DUKE COGEMA STONE & WEBSTER			
DUKE COGEMA STONE & WEBSTER	**MOX Project Quality Assurance Plan**	Approved By: _____ QA Manager Approved By: _____ Project Manager	Date: 20 February 2002 Date: 21-Feb-02
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DUKE COGEMA
STONE & WEBSTER

QUALITY ASSURANCE PROGRAM
POLICY STATEMENT

18 March 2002

Duke Cogema Stone & Webster (DCS), as a contractor to the U.S. Department of Energy (DOE) has developed a comprehensive quality assurance program that establishes the quality assurance requirements and applicable management measures to control DCS Base Contract and Option 1 activities for the U.S. Department of Energy (DOE) MOX Fuel Project. The resulting DCS MOX Quality Assurance (QA) Program applies as written to date to both Base Contract and Option 1 DCS quality affecting activities (i.e., deeds, actions, processes, tasks or work, which influence the achievement or verification of quality requirements and objectives for Quality Level 1 (IROFS – Items Relied on for Safety) and 2 structures, systems and components (SSCs) and their associated activities) on the entire DCS MOX Fuel Project. Base Contract quality affecting activities for fuel qualification, design, and lead assembly fabrication, mission reactor modification identification and design, licensee amendment for use of MOX fuel, lead assembly irradiation, and design and licensing of the MFFF and Option 1 quality affecting activities for MFFF construction and installation of mission reactor modifications shall meet the requirements established in the MOX QA Program. This QA program is a living program that shall be revised prior to Option 2 for operations (startup and operation of the MFFF and irradiation of MOX fuel) and Option 3 for deactivation of the MFFF. This program consists of this policy statement, MOX Project Quality Assurance Plan (MPQAP) and implementing 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 10 CFR Part 70), 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 implementing 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 QA organization is charged with verifying the achievement of quality through audits, surveillances, 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 MOX QA Program described in the MPQAP and implementing QA procedures is assigned to the MOX Quality Assurance Manager who reports directly to me.

All Functional Area Managers are responsible for implementing 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.

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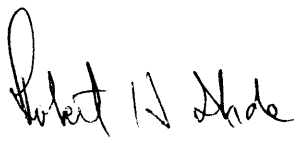


R.H. Ihde
DCS President & CEO

Change Summary for Revision 3 of the MPQAP

Changes are indicated in the document by sidebars.

MPQAP REV. 3 SECTIONS	STATUS/REASON FOR CHANGE
QA Policy Statement	Changed date for Revision 3.
Table of Contents	All sections reflect change to Rev. 3.
Introduction	Pages 1 & 2 of 7 – change reflects Item 1 DCS response to draft NRC SER. Change clarified that the MPQAP applies to QL-1 and QL-2 SSCs and that application to QL-3 and 4 SSCs is elective at the discretion of DCS management. Response accepted by NRC in 1 Oct. 2001 SER.
1.0 Organization	Sections 1.1, 1.2.1-1.2.4, and Figures 1.0-1, 1.0-2 and 1.0-4 – changes were made to better describe the DCS organization for construction in response to NRC RAI Item 1 on Rev.2 of the MPQAP. Response accepted by NRC in 1 Oct. 2001 SER. • Project Controls Manager moved to Section 1.2.2.5 • Project Services & Administration Manager moved to Section 1.2.2.1 • Packaging and Transportation Manager moved to Section 1.2.4.3, reporting to the MOX Fuel Irradiation Manager. • MFFF Equipment Design Manager moved to Section 1.2.3.6 • MFFF Site Engineering Manager moved to Section 1.2.3.3 • MFFF Construction Manager moved to Section 1.2.3.8 • Added MFFF Manufacturing Design Manager as Section 1.2.3.4 • Added MFFF Software Design Manager as Section 1.2.3.5 • Added MFFF Systems Engineering Manager as Section 1.2.3.7 • MFFF Licensing Manager Moved from Section 1.2.4.5 to Section 1.2.2.2 • MFFF Manufacturing Manager renamed MFFF Plant Operations & Startup Manager and moved from Section 1.2.4.6 to Section 1.2.2.6

Change Summary for Revision 3 of the MPQAP

Changes are indicated in the document by sidebars.

MPQAP REV. 3 SECTIONS	STATUS/REASON FOR CHANGE
2.0 Quality Assurance Program	(1) Sections 2.1 – removed reference to NQA-1 supplement 2S-3 as this is discussed in section 18.0 and not 2.0. (2) Section 2.1.2.1 heading was added to distinguish between DCS Team Members and non-team member subcontractors/suppliers. (3) Section 2.1.2.1 Table typo corrected –"Transnuclear" (4) Section 2.1.2.1 pg. 4 of 13 – added for completeness that design procedures will be used "as well as for design support of construction" - typo corrected "Transnuclear" - updated name to "Framatome ANP, formerly Framatome Cogema Fuels" (5) Section 2.1.2.2 was added to address flowdown of QA requirements to non-team subcontractors/suppliers in response to NRC RAI Item 3 on Rev. 2 of the MPQAP. Response accepted by NRC in 1 Oct. 2001 SER. (6) Section 2.2 on Graded QA was revised in reflect response to NRC RAI Item 4 on Rev.2 of the MPQAP and Item 2 DCS response to draft NRC SER. Response accepted by NRC in 1 Oct. 2001 SER. (7) Section 2.2.1.2 Table 2-1 reference to "a condition compromising criticality safety" was changed to "a criticality accident" in response to NRC RAI Item 5 on Rev. 2 of the MPQAP. Response accepted by NRC in 1 Oct. 2001 SER.
3.0 Design Control	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
4.0 Procurement Document Control	(1) Section 4.1 was revised to clarify that 10CFR21 (Part 21) is invoked during design, construction, testing and operations for all QL-1 (IROFS) procurements in response to NRC RAI Item 2 on Rev. 2 of the MPQAP. Response accepted by NRC in 1 Oct. 2001 SER. (2) Sections 4.1 and 4.2.1 C.1 were revised to only require that 10CFR50, Appendix B requirements be met as some vendors may not have NQA-1 based programs but their programs may meet 10CFR50, Appendix B requirements for their scope of work. This was an editorial change found during internal team review.
5.0 Instructions, Procedures, and Drawings	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
6.0 Document Control	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
7.0 Control of Purchased Material, Equipment and Services	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**

Change Summary for Revision 3 of the MPQAP

Changes are indicated in the document by sidebars.

MPQAP REV. 3 SECTIONS	STATUS/REASON FOR CHANGE
8.0 Identification and Control of Materials, Parts and Components	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
9.0 Control of Special Processes	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
10.0 Inspection	Section 10.2.4 was revised in response to NRC RAI Item 9 on Rev. 2 of the MPQAP. Response accepted by NRC in 2 Oct. 2001 SER.
11.0 Test Control	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
12.0 Control of Measuring and Test Equipment	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
13.0 Handling, Storage and Shipping	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
14.0 Inspection, Test, and Operating Status	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
15.0 Nonconforming Materials, Parts and Components	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
16.0 Corrective Action	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**
17.0 Quality Assurance Records	Section 17.2.4.1 was revised to remove the locations for the record storage facilities.
18.0 Audits	Revision Number and effective date changed. Pagination affected by reformatting. **No changes were made to the requirements in this section.**

The U.S. Department of Energy (DOE) Chicago Office has acquired the services of Duke Cogema Stone & Webster (DCS) to assist DOE in their mission of disposing of US owned, surplus, weapons-usable plutonium in accordance with DOE Contract No. DE-AC02-99CH10888. DCS manages the DCS Mixed Oxide (MOX) Fuel Project for DOE and is the licensee for the construction and operation of the MOX Fuel Fabrication Facility (MFFF).

DOE MIXED OXIDE (MOX) FUEL PROJECT

The DOE MOX Fuel Project has been divided 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

NOTE: This revision of the MPQAP provides the quality assurance requirements needed for both Base Contract and Option 1 quality affecting activities for the entire DCS scope of work. Quality assurance (QA) requirements contained in the MOX Project Quality Assurance Plan (MPQAP) apply to all Quality Level 1 and 2 structures, systems and components (SSCs) during MOX Fuel Fabrication Facility (MFFF) design and construction. Quality Level 1 (QL-1) SSCs as defined in section 2 of this document include principal SSCs[1] and Items Relied on for Safety[2] (IROFS). 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 that support normal operations of the facility and reduce public, worker, and environmental radiological and chemical risks.

MFFF QL-1 and -2 SSCs and their associated activities are controlled by implementation of applicable QA requirements as applied through the use of graded QA as detailed in section 2 of this document. Design, document, and configuration control and records management QA requirements are implemented from the start of the project. During construction the applicable QA requirements for procurement, materials control

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

[2] The word **safety**, when used in this MPQAP, means safety 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.

(including consumable materials used during construction), installation, use of measuring and test equipment for installation and testing (including computer hardware and software) are implemented to ensure that installed SSCs are available and can be relied on to perform their intended functions.

In general, QA requirements are electively applied to QL-3 and -4 SSCs at the discretion of DCS management as these SSCs do not impact the regulatory basis of the facility. During licensed operation, 10 CFR 70.72 provides for evaluation, implementation, and tracking of changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. These provisions include evaluation of changes to non-IROFS (i.e., including QL-2, -3, and -4 SSCs) to ensure no inadvertent changes or impacts to IROFS occur as a result.

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

DUKE COGEMA STONE & WEBSTER (DCS)

Duke Engineering & Services, Inc. (DE&S), COGEMA, Inc., and Stone & Webster Inc. (S&W) are the equity owners of the Limited Liability Company (LLC) known as Duke Cogema Stone & Webster (DCS) LLC. Subcontracted to DCS are three major subcontractors with the following specific elements of the DOE Contract DE-AC02-99CH10888 Statement of Work (SOW):

- 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: McGuire Units 1 & 2 and Catawba Units 1 & 2.

Additional technical support to the DCS MOX Fuel Project for Base Contract and Option 1 activities is provided through subcontracts with Cogema, Inc. to:

- Electricite de France (EDF) (the French national utility) 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 Option 1 MFFF construction activities shall be evaluated, selected, and contracted under the controls of the DCS QA Program.

For purposes of understanding the applicability of this MPQAP to DCS and subcontractor activities, personnel assigned to the DCS MOX Fuel Project are referred to as "DCS employees" throughout this MPQAP and implementing procedures. Applicability of subcontractor's QA Programs are discussed in section 2.1.2 of this document.

MOX PROJECT QUALITY ASSURANCE PLAN (MPQAP)

The MOX Project Quality Assurance Plan (MPQAP) is presently written to establish and implement the needed quality assurance requirements and management measures to control both DCS Base Contract and Option 1 quality affecting activities. The MPQAP meets the requirements of 10CFR50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants* and 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 is applicable to all DCS quality affecting activities performed by DCS personnel and subcontractors on the MOX Project.

