Records may be temporarily stored in a container or facility with a fire rating of one (1) hour. 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

DCS 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.

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 DCS 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.

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.

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.*

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

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 principal 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

18. AUDITS

18.1 GENERAL

The DCS 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).

QA verifies DCS 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. Change 1

18.2 REQUIREMENTS

DCS 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. 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 DCS functional area quality-affecting activities shall be performed annually. The frequency for audits Change 1

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. Change 1

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.

18.2.2 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.

18.2.3 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 18.2.9 and 18.2.11.

18.2.4 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.

18.2.5 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. 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.

18.2.6 Responding to Audits

Management of the audited organization shall respond to conditions adverse to quality according to the requirements of Section 16, *Corrective Action*.

18.2.7 Evaluating Audit Responses

The adequacy of corrective actions for conditions adverse to quality shall be evaluated according to the requirements of Section 16, *Corrective Action*.

18.2.8 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.

18.2.9 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) DCS QA indoctrination to provide a working knowledge and understanding of this document, general structure of the QA Program, 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, and evaluating corrective actions. Lead auditors shall be current with 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 comprehensive surveillances, 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) 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.

6) Upon satisfaction of the above requirements, lead auditors shall be certified as being qualified to lead audits

7) 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 DCS QA Program and program auditing.
   iii. Participation in training programs.

8) DCS 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.

9) 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.

D. Acceptance of Auditor/Lead Auditor Qualifications

Auditors and lead auditors certified under other programs may be accepted by DCS 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. Change 1

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).

18.2.10Lead Auditor Examination

The test may be oral, written, practical or any combination. Quality Assurance shall: Change 1

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.

18.2.11Lead Auditor Certification

Each lead auditor shall be certified as being qualified to lead audits. This certification shall document:

A. DCS Lead Auditor Certification.

B. Name of the lead auditor.

C. Dates of certification or re-certification.

D. Basis of certification (i.e., skills and training).

E. Approval. Change 1

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