DCS has developed its comprehensive quality assurance (QA) program to control DCS MOX Fuel Project principle structures, systems and components (SSCs) (prior to completion of the Integrated Safety Analysis (ISA)) and (after completion of the ISA) Quality Level 1 (IROFS – Items Relied on For Safety) and 2 SSCs and their associated Base Contract and Option 1 quality affecting activities for: MOX fuel qualification, design and licensing; identification and implementation of utility modifications needed for fuel irradiation; and design, licensing and construction of the MOX Fuel Fabrication Facility (MFFF). (The definitions for Quality Level 1 and 2 are in section 2.2 of this document.) The requirements of this MPQAP also apply to materials, parts, components, measuring and test equipment and computer software and hardware associated with principle SSCs and IROFS. The DCS QA program provides the necessary management controls to ensure that 10CFR50, Appendix B, NQA-1-1994 through NQA-1a-1995 Addenda, and NRC Regulatory Guide 1.28 (Rev.3) committed QA requirements are flowed to and implemented for applicable DCS Base Contract and Option 1 project quality affecting activities. The DCS Quality Assurance Program Policy Statement, MOX Project Quality Assurance Plan (MPQAP), and implementing QA procedures make up the DCS MOX QA Program. The controls provided by these documents requires personnel training and internal DCS oversight ensures and verifies: that DCS work activities are performed in compliance with committed QA requirements; performed in a consistent manner; and properly documented. The selective application of these controls is discussed in section 2.2.

MPQAP STRUCTURE

The MPQAP satisfies the requirements of Title 10 of the Code of Federal Regulations, Part 50 (10CFR50), Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.* Sections one (1) through 18 of this document describe the quality assurance requirements for quality affecting activities on the entire project and coincide with the 18 criteria of 10CFR50, Appendix B. The definition of "quality

affecting" and the hierarchy of QA documents for the project are further discussed in section 2.0 Quality Assurance Program. Quality Level definitions and the methodology used for applying a graded QA approach to principal and potential IROFS SSCs during design and construction and IROFS after completion of the Integrated Safety Analysis (ISA) are found in section 2.2 Graded Quality Assurance. QA requirements in the MPQAP address the management controls applicable to project activities with emphasis on controls being established in applicable implementing QA procedures for Base Contract and Option 1 activities.

NUREG 1718 SRP SECTION 15 MANAGEMENT MEASURES

The MPQAP 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 Base Contract and Option 1 DCS 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 items relied on for safety (IROFS) are available and reliable in performing their designed function. The MPQAP in its entirety details the DCS QA Program that is submitted with the Construction Authorization Request (CAR) for construction approval review. Correlation of the applicable sections of the MPQAP with the management measures of NUREG 1718 are in Table I-1.0. MPQAP sections that are **bold** in the table indicate the main MPQAP section that pertains to the individual management measure or contain the most discussion.

Table I-1.0: NUREG 1718 Management Measures

Management Measure	Applicable MPQAP Sections
15.1 Quality Assurance	Policy Statement, **Introduction**, Sections 1-18
15.2 Configuration Management	Sections 2, **3**, 5, 6, 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 1-16, **17**, 18

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

Management measure 15.1, "Quality Assurance," is implemented by DCS by implementing the controls established in the entire DCS MPQAP (all sections).

Management measure 15.2, "Configuration Management," is implemented as an essential part of the design control process meeting the requirements of MPQAP Section 3.0, "Design Control." Engineering personnel are trained according to the requirements of section 2.3, "Quality Assurance Training." Engineering generates design output documents according to DCS approved procedures that meet the requirements of Section 5.0, "Instructions, Drawings and Procedures," and Section 3.0, "Design Control" requirements for specific design procedure content. Design output documents are distributed for use according to the requirements of Section 6.0, "Document Control." Completed design documents are maintained in the DCS Records Management System according to the requirements of Section 17.0, "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.

Management measure 15.3, "Maintenance," shall be implemented during facility operation in accordance with the revision to the MPQAP that is approved by the NRC for the License Application. Maintenance personnel shall be trained in accordance with section 2.3, "Quality Assurance Training." Procedures used to perform maintenance shall utilize the applicable requirements of the basis for the MOX QA Program (sections 2.1, "General," and 2.1.1, "Program Basis") and meet the requirements of Section 5.0, "Instructions, Drawings and Procedures." Where applicable, grading of QA controls according to the Quality Level classification of the SSC shall be used as required in section 2.2, "Graded Quality Assurance." Needed parts shall be used that have been 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 shall be performed meeting the requirements of Section 9, "Control of Special Processes." Equipment used to perform maintenance and inspections shall be calibrated in accordance with the requirements of Section 12, "Control of Measuring and Test Equipment." Nondestructive Examination personnel shall be certified in accordance with section 2.5, "Qualification/Certification of Nondestructive Examination (NDE) Personnel," and inspection and test personnel shall be certified in accordance with section 2.6, "Qualification/Certification of Inspection and Test Personnel." Inspections shall be performed meeting the requirements of Section 10, "Inspection," and testing after maintenance shall meet the requirements of Section 11, "Test Control." Getting ready for, performing, testing and putting the applicable SSC back in service shall meet the requirements of Section 14, "Inspection, Test and Operating Status." Completed records of maintenance shall be distributed, if applicable to other facility work, meeting the requirements of Section 6, "Document Control," and maintained in the DCS Records Management System meeting the requirements of Section 17.0, "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 MFFF. Training of plant personnel shall be commensurate with the complexity of assigned tasks. Personnel shall be 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 5.0, "Instructions, Drawings and Procedures." QA training during design, construction and operations shall meet the requirements of section 2.3, "Quality Assurance Training," by qualified instructors or by self study. Training records shall be maintained in the DCS Records Management System in accordance with the requirements of Section 17.0, "Quality Assurance Records." Retraining, when applicable, to maintain proficiency or when changes to work methods, technology, or job responsibilities occur shall meet the requirements of section 2.3, "Quality Assurance Training."

Management measure 15.5, "Plant Procedures," shall be implemented by personnel that are appropriately trained to the applicable procedures according to requirements of section 2.3, "Quality Assurance Training." The plant maintenance, testing, and operating procedures shall meet the requirements of Section 5.0, "Instructions, Drawings and Procedures." Plant procedures are distributed according to the requirements of Section 6, "Document Control." When completed the procedure results are maintained in the DCS Records Management System in accordance with the requirements of Section 17.0, "Quality Assurance Records."

Management measure 15.6, "Audits and Assessments," are 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 in section 2.3, "Quality Assurance Training." Audits are performed to the applicable project procedure that meets the requirements of Section 18.0, "Audits," and Section 5.0, "Instructions, Drawings and Procedures." Assessments are performed to the applicable project procedure that meets the requirements of section 2.4, "Management Assessments;" and Section 5.0, "Instructions, Drawings and Procedures." Completed assessments and audits results are reported to management for program improvements and maintained in the DCS records management system in accordance with the requirements of Section 17.0, "Quality Assurance Records."

Management measure 15.7, "Incident Investigations," is implemented by personnel trained in accordance with the requirements of section 2.3, "Quality Assurance Training." The applicable procedures used to identify, investigate, report and trend conditions adverse to quality implement the requirements for non-conforming items in Section 15.0, "Nonconforming Materials, Parts or Components," and the corrective action process in Section 16.0, "Corrective Action." Investigation and corrective action are documented and retained in the DCS records management system meeting the requirements of Section 17.0, "Quality Assurance Records."

Management measure 15.8, "Records Management," is implemented by utilizing records management procedures meeting the requirements of Section 5.0, "Instructions, Drawings and Procedures," and records management personnel who are trained in accordance with the requirements of section 2.3, "Quality Assurance Training." Completed QA records are maintained for the project meeting the requirements of Section 17.0, "Quality Assurance Records." This management measure is used to maintain all QA records generated by implementation of all sections of the MPQAP.

PROVISIONS FOR CONTINUING QA

The MPQAP is a living, controlled document that has been revised to reflect QA controls needed for MFFF construction while containing the controls presently in use for Base Contract phase quality affecting activities. This document, as written in this revision, will be submitted with the Construction Authorization Request (CAR) and again, after revision for operations, with the DCS License Application. As a living document that controls the DCS QA Program, the MPQAP is required to be updated and maintained as necessary to support project options. Needed changes to the MPQAP as a result of NRC review of the application for construction approval shall be incorporated prior to submittal for the MFFF License Application to possess and use SNM. This subsequent revision to the MPQAP shall include the needed Option 2 controls for MFFF startup, operation and irradiation of MOX fuel in the mission reactors. Prior to the start of Option 3 the MPQAP shall be revised to detail the QA controls needed for deactivation activities. Major and minor revisions to the MPQAP shall be submitted to the NRC as a result of program corrective actions and regulatory, organizational, or work scope changes that warrant changes to the DCS QA Program. These changes shall either be submitted to the NRC with the revision required for project phase changes in accordance with the license process or within 30 days after the end of the calendar year in which the change occurred. Changes that lessen the QA requirements of the NRC approved DCS MOX Project Quality Assurance Plan shall be submitted with written justification to the NRC for approval prior to implementation.

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 as applicable to DCS Base Contract and Option 1 workscope.

The DCS organizational structure for the Base Contract and Option 1 (MFFF construction and installation of mission reactor modifications) is shown in Figure 1.0-1 for the DOE Mixed Oxide (MOX) Fuel Project. Figure 1.0-2 shows the functional chart for the Construction Management organization for Option 1. Figure 1.0-3 shows the organizational structure and responsibilities for the DCS QA organization for the Base Contract. Figure 1.0-4 details the structure and responsibilities for the DCS QA organization for Option 1. Position responsibilities in section 1.2 include both Base Contract and Option 1 responsibilities. During Option 1 as the design activities are completed it is expected that the Engineering and Construction organization will be separated into two organizations. The DCS organization shall be revised prior to Options 2 (operations and MOX fuel irradiation) and 3 (MFFF deactivation) of the contract to reflect the change in emphasis for those phases of the project. The functional responsibilities, levels of authority, and lines of communication for the various organizational entities are described below for the Base Contract and Option 1 phases of the project.

1.2 POSITION RESPONSIBILITIES

1.2.1 DUKE COGEMA STONE & WEBSTER (DCS) PROJECT MANAGER

This position is responsible for project management of all DCS MOX Fuel Project activities and is the single point of contact for DOE regarding all project matters. The DCS Project Manager reports to the DCS Board of Governors. The members of the Board of Governors are corporate executives of the three corporate owners of DCS (Duke Engineering & Services, Cogema Inc., and Stone & Webster) and Duke Power. The Project Manager also serves as President and Chief Executive Officer of Duke Cogema Stone & Webster LLC (DCS) and is the highest level of management responsible for establishing DCS quality policies, goals and objectives. The Project Manager has documented the team's commitment to quality in the "Quality Assurance Policy Statement." The Quality Assurance Policy Statement is contained in the front of the MOX Project Quality Assurance Plan (MPQAP). The Project Manager jointly approves the MPQAP and Project QA Procedures with the QA Manager. Reporting to the Project Manager are the Deputy Project Manager – Technical & Project Integration, Deputy Project Manager – MFFF Engineering and Construction, and managers for Quality Assurance, Fuel Qualification, Irradiation Services, Lead Assembly, and Outreach & Communications Coordinator.

1.2.2 DEPUTY PROJECT MANAGER – TECHNICAL & PROJECT INTEGRATION

This position is responsible for identifying and overseeing the cross-coordination functions of the project, as directed by the Project Manager. Key elements are achieving an integrated effort in responding to project mission objectives and compliance with the DCS contract and commitments. Direct reports are Project Services and Administration, Licensing, Procurement, ES&H, Project Controls, and MFFF Plant Operations and Start-up managers. The Deputy Project Manager – Technical & Project Integration also serves as Executive Vice President and Chief Operating Officer of DCS and reports to the Project Manager.

1.2.2.1 Project Services & Administration (PS&A) Manager

The Project Services & Administration Manager reports to the Deputy Project Manager – Technical & Project Integration and is responsible for managing document control, records management, training, finance and accounting, contract administration, human resources, facilities management, project security control and technology control programs, and subcontract administration. This position also serves as DCS Corporate Secretary, Treasurer, and DCS Facility Security Officer. In his role as the DCS Facility Security Officer he reports directly to the DCS Board of Governors.

1.2.2.2 MFFF Licensing Manager

The MFFF Licensing Manager reports to the Deputy Project Manager –Technical & Project Integration and is responsible for successful planning and execution of MOX Fuel Project licensing activities, including interfaces with regulatory agencies, establishing the format and content and managing the preparation of the MFFF license application and conducting the integrated safety analysis. This function is responsible for the direct interface with the NRC and the coordination required between the DOE and the NRC.

1.2.2.3 Procurement Manager

The Procurement Manager reports to the Deputy Project Manager –Technical & Project Integration and is responsible for managing the total procurement process for DCS procurements including long lead procurements of equipment and materials supporting the construction of the MOX Fuel Fabrication Facility (MFFF). This position is responsible for establishing and implementing the MFFF Long Lead Procurement Plan, coordinating supplier evaluations, developing procurement packages and obtaining legal input and review of contract terms and conditions.

1.2.2.4 Environmental, Safety, & Health (ES&H) Manager

The ES&H Manager reports to the Deputy Project Manager – Technical & Project Integration and serves as the project authority for environmental, safety and health requirements. This position works closely with line managers to ensure consistent interpretations of ES&H requirements, supports licensing, performs design reviews, and

manages development of the Environmental Report. During Option 1 this position manages field ES&H activities.

1.2.2.5 Project Controls Manager

The Project Controls Manager reports to the Deputy Project Manager – Technical & Project Integration and is responsible for managing the systems that establish and monitor the scope, cost and schedule baselines of the project. These systems are used to monitor status and project risk through baseline planning, scheduling of all activities, cost and financial reporting/tracking and reporting of performance measures. This position has no specific duties or responsibilities required by the DCS QA Program.

1.2.2.6 MFFF Plant Operations & Start-up Manager

This position reports to the Deputy Project Manager – Technical & Project Integration and is responsible during the Base Contract for operability reviews during design and licensing support of the MFFF and during Option 1 for development and qualification of operational and maintenance processes, procedures, operations readiness and staff in preparation for startup testing and operations.

1.2.3 DEPUTY PROJECT MANAGER – MFFF ENGINEERING AND CONSTRUCTION

This position is responsible for the MOX Fuel Fabrication Facility (MFFF) process and facility design, construction management and constructability reviews during design, and design support for the licensing application. The MFFF Process Design, MFFF Facilities Design, MFFF Site Engineering, MFFF Manufacturing Design, MFFF Software Design, MFFF Equipment Design, MFFF Systems Engineering, and MFFF Construction Management Managers report to this Deputy Project Manager. The Deputy Project Manager – MFFF Engineering and Construction also serves as Senior Vice President and Chief Engineer of DCS and reports to the Project Manager.

The engineering group also provides technical assistance to the Licensing organization to support the site construction work permits, SER, EIS/ROD, Construction Authorization, and Special Nuclear Material (SNM) Possession and Use License. Since application for these authorizations are submitted under the Base Contract, the construction activities involve interaction with the NRC and public defense of the applications as required for their issuance. Support activities include responses to NRC requests for additional information, public hearing support and preparation of application amendments.

1.2.3.1 MFFF Process Design Manager

The MFFF Process Design Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible during the Base Contract for the design of the MFFF process. During Option 1 this position is responsible for coordinating process design support of MFFF construction.

1.2.3.2 MFFF Facilities Design Manager

The MFFF Facilities Design Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible during the Base Contract for the successful design of the facility and site-related interfaces for the MFFF. During Option 1 this position is responsible for coordinating facilities design support of MFFF construction.

1.2.3.3 MFFF Site Engineering Manager

The MFFF Site Engineering Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible during the Base Contract for developing and maintaining Savannah River Site (SRS) engineering and technical interfaces and implementing Work Task Agreements needed to construct the MFFF. This position will continue during Option 1 to coordinate the implementation of Work Task Agreements as well as other needed management support of MFFF construction.

1.2.3.4 MFFF Manufacturing Design Manager

The Manufacturing Design Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible for the detailed design of the gloveboxes for the MFFF. Design documents are translated into manufacturing drawings, which are transmitted to the glovebox manufacturers for manufacturing of the individual gloveboxes.

1.2.3.5 MFFF Software Design Manager

The MFFF Software Design Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible for the design of the software needed to operate the integrated control system for the MFFF. Software design, development, testing, and installation are performed meeting the requirements of Section 3.2.7 of the MPQAP for QA software.

1.2.3.6 MFFF Equipment Design Manager

The MFFF Equipment Design Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible for design of the MOX process and aqueous polishing gloveboxes including internal equipment. This position is also responsible for developing glovebox and equipment technical specifications for detailed design and procurement and coordinating with the Manufacturing Design Manager, Procurement Manager and QA Manager to ensure engineering requirements are met. This position functions as the design authority for process units during detailed fabrication design performed by the manufacturing design group. During Option 1 this position is responsible for coordinating equipment design support of MFFF construction.

1.2.3.7 MFFF Systems Engineering Manager

The MFFF Systems Engineering Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible during the base contract for development

and maintenance of engineering integration processes, configuration management, technical baseline, Design Requirements Document, and designated risk management activities.

1.2.3.8 MFFF Construction Manager

The MFFF Construction Manager reports to the Deputy Project Manager – MFFF Engineering and Construction and is responsible during the Base Contract for construction review of the MFFF design, the construction cost estimate and construction schedule, construction subcontracting, procurement, and program and licensing support. During Option 1 this position is responsible for managing the construction management organization for construction of the MFFF. The construction management organization has overall responsibility for the construction and construction acceptance of the MOX Fuel Fabrication Facility (MFFF) construction project. The construction management organization relies upon personnel support from project support organizations that provide specialized services and expertise. This is accomplished through a line construction organization supported by personnel in the areas of project control, QA, ES&H, contracts, and procurement. The direct report and support staffs are under the operational control and direction of the MFFF Construction Manager. The support staff is also under the administrative and technical control of its respective project support organization manager. The Construction Management organization provides oversight and management of the subcontractors and vendors that are subcontracted to execute specific construction work scopes. The organizational structure of the MOX Fuel Project during the construction phase is shown in Figures 1.0-1 and 1.0-2.

The Engineering organizations will be supporting construction with primary responsibilities in the areas of Title III engineering, equipment procurement and licensing support. Title III engineering support activities include:

- Resolution of technical issues
- Review and approval of subcontractor technical submittals
- Response to subcontractor technical questions
- Interpretation of drawings and specifications
- Review of corrective action disposition proposals
- Technical evaluation of change requests
- Correction of design errors/omissions
- Assessment of subcontractor drawing/specification compliance

Configuration change control is managed through a formal process that authorizes and documents all changes to the design after subcontract award. Configuration management of the MFFF basis of design in accordance with the design documents generated, approved and issued for construction under the controls of the DCS QA Program is essential in ensuring the plant is built as designed. No construction change can be implemented without approval from design engineering, QA, ES&H and construction management. The construction management individual responsible for the affected construction subcontract is responsible for change implementation and must coordinate formal approvals from

design engineering, QA, ES&H and construction management of the construction change package. Drawings are periodically reviewed by construction management personnel during the prosecution of the work and the drawings are updated at subcontract completion for operations use.

Oversight and management of the construction subcontractors and vendors is the responsibility of the construction area management teams. Each construction area management team will be managed by a **Construction Management Area Superintendent** who has the overall responsibility to (1) monitor and coordinate area construction work-in-progress and (2) ensure that it meets the requirements of the plans and specifications and good work practices. Daily oversight and direct coordination with the subcontractor QA/QC organization are the responsibility of the QA member of the construction area team (reports through the site assigned QA supervisor to the DCS QA Manager). Results of QA oversight activities will be reported to both the MFFF Construction Manager and the DCS QA Manager. The construction engineers and discipline specialists will interface directly with their assigned subcontractors providing a point of contact for technical oversight and management. They also perform subcontractor/equipment vendor submittal reviews, construction acceptance of in progress and completed work, payment and schedule approval, coordination between subcontractors, issue resolution, change coordination, and corrective action resolution.

The **Resident Engineer** supports the construction area management teams directly and indirectly at the site level. This position provides construction acceptance and other miscellaneous support to the area management teams as required. The Resident Engineer serves as a point of contact between construction management and Title III Design Engineering for engineering changes and as-built drawing information. This position provides site level survey control establishing site control points for subcontractor survey crew use and performs checks of subcontractor survey work as required. This position also performs the site materials management function for coordination and control of material/equipment warehouses and outside storage.

The Site Office group provides administrative support to the construction area management teams and the site level support groups. It is also the contact for the site security and building maintenance contracts and is the contact on matters related to local document control, records management, internal security, training and personnel.

As work is completed, construction acceptance testing (CAT) is performed in accordance with the terms and conditions of the construction subcontract. The subcontractors shall prepare the CAT procedures in accordance with specification requirements established by the Process and Facility Design organizations and approved by the construction management, QA, ES&H and Operations organizations. The purpose of the CAT is to confirm proper installation of components and readiness for start-up testing prior to construction management acceptance from the subcontractor. Coordination between construction management and the Start-up organization for start-up testing and remediation of problems and final turnover is in accordance with the Functional and Operability Testing Plan. Each construction subcontract will have construction acceptance testing

requirements specified as criteria for subcontract completion. DCS QA will witness specified testing.

Construction Acceptance is the completion status of construction at the point of turnover from the construction subcontractor to the construction management and includes the following:

- Completion of erection and assembly of facilities including erection of equipment, sub-assemblies and parts
- Performance of non-operating adjustments, cold alignment checks
- Performance of leak, pressure and other non-destructive testing
- Instrument calibration and loop checks
- Electrical continuity and motor rotation checks
- Construction, construction punchlist and clean-up activities
- Documentation turnover to DCS

Documentation includes as-built drawings, inspection records, completed test records, punch lists, startup and operating instructions or manuals from the subcontractor vendors, spare parts data, etc.

1.2.4 FUNCTIONAL AREA MANAGERS REPORTING TO PROJECT MANAGER

1.2.4.1 Outreach & Communications Coordinator

The Outreach & Communications Coordinator reports to the Project Manager and is responsible for coordinating internal and external communications programs for the project. This position has no specific duties or responsibilities required by the DCS QA Program.

1.2.4.2 QA Manager

The QA Manager reports directly to the Project Manager and is responsible for establishing and maintaining the DCS MPQAP and verifying its effective implementation at all 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. The QA Manager and Project Manager jointly approve the DCS MPQAP and QA Procedures contained in the MOX Project Procedures Manual.

The QA 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 QA Manager has the same access to the Project Manager 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; and assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency or unsatisfactory condition has occurred.

During the Base Contract the QA Manager has a quality assurance staff consisting of quality engineering and verification services personnel. These individuals report directly to the QA Manager as shown in Figure 1.0-3. Quality Engineering personnel maintain the MPQAP and QA assigned project procedures, perform QA reviews of project documents, administer the DCS Corrective Action Process, review procurement documents and maintain the DCS Approved Supplier's List (ASL). Quality Verification personnel perform DCS audits, surveillance, assessments, and supplier evaluations. These oversight activities are focused on providing DCS management with feedback on the effectiveness of the implementation of the DCS QA program. Management review of oversight results allows for continuous evaluation for QA program improvements. QA personnel may be assigned to provide QA support to the functional area managers; however, they remain in contact with the QA management for their day-to-day direction.

Prior to the start of Option 1, the DCS QA organization will be restructured as shown in Figure 1.0-4 for Option 1 activities. Under this organizational structure QA personnel are assigned to Quality Engineering (QE), Quality Verification (QV) and Operations QA. The Quality Engineering function is further divided into Project QA, which provides the same QE support provided during the Base Contract in support of the entire project, Start-Up QA, which supports the start-up organization, and Construction Management, which supports construction management by providing QE support, QA reviews of proposals, oversight of equipment vendor QA program implementation, shop inspections, witnessing of vendor acceptance testing and administration of corrective action procedure documentation. Operations QA will be staffed late in Option 1 to support the plant operating staff in developing programs and operating/maintenance procedures for plant operations. This group will also provide oversight of operations and maintenance.

Quality Assurance Support of MFFF Construction (Option 1)

The conduct of work in accordance with the requirements of the DCS Quality Assurance (QA) Program is the responsibility of the line organization conducting the work. The overall administration of the DCS QA Program and verification of quality achievement at the construction site is the responsibility of the DCS QA Manager and the site assigned QA personnel. QA audit, oversight and direction for quality functions will be the responsibility of the DCS QA Manager. Construction subcontractors and long lead-time equipment suppliers responsible for 10CFR50, Appendix B installations shall provide a Quality Assurance program that complies with 10CFR50, Appendix B meeting the applicable requirements of NQA-1-1994 as revised by NQA-1a-1995 and Regulatory Guide 1.28 (Rev.3). Audit and approval of subcontractors' Quality Assurance Programs for placement on the DCS Approved Supplier's List (ASL) is the responsibility of the DCS QA Manager.

The execution concept for the construction management organization is to award competitive subcontracts to construction contractors who will procure and install all

construction materials and equipment. The major subcontracts in the MOX building will require 10CFR50, Appendix B compliant Quality Assurance programs. Equipment identified as long lead-time will be procured by DCS and will be provided to the construction subcontractors for installation. The majority of the long lead-time equipment procurement vendors will require 10CFR50, Appendix B compliant programs.

The construction subcontractors will be responsible to provide all labor, equipment and materials to complete the contracted scope of work. DCS QA has the responsibility for approval of the subcontractor QA programs and oversight and audit functions during the course of the construction. The site assigned QA personnel will provide daily oversight of construction activities and the Quality Verification Group, who reports to the DCS QA Manager, will perform audits. Each construction subcontractor will have a defined scope of work, contract terms and conditions specifying the QA/QC requirements and technical specifications and drawings, which specify the quality and technical requirements of the scope of work. Each subcontractor is required to perform the QA audits and QC inspections required by their DCS approved QA program. DCS Construction Management is responsible for management of the subcontract and DCS QA assures that the subcontractor conforms to the quality program approved for the subcontract work scope by providing oversight witness of final testing and audits of selected test activities.

1.2.4.3 MOX Fuel Irradiation Manager

This position reports to the Project Manager and is responsible for core design, core physics, license modifications to the mission reactors and development of the irradiation plan during the Base Contract. During Option 1 this position is also responsible for coordination with the mission reactors on implementation of modifications for use of the MOX fuel. This position manages the interface between the Duke Power (DP) mission reactors and DCS. The Packaging & Transportation Manager also reports to the MOX Fuel Irradiation Manager and is responsible for the development and implementation of the MOX Fresh Fuel Package Certification Plan, Transportation Integration Management Plan, MOX fuel package design, and lead assembly transportation.

1.2.4.4 MOX Fuel Qualification Manager

This position reports to the Project Manager and is responsible for fuel qualification, fuel assembly mechanical design and support for licensing. The qualification program is managed as a scope of the Base Contract.

1.2.4.5 Lead Assembly Manager

The Lead Assembly Manager reports to the Project Manager and is responsible for the development and implementation of the plan for the design, manufacture and transportation of the lead assemblies from Europe.

1.3 ORGANIZATIONAL INTERFACES

The organizational interfaces between DCS, subcontractors, the DOE Chicago and Headquarters 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 implementing procedures. These documents contain the appropriate protocols, applicable roles, responsibilities and approval authorities for the specific topics for which they apply.

DOE Contract No. DE-AC02-99CH10888 specifically requires the DCS MPQAP to be approved by the U.S. Nuclear Regulatory Commission (NRC) and that DOE be provided with an "information only" copy. While DCS QA will evaluate, as appropriate, DOE comments for incorporation into the next revision when received, NRC approval is required for changes to the MPQAP. Revisions for project phase changes shall be submitted in accordance with 10CFR70 licensing requirements. Major and minor revisions to the MPQAP shall be submitted to the NRC as a result of program corrective actions and regulatory, organizational, or work scope changes that warrant changes to the DCS QA Program. Changes that lessen DCS QA Program NRC approved requirements shall be submitted with written justification to the NRC for approval prior to implementation.

1.4 DELEGATION OF WORK

The delegation of work between DCS team locations and subcontractors is identified in applicable plans, work task agreements, basic ordering agreements, subcontracts and implementing procedures. In all cases of delegation, DCS retains the overall responsibility for all work performed under the direction of DCS. All DCS quality affecting activities shall meet the requirements of this document except when work is performed under an approved subcontractor QA program as addressed in section 2.1. Responsible managers have the authority to delegate tasks to another qualified individual within their organization provided the designated individual possesses the required qualifications and these qualifications are documented. All delegations shall be in writing. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

1.5 RESOLUTION OF DISPUTES

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. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the Project Manager for final resolution.

1.6 STOP WORK AUTHORITY

Stop work authority within DCS is vested in each DCS employee with respect to work within their scope of responsibility 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 MOX Project QA Program. This process is controlled by a DCS QA procedure, which applies across the entire project except when work is performed under an approved subcontractor's QA program as described in section 2.1. The DCS procedure details the authorities and responsibilities for stopping work, the criteria and documentation required to process the stop work order and the actions required before work may resume. This process ensures that safety related activities are controlled until the deficiency, or unsatisfactory condition, has been resolved. Stop work is further discussed in Section 16 of this document.

ATTACHMENTS:

Figure 1.0-1: DCS MOX Fuel Project Organizational Chart for Base Contract and Option 1
Figure 1.0-2: MOX Construction Management Organization (Functional Chart)
Figure 1.0-3: DCS QA Organization for Base Contract
Figure 1.0-3: DCS QA Organization for Option 1

Figure 1.0-1: MOX Project Organization for Base Contract and Option 1

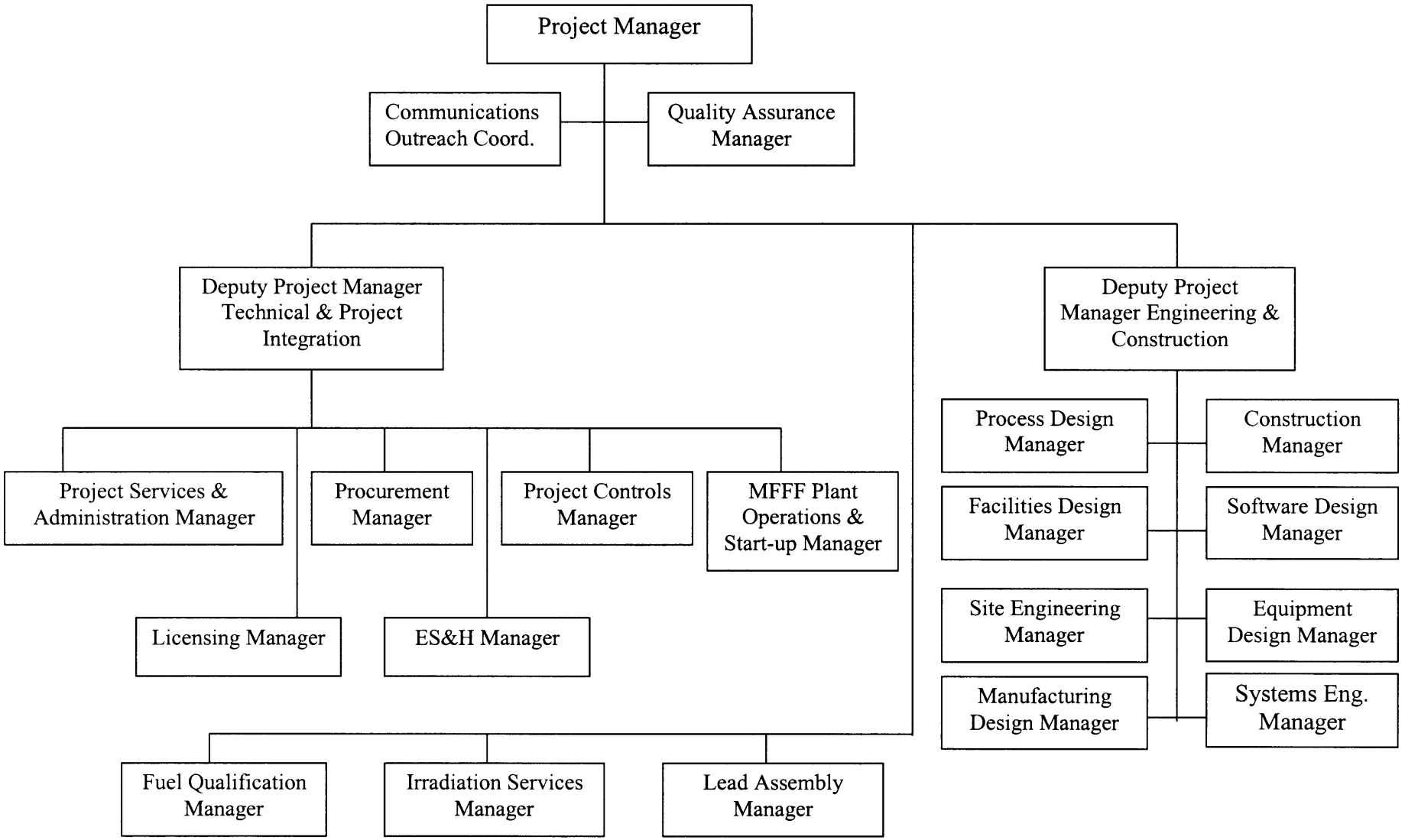


Figure 1.0-2: MOX Construction Management Organization (Functional Chart)

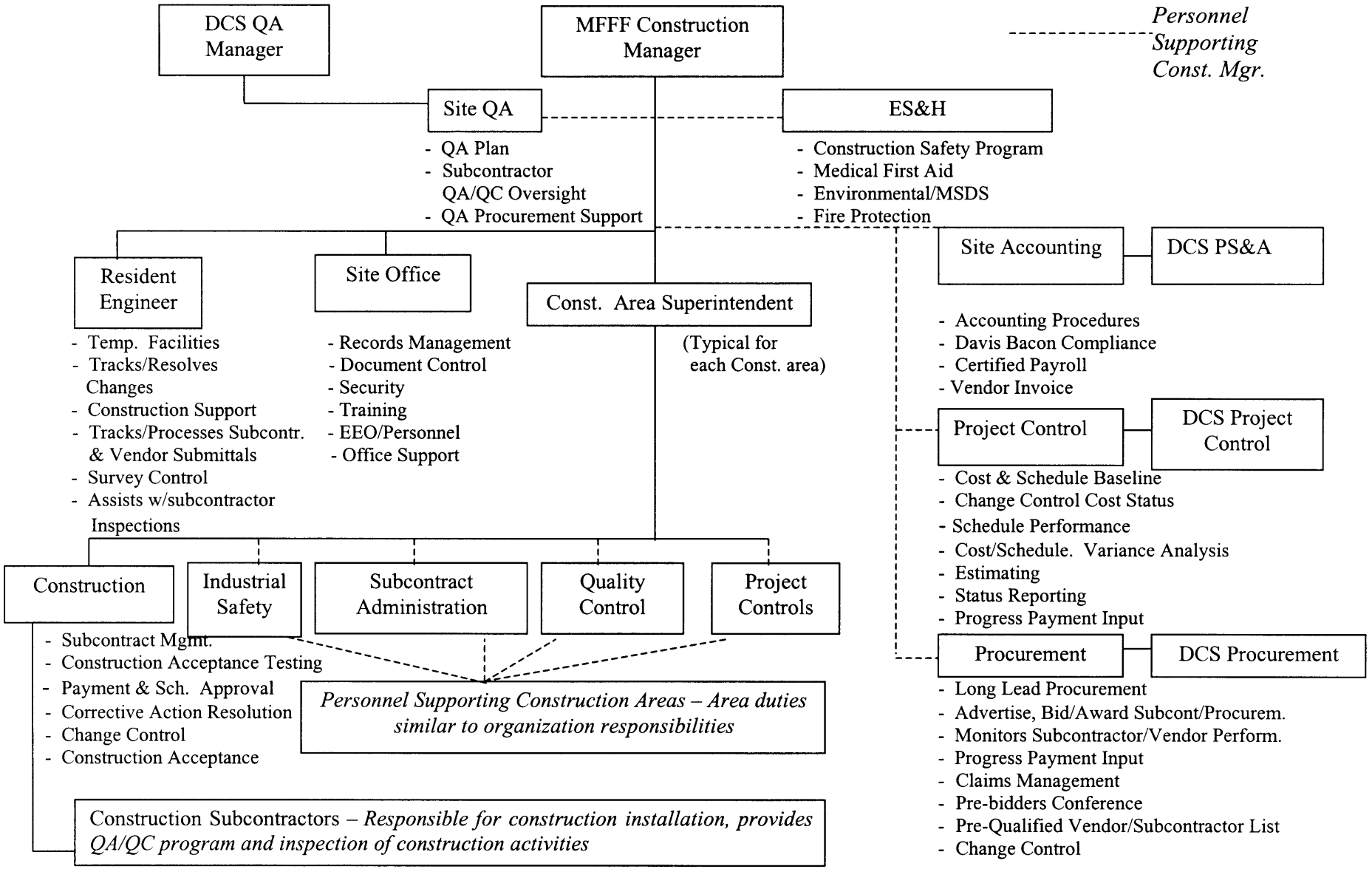
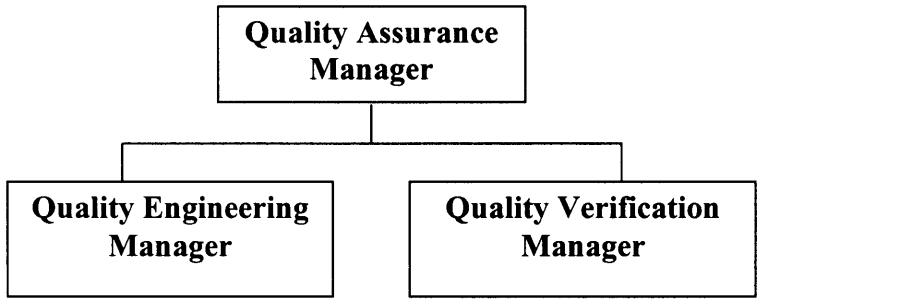


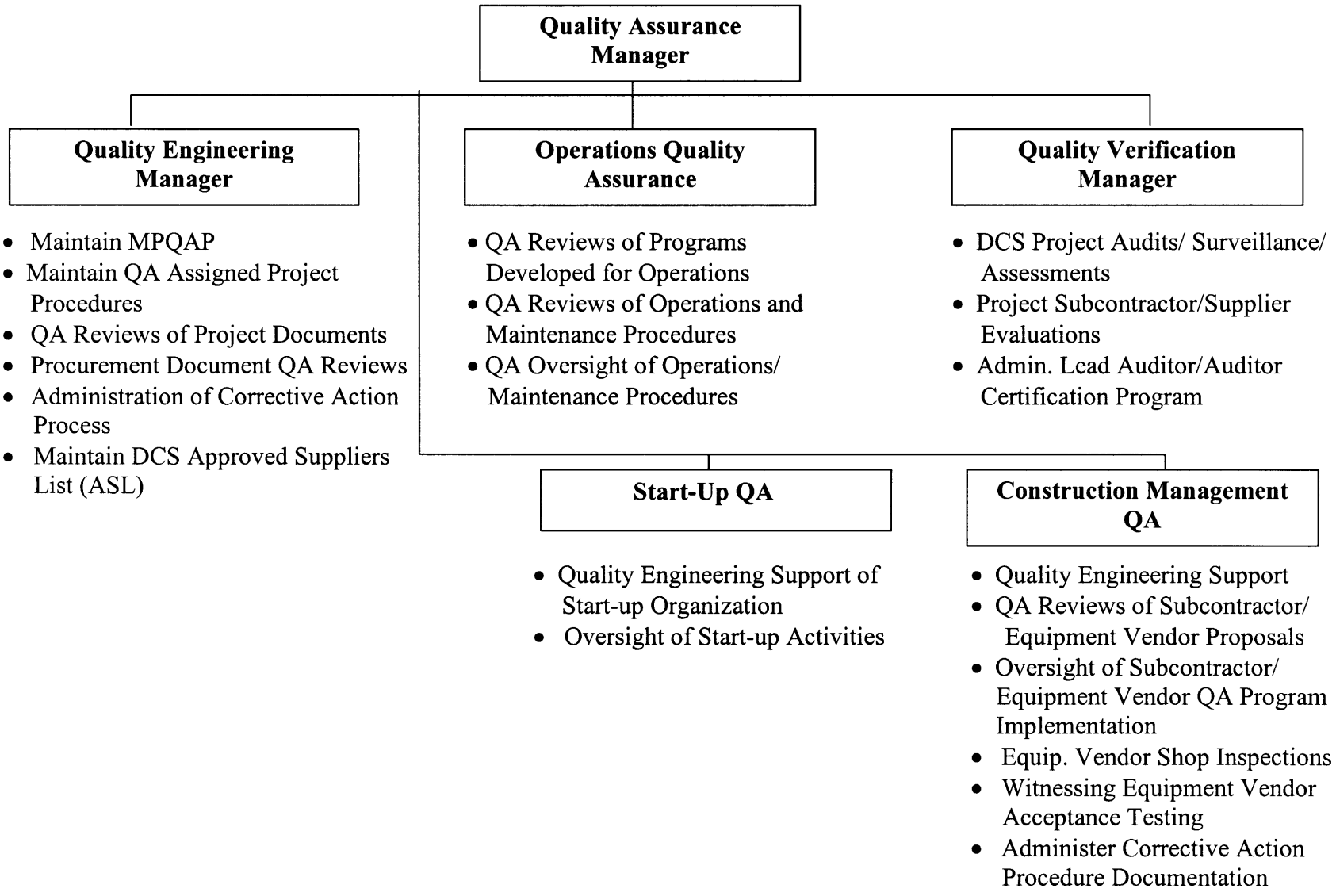
Figure 1.0-3 DCS Quality Assurance Organization for Base Contract



- Maintain MOX Project Quality Assurance Plan
- Maintain QA Assigned Project Procedures
- Quality Engineering Reviews of Project Documents
- Procurement Document QA Reviews
- Administration of Corrective Action Process
- Maintain DCS Approved Suppliers List (ASL)

- DCS Project Audits/Surveillance/ Assessments
- Project Subcontractor/Supplier Evaluations
- Administer Lead Auditor/Auditor Certification Program

Figure 1.0-4 DCS Quality Assurance Organization for Option 1



2.1 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 2 Quality Assurance Program of 10CFR50, Appendix B, and Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-4 and Appendix 2A-1[1] of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994 and Regulatory Guide 1.28 (Rev. 3) as applicable to DCS Base Contract and Option 1 workscope.

The following NQA-1-1994 Part II subparts also apply to applicable activities performed during Option 1 construction of the MFFF:

Subpart	Titled
2.1	Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants
2.2	Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants
2.3	Quality Assurance Requirements for Housekeeping for Nuclear Power Plants
2.4	Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities
2.5	Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants
2.7	Quality Assurance Requirements for Computer Software for Nuclear Facility Applications[2]
2.8	Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants
2.15	Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants
2.16	Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities
2.20	Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants

2.1.1 PROGRAM BASIS

The DCS MOX Project Quality Assurance Plan (MPQAP) complies with 10CFR50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*, and applies to all levels of the organization, including subcontractors, who perform quality affecting activities.

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[1] Regulatory Guide 1.28 (Rev.3) requires that the NQA-1-1983 version of this appendix be used. 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.

[2] MPQAP Section 3 contains Subpart 2.7 requirements for computer software. This subpart is listed to identify computer software requirements for subcontractors.

For purposes of understanding the applicability of the DCS QA Program to the DCS MOX Project "**quality affecting**" is defined as "**deeds, actions, processes, tasks or work which influence the achievement or verification of quality requirements and objectives for Quality Level 1 and 2 structures, systems and components (SSCs) and their associated activities.**" Quality Levels are defined in section 2.2.

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),* are used in conjunction with 10CFR50, Appendix B and provide additional detailed implementing quality assurance requirements for the DCS MOX QA Program. The DCS MPQAP describes DCS' overall commitments to 10CFR50 Appendix B and ASME NQA-1. This document states DCS policies, assigns responsibilities and specifies requirements governing implementation of QA requirements on the MOX Project. All 18 criteria of 10CFR50, Appendix B have been addressed to identify the total set of QA requirements required for the Base Contract and Option 1 phases of this project. Applicable QA criteria will also apply to subcontractors as delineated in procurement documents controlled under section 4 of this MPQAP. The necessary management measures to control the quality of subcontracted activities for the MFFF design, procurement, and installation and testing of principal SSCs and IROFS and DCS Project activities during the Base Contract and Option 1 have been established in this revision of the MPQAP. The MPQAP will be reviewed for needed revisions prior to the start on Options 2 and 3 as described in the Introduction section under "PROVISIONS FOR CONTINUING QA."

Specific processes and controls, which implement 10CFR50, Appendix B and NQA-1 commitments, are specified in QA procedures contained in the DCS Project Procedures Manual. Development, review, approval and training of QA implementing procedures shall be 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. Applicable QA requirements contained in this MPQAP are also invoked on DCS subcontractors for their contracted scope of work.

When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an adverse condition, work is stopped until proper corrective action is taken. If procedures cannot be used as written, then work is stopped until the procedures are changed. Requirements for stop work are further discussed in section 16.

2.1.2 USE OF SUBCONTRACTOR QA PROGRAMS

2.1.2.1 DCS MOX Fuel Project Team Members

As the overall controlling QA plan for MOX Fuel Project DCS Base Contract and Option 1 activities, the DCS MPQAP invokes QA requirements for controlling DCS performed quality affecting activities as well as allows selected subcontractors to DCS and to COGEMA, Inc. to perform their assigned quality affecting activities to their own QA Programs. These are subcontractors on the DCS MOX Fuel Project Team. The authorization to perform work to these other QA Programs is based on:

A. DCS's desire to take advantage of the effective QA Programs that resulted in the successes that justified DCS selection of these companies to work on the DCS MOX Fuel Project;

B. DCS QA Manager's review, verification of compliance with 10CFR50, Appendix B requirements and acceptance of the subcontractor QA Plans for their respective assigned work; and

C. DCS's desire to authorize use of acceptable QA Plans and implementing procedures in order to minimize training on new procedures and allow continued continuity of implementation of a proven program.

The following table lists the applicable QA Programs used for the specified DCS Base Contract and Option 1 activities:

Duke Cogema Stone & Webster
Quality Assurance Program

MOX Contract Project Activity	QA Program To Be Used
MFFF Facility Design	DCS MPQAP
MFFF Process Design	SGN QA Manual/DCS MPQAP
Transportation	Transnuclear/PacTec QA Plan
MFFF CAR/License Application	DCS MPQAP
Fuel Qualification and Design	FCF Quality Assurance Program Manual
Identification and Installation of Utility Modifications for Irradiation Services	Duke Power Company Topical Report
MFFF Construction	MPQAP for Construction Management and Subcontractor QA Plans for Subcontracted Activities

The DCS MFFF design effort has the facility design being performed in the DCS Charlotte Office by S&W and DE&S personnel assigned to DCS. Facility design is also supplemented by Nuclear Fuel Services (NFS) for security and material control and accountability (MC&A) related design input. Quality affecting facility design comes

completely under the controls of the MPQAP and the DCS MOX Project Procedures. DCS QA provides oversight of the MFFF design in accordance with the MPQAP.

The engineering company of COGEMA – SGN in Bagnols, France, is assigned MFFF Process Design. The SGN Process Design Group (PDG) was authorized in Rev. 0 of the MPQAP to perform their initial work to the controls of the SGN QA Manual and applicable SGN procedures for the Advanced Preliminary Design (APD) of the MFFF process systems. This authorization was based on DCS QA acceptable review of the SGN QA Manual that verified application of 10CFR50, Appendix B QA controls on SGN nuclear design. This authorization was to start the APD while DCS QA procedures were being developed, reviewed, approved and issued. As the DCS engineering procedures were approved and SGN personnel trained in the use of these procedures, PDG work products for APD were completed under the controls of the applicable DCS engineering procedures and transmitted to the Facilities Design Group (FDG) for DCS "Americanization" of the design, integration with the facility design, design verification of Quality Level 1 (IROFS) SSCs and compliance review for Quality Level 1 and 2 SSCs. After APD all PDG work products are controlled by the applicable DCS engineering procedures. These procedures are used for Final Preliminary Design (FPD) and will continue to be used for the Final Design (FD) as well as for design support of construction. DCS QA continues to provide oversight of the process design effort in accordance with the DCS MPQAP. COGEMA also provides oversight of SGN PDG.

Quality affecting transportation activities during Base Contract and Option 1 involves transportation interfaces with MFFF design and the mission reactors. COGEMA subcontracts this activity to Transnuclear and PacTec. COGEMA provides oversight over this subcontracted activity. The Facilities Design Group handles interfacing issues that affect MFFF design.

Although development of the Construction Authorization Request (CAR), and License Application (LA) is not quality affecting, design output documentation that provides the technical input and analysis needed for the application is quality affecting for principal SSCs and Quality Level 1 (IROFS) and 2 SSCs. The DCS QA Program controls the development of this input and analysis and DCS QA provides oversight of these activities. Graded QA as discussed in section 2.2 is applied to the development of the Construction Authorization Request, Integrated Safety Analysis (ISA), and License Application. These documents are developed by experienced, trained staff, reviews are controlled, comments resolved, documents are internally approved prior to submittal to the NRC, placed under document control, and maintained in the DCS Records Management System.

Fuel design and qualification is assigned to Framatome ANP, formerly Framatome Cogema Fuels (FCF). Quality affecting Base Contract activities, including Base Contract activities that extend into and through Option 1, for Framatome's assigned workscope is controlled by the FCF Quality Assurance Program Manual and associated implementing QA procedures. DCS QA provides oversight of Framatome's quality affecting activities.

MOX Fuel Project Base Contract and Option 1 workscope assigned to Duke Power to identify and implement needed modifications for future irradiation services by nature of having existing 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.

Subcontractors authorized to use their QA programs are routinely audited against their QA Program Plan and procedures to assess compliant implementation and effectiveness of their authorized QA Program for use on DCS Base Contract and Option 1 workscope.

2.1.2.2 Flowdown of QA Requirements to Non-Team Member Subcontractors and Suppliers

The applicable QA requirements for quality affecting activities are flowed to DCS subcontractors and suppliers through the respective procurement documents for the particular scope of work being contracted. Determination of QA requirements, supplier evaluations, and proposal/bid evaluations are in accordance with the requirements of sections 4, Procurement Document Control, and 7, Control of Purchased Material, Equipment and Services, of this document. Applicable 10CFR50, Appendix B QA Program elements required for the particular scope of work are first identified in the request for proposal and/or procurement specification. Potential subcontractors/suppliers are required to submit their QA Plans to DCS QA for review in accordance with the request for proposal/procurement specification. DCS QA performs an audit at the subcontractor's/supplier's facility of their QA program and its implementation verifying that the subcontractor's/supplier's QA program meets the requirements established in the request for proposal/procurement specification. If the audit is acceptable then the subcontractor/supplier is added to the DCS Approved Supplier's List (ASL) and a contract between DCS and the subcontractor/supplier may be issued. For procured items DCS may also require that DCS QA perform source inspections or witnessing of tests at the supplier's facility prior to shipment if the equipment/component warrants inspection due to its safety significance and/or complexity. Such requirements are also identified in the procurement documents and/or contract.

Construction subcontractors for DCS QA Program controlled construction activities are also required to be placed on the ASL prior to contract award. Construction subcontractors are required to perform the QA activities required by their QA program including audits of their own activities as well as any required quality control (QC) inspections. DCS QA will provide oversight of these subcontractors in the form of audits and surveillances verifying that each subcontractor is properly implementing the subcontractor's QA program as approved by DCS QA. Contractually subcontractors will be required to correct DCS identified deficiencies.

2.2 GRADED QUALITY ASSURANCE

DCS is implementing a graded QA program for quality affecting SSCs and their associated activities based on the significance of the SSC or activity to ensuring safety for workers,

the public, and the environment. 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 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. In this context grading refers to the selection of QA controls to be applied to a structure, system or component (SSC). Graded QA provides a safety benefit by allowing preferential allocation of resources based on the safety significance of SSCs. The focus of the DCS 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. Grading an SSC shall not degrade its performance or prevent it from meeting its intended safety function.

The requirements delineated in Appendix B to 10 CFR Part 50 recognize that QA program controls should be applied in a manner consistent with the importance to safety of the associated SSCs. Because the quality level of an SSC is determined by the role of the SSC in meeting the performance requirements of 10CFR70.61 (which provides the Part 70 definition of items relied on for safety [IROFS]), the quality level also serves as an indicator of the safety significance of the SSC in the context of grading. Additional SSCs that are not IROFS, but which help minimize risk below the criteria of 10CFR70.61, are also controlled under selected elements of the DCS QA program (i.e., under QL-2). These SSCs are not required to demonstrate safety in the context of Part 70, but are controlled voluntarily as "augmented quality provisions."

2.2.1 CATEGORIZATION (Classification) OF STRUCTURES, SYSTEMS AND COMPONENTS (SSCs)

Table 2-1 defines the quality levels used for the MOX Fuel Project.

MFFF SSCs are initially assigned a quality level (QL) commensurate with each SSC's function and safety significance. The initial QL designations (or QA classifications) of SSCs were established at a functional level based on engineering review of the following:

- design criteria and design requirements;
- safety significance relative to 10CFR70.61 performance requirements;
- consideration of failure consequences (i.e., single failure and defense in depth);
- consideration of the MELOX and La Hague design and operating experience; and
- MPQAP definitions for quality levels.

This review resulted in a deterministic QL designation for each SSC. This QL was documented and controlled in a "functional classification list" as part of the design hierarchy, and on the applicable design documents, to indicate where QA controls were needed during initial design development.

Table 2-1 Quality Level Definitions for Structures, Systems, and Components (SSCs)

Quality Level (QL)	Description	
QL-1 (IROFS)	Structures, systems, and components (SSCs) that are items relied on for safety (IROFS) to prevent potential accidents such that high-consequence events are made highly unlikely and intermediate-consequence events are made unlikely, or to mitigate their potential consequences, or that are relied on to prevent criticality. (Note: SSCs determined to be QL-1 prior to the definition of QL-1a and -1b will be assumed to be QL-1a until otherwise determined and documented in accordance with appropriate QA procedures.)	
	QL-1a (IROFS)	SSCs whose failure could directly result in a condition adversely affecting safety. The failure of a single QL-1a item could cause: • a loss of a primary confinement feature leading to release of radioactive material to the environment; • a criticality accident; or • a loss of other safety function required to meet 10CFR70.61 public exposure performance requirements. (This definition includes: an SSC whose single failure can result in exceeding 10CFR70.61 performance requirements [i.e., a *sole IROFS* per 10CFR70.65(b)(8)]; an SSC that is one of two redundant active components providing the same safety function [e.g. emergency diesel generators]; and an SSC which may meet the requirements for a lower classification but is conservatively determined to be QL-1a [e.g., C3 and C4 confinement systems].)
	QL-1b (IROFS)	SSCs whose failure or malfunction could indirectly result in a condition adversely affecting public or worker safety or the environment. The failure of a QL-1b item, in conjunction with the independent, unlikely failure of an additional item or administrative control, could result in exceeding 10CFR70.61 performance requirements (includes SSCs which may meet the requirements for a lower classification but are conservatively determined to be QL-1b).
QL-2	SSCs not relied on to satisfy 10CFR70.61 performance requirements, but that perform the following functions: • maintaining public and worker radiological exposure during normal operations and anticipated occurrences within normal operating limits (i.e., 10CFR20); • radioactive waste management; • protection of QL-1 SSCs from physical interactions • monitoring and alarm features provided to alert workers to changes in process or radiological conditions potentially affecting worker or public safety (including criticality detection and alarm and radiation monitoring)	
QL-3	SSCs with no safety function but whose performance may be important to ensuring operational or mission-critical goals are achieved (see note below).	
QL-4	SSCs that are not QL-1, -2, or -3; these SSCs are conventional quality (see note below).	

NOTE: QLs-3 and -4 are used for management designation of certain SSCs for reasons unrelated to safety. ***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. ***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 similarly do not impact the regulatory basis of the facility. QL-3 and QL-4 SSCs are designed, procured, constructed, operated, and maintained in accordance with conventional industry standards and good engineering practice. Applicable requirements for design, document, and configuration control and records management are also applied to Quality Level 3 and 4 SSCs as the project procedures controlling these activities cover all Quality Levels.

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. Changes to quality level designations necessitates re-evaluation of any QA grading applied up to that time (see "Feedback Mechanisms and Reassessing Safety Significance" below).

2.2.2 IDENTIFICATION OF QA CONTROLS

2.2.2.1 Grading Process

Note: Regulatory Guide 1.176, *An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance*, provides guidance in the development of a framework for the grading process and for the establishment of criteria for determining which 10CFR50 Appendix B controls apply to SSCs with limited safety significance.

The grading process defines the selection of QA controls on the basis of SSCs' safety significance. The MPQAP controls are evaluated for SSCs or categories of SSCs based on their quality levels and functional requirements. The grading process reflects the criteria used for determining which MPQAP requirements are not applicable to IROFS and QL-2 SSCs as described below.

- QL-1a is used to designate SSCs whose single failure could cause an accident or loss of safety function resulting in consequences exceeding the 10CFR70.61 performance criteria. (Note: This designation is generally comparable to "high safety significance" described in RG 1.176. [3])
- QL-1b is used to designate SSCs whose failure could contribute to exceeding 10CFR70.61 performance criteria (i.e., failure in conjunction with an independent, unlikely failure of another item or administrative control). (Note: This designation is comparable to "medium safety significance" described in RG 1.176.)

[3] RG 1.176 includes discussion that indicates that the diversity of systems that are able to fulfill critical high level functions (e.g., reactivity control, decay heat removal) can have the result that each individual system could meet all quantitative guidelines to be categorized in the low safety-significance group. The guidance indicates that the licensee is expected to designate at least one system associated with critical high-level functions as high safety significant. DCS complies with this guidance by (a) providing that "critical high-level" safety functions of confinement and single-failure-prone criticality (if any) are QL-1a; (b) designating all "sole IROFS" as QL-1a; and (c) *not* taking credit for single-failure-based redundancy in determining QL-1b designations (i.e., if an SSC is one of two active components providing the same function, it is still designated as QL-1a).

- QL-2 is used to designate SSCs that do not contribute to safety as defined in 10CFR70, but which minimize risks that do not exceed the performance requirements of 10CFR70.61 (i.e., reduces risks that would not exceed the performance requirements of 10CFR70.61 without the presence of the SSC). (Note: This designation is comparable to "low safety significance" in that the SSCs, by definition, are not relied on for safety.)

The grading process is conducted by engineering and subject to review and approval by licensing, QA, and engineering management in accordance with QA procedures. Grading will apply to QL-1b and -2 SSCs.

2.2.2.2 Grading Criteria

The evaluation of SSCs for selection of QA controls takes into account the following considerations:

- the function or end use of the SSC;
- the consequence of failure of the SSC;
- the importance of the data being collected or analyzed by the SSC;
- the complexity of design or fabrication of the item or design or implementation of the activity;
- the reliability of the associated processes and components;
- the reproducibility of results;
- the uniqueness of the item or service quality;
- the necessity for special controls or processes;
- the degree to which functional compliance can be demonstrated through inspection or test; and
- any other relevant factors, including program risk, as applicable.

These criteria, and the basis for grading them are appropriately considered in detailed grading analyses.

QL-1 SSCs (QL-1a and QL-1b)

QL-1a SSCs and their associated activities (to prevent or mitigate a postulated confinement or criticality accident) are subject to all the requirements in sections 1-18 of the MPQAP. No grading of QA controls applies to QL-1a SSCs (unless justified on a case-by-case basis in discrete SSC-specific analyses.).

QL-1b SSCs and their associated activities (criticality controls subject to double contingency, except for geometry control, and SSCs that provide defense-in-depth) are evaluated against the requirements in sections 1-18 of the MPQAP. Based on the SSC's

function, this evaluation determines which (if any) MPQAP requirements are not applicable or are only partially applicable (i.e., are not required to provide assurance the SSC will perform its intended function). Since the single failure of a QL-1b SSC cannot, by definition, result in exceeding 10CFR70.61 performance requirements, they have more potential to be graded. Justification for grading these SSCs may include unnecessary credit attributed to the SSC in the ISA; application of additional control from other SSCs or management measures; and industry precedent in justifying exclusion or partial application.

QL-2 SSCs

QL-2 SSCs and their associated activities – i.e., those SSCs that provide support of normal operations of the facility (e.g., occupational exposure, radioactive waste management) and SSCs that minimize public, worker, and environmental risks below 10CFR70.61 performance criteria (e.g., physical interaction protection, radiological and criticality alarms) – are also evaluated against the requirements in sections 1-18 of the MPQAP. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions. (This evaluation may also include nuclear industry precedent in the application of augmented QA requirements.)

2.2.3 APPLICATION OF GRADED QA CONTROLS

QA grading analyses for QL-1a, QL-1b and QL-2 SSCs are used to identify QA requirements to the design, construction, and operation of these SSCs. These requirements are reflected in applicable project procedures, analyses, specifications, and other QA program documents. Revision and approval of these documents is in accordance with applicable procedures.

2.2.4 FEEDBACK MECHANISMS AND REASSESSING SAFETY SIGNIFICANCE

Changes in design, equipment procurement requirements, lessons learned from adverse trends, corrective actions due to nonconfomances and deficiencies from audits, surveillance or assessments, construction activities, ISA completion, or elevation to a higher quality level by management decision shall be evaluated for determining any needed changes to the application of QA controls. Reviews and documentation of needed changes in QA controls shall be performed and documented in accordance with applicable QA project procedures. Design changes and changes in construction activities require that the requirements of section 3.2.5, Design Change Control, be met. Changes due to procurement requirements will be evaluated in accordance with the requirements of section 4.2.3, Procurement Document Change. Changes as a result of lessons learned from adverse trends, corrective actions due to nonconformances and deficiencies from audits, surveillance or assessments are evaluated to the requirements of Section 15, Nonconforming Materials, Parts and Components, or Section 16, Corrective Action. The corrective action process requires for significant conditions adverse to quality that the root cause be determined. Root cause evaluations including common cause/mode failures are

controlled by the applicable QA project procedure. 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 project procedure in order to maintain reasonable confidence in SSC performance.

SSCs that are affected by changes in 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 according to 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. Changes in classification 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.

Quality level classification 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.

2.3 QUALITY ASSURANCE TRAINING

All DCS employees, as well as loaned/part-time personnel who perform quality affecting activities on the MOX Fuel Project, receive MOX QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements and job responsibilities and authorities. All DCS personnel assigned to perform quality affecting activities are also required to complete training in the specific DCS QA procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on DCS QA Program and job specific QA procedures prior to an employee beginning quality affecting work. Supervision is responsible for assuring that personnel performing work under their supervision are appropriately trained.

The Training Coordinator (TC) is responsible for coordinating QA training activities for DCS. This position reports to the Project Services & Administration Manager. The TC serves as a centralized training support service for supervision in coordinating training and maintaining QA training records. This responsibility is carried out as support for line management. DCS supervisory personnel are responsible for determining the type and extent of the training to be provided to an individual, and ensuring that the training is properly documented for personnel performing quality affecting activities. Retraining, when applicable, shall occur in order to maintain proficiency or when changes to work methods, technology, or job responsibilities occur. Such retraining is also documented.

2.4 MANAGEMENT ASSESSMENTS

The Project Manager conducts a Project Assessment every year to determine if the Quality Assurance Program is effective on a corporate-wide basis. The Project Manager appoints a team of DCS managers and/or supervisors to conduct this assessment. Recommendations are provided to the Project Manager for action.

Functional Area Managers and the QA Manager conduct an Internal Management Assessment annually of QA activities under their control. The managers report the results of the Internal Management Assessments to the Project Manager for review. The results of both the Corporate and Internal Management Assessments are reviewed by senior management to determine the adequacy of implementation of the MOX QA Program and to direct any needed changes for program improvements.

2.5 QUALIFICATION/CERTIFICATION OF NONDESTRUCTIVE EXAMINATION (NDE) PERSONNEL

Nondestructive Examination (NDE) personnel used on the MOX Project shall be certified in accordance with NQA-1a-1995 Part 1 Supplement 2S-2, Supplementary Requirements for the Qualification of Nondestructive Examination Personnel and American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing, December 1988 Edition. Qualification/certification records meeting the requirements of Supplement 2S-2 shall be established and maintained as QA records.

2.6 QUALIFICATION/CERTIFICATION OF INSPECTION AND TEST PERSONNEL

Inspection and test personnel used on the MOX Project shall be certified in accordance with NQA-1-1994 Part I Supplement 2S-1, Supplementary Requirements for the Qualification of Inspection and Test Personnel, and meet the capability, education and experience requirements of Appendix 2A-1, Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel.[4] Qualification/certification records meeting the requirements of Supplement 2S-1 shall be established and maintained as QA records.

2.7 QUALITY ASSURANCE PROGRAM REPORTING TO MANAGEMENT

Management is regularly informed by the DCS QA Manager on pertinent information as a result of reviews conducted on audit reports, internal surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary.

[4] Required by Regulatory Guide 1.28 (Rev.3), Quality Assurance Program Requirements (Design and Construction). See footnote 1 for justification for using NQA-1-1994 version instead of NQA-1-1983.

3.1 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 3 Design Control of 10CFR50, Appendix B, and Basic Requirement 3 and Supplement 3S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994 applicable to DCS Base Contract and Option 1 workscope. Part II ASME NQA-1-1994 Subpart Part 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,* as revised by NQA-1a-1995 Addenda of NQA-1-1994 and ASME NQA-1-1994, Part I, Supplement 11S-2, *Supplementary Requirements for Computer Program Testing*, requirements for computer software qualification and use are also implemented by the DCS QA Program.

Measures are established in DCS QA implementing procedures to assure that applicable requirements are correctly translated by DCS into design documents. Design inputs are specified on a timely basis to support base contract 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. DCS design documents are prepared, reviewed, and approved by qualified individuals. 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 Subpart Part 2.7 as revised in NQA-1a-1995 and Supplement 11S-2. Configuration management is maintained in accordance with the applicable QA project procedure and 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 by DCS MOX Fuel Fabrication Facility (MFFF) engineering 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 base contract 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 implementing procedures.

3.2.2 DESIGN PROCESS

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

A. DCS design work for the base contract 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. Facility and process 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 by DCS MFFF engineering.

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

E. DCS 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 to DCS MFFF engineering personnel as design input.

G. DCS 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/engineering discipline can understand the documents and verify their adequacy without recourse to the originator of the design document.

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

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

3.2.3 DESIGN ANALYSIS

A. DCS 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. DCS 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 ASME NQA-1-1994, Part II, Subpart 2.7 as revised by NQA-1a-1995 Addenda and Supplement 11S-2. Computer software developed and/or qualified under the DCS or it's subcontractor QA programs may also be used to perform design analyses for DCS, provided DCS QA confirms these QA programs meet NQA-1-1994, Part I, Supplement 11S-2 and NQA-1-1994 Part II, Subpart 2.7 requirements as revised by NQA-1a-1995 Addenda.

E. DCS 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. The conclusion of the design/analysis, and

9. Design/analysis final review and approval.

3.2.4 DESIGN VERIFICATION

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

A. DCS design verification is required for Quality Level 1 (IROFS) design documents, 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 by DCS MFFF engineering 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 MFFF engineering organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided:

1. The engineering 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 MFFF engineering discipline competent to perform the verification.

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

E. DCS 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. DCS 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 "Americanization" of previously proven French designs shall be documented in accordance with the applicable QA implementing procedure.

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

5. 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

DCS 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

The appropriateness of assumptions, input data, and the computer program or other calculation methods used, shall be evaluated and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses. Documentation of the alternate calculation used shall include the information required in 3.2.3.C.

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 as "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 DCS engineering disciplines/groups that reviewed and approved the original design documents, with the following clarifications:

1. If the DCS engineering discipline/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 DCS engineering disciplines/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 16.0. 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 15.0, Nonconformances.

E. When a field change is approved other than 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. DCS design internal and external interfaces shall be identified and procedurally controlled.

B. Design efforts shall be coordinated among interfacing organizations as detailed in applicable implementing DCS 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. MOX project design information transmitted across interfaces shall be documented and procedurally controlled.

E. DCS transmittals of design information and/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 implementing document.

G. The QA Manager shall review design documents to assure inclusion of the applicable quality requirements as specified in implementing QA procedures.

3.2.7 COMPUTER SOFTWARE CONTROL

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

A. COMPUTER SOFTWARE VERIFICATION AND VALIDATION

DCS QA software verification and validation activities shall ensure that quality affecting software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

Software verification and validation activities shall be planned to support base contract milestones and performed by MFFF engineering for each system configuration which may impact the software. Results of software verification and validation activities shall be documented in accordance with applicable DCS QA implementing procedures. Individuals other than those who designed the software shall perform software verification and validation.

1. Software Verification

Software verification shall be performed during software development to ensure that the products of a given cycle phase fulfill the requirements of the previous phase or phases. Applicable software life cycle phases adopted by DCS are:

a) Requirements,
b) Design,
c) Implementation,
d) Testing,
e) Installation and Checkout,
f) Operation and Maintenance, and
g) Retirement Phases.

Applicable DCS implementing QA procedures shall procedurally control the performance and documentation of each of these phases.

2. Software Validation

Software validation is performed at the end of the implementation phase to ensure the computer software code satisfies the requirements. Software validation activities, such as the development of test plans and test cases shall be integrated into each phase of the software life cycle. Testing shall be the primary method of software validation. Software testing is conducted in accordance with the requirements in ASME NQA-1-1994 Part I Supplement 11S-2. Validation of modifications to the software shall be subject to selective regression testing to detect errors introduced during the modification of systems or system components, to verify that the modifications have not caused unintended adverse effects, or to verify that a modified system(s) or system component(s) still meets specified requirements.

B. SOFTWARE CONFIGURATION CONTROL

1. Configuration Identification

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.

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

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.

Changes shall be formally evaluated and approved by MFFF engineering unless an alternate organization has been given the authority to approve the change. Only authorized changes shall be made to software baselines. 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. Software validation shall be performed as necessary for the change. QA shall verify that the requirements of this section are met prior to approving the software for use.

3. Configuration Status Accounting

Information that is 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. DOCUMENTATION

1. Procedures for Software Quality Assurance

Applicable QA procedures shall be used for assuring software quality assurance requirements are met. These procedures shall be developed for each new software program at the start of the software life cycle or for procured software. These documents 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 MFFF engineering.

Procedures for controlling software program QA qualification shall identify:

(a) the software products to which it applies;
(b) the organizations responsible for performing the work and achieving software quality and their tasks and responsibilities;
(c) required documentation;
(d) standards, conventions, techniques or methodologies which shall guide the software development, as well as methods to assure compliance to the same;
(e) the required software reviews; and
(f) the methods for error reporting and corrective action.

2. Software Requirements Documentation

Software requirements documentation shall outline the requirements that the proposed software must satisfy. The requirements shall, 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.; and
(e) external interfaces - interactions with people, hardware and other software.

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.

3. Software Design and Implementation Documentation

Software design and implementation documentation includes 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 can be translated into code; and
(e) computer program listing(s).

4. Software Verification, Validation and Documentation

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. The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. 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. Upon satisfactory completion of verification/validation and completion of all required QA requirements the QA approved software program shall be placed on the DCS Computer Software Index as approved for use on the MOX Project.

5. User Documentation

User documentation, as a minimum, shall include:

(a) 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;
(b) input and output specifications;
(c) input and output formats;
(d) a description of system limitations;

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

(f) information for obtaining user and maintenance support.

D. VERIFICATION REVIEWS

Verification reviews shall identify participants, their specific review responsibilities and distribution of review documentation.

Reviewed documents shall be updated and placed under configuration control.

Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Not incorporated comments and their disposition shall be retained in accordance with established procedures.

1. Software Requirements Review

The review of software requirements shall be performed at the completion of the software requirements phase documentation. This review 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. Software Design Review

The software design review shall be held at the completion of the software design phase documentation. This review shall meet the design verification requirements of ASME NQA-1-1994 Part I, Supplement 3S-1. This review shall evaluate the technical adequacy of the design approach and assure internal completeness, consistency, clarity and correctness of the software design, and shall verify that the software design is traceable to the requirements.

3. Development Documentation Review

Upon completion of the testing phase (and the installation phase if necessary) the development phase documentation shall be reviewed and approved to assure completion and acceptability.

E. SOFTWARE PROBLEM REPORTING AND CORRECTIVE ACTION

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.

Problems found in previously approved QA software are classified by the MFFF engineering organization responsible for the evaluation. Classification shall be defined based on the impact of the software output.

Corrective action by the responsible organization shall assure that:

1. problems are identified, evaluated, documented and, if required, corrected;

2. problems are assessed for impact on past and present applications of the software by the responsible organization;

3. corrections or changes shall be controlled in accordance with Section 3.2.5; and

4. preventive actions and corrective actions results are provided to affected DCS organizations.

F. ACCESS CONTROL

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

G. SOFTWARE PROCUREMENT

1. Contracted Software

Individuals or organizations developing and supplying QA software under contract to DCS shall be required to have policies and QA procedures that meet the applicable requirements of this section as specified in procurement documents. 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 purchaser upon receipt of software. 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 Developed Not in Accordance With ASME NQA-1-1994, Subpart 2.7

Software that has been developed not using ASME NQA-1-1994 Part II Subpart 2.7 shall be placed under the configuration controls required by this section prior to use. 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:

(i) user application requirements
(ii) test plans and test cases required to validate the software for acceptability
(iii)user documentation required by section 3.2.7.C.5.

After the specified activities are performed, reviewed and approved, the software shall be placed under configuration control.

As an alternate, the user organization shall obtain the above documentation from the supplier or perform a documented review of the documentation at the supplier facility to determine acceptability. This review shall meet the requirements as specified above.

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 section 3.2.7.C.1. The user organization shall determine the adequacy of this plan.

4. DCS and Subcontractor Supplied QA Software

Computer software developed and/or qualified under the DCS or it's subcontractor QA programs may also be used to perform design analyses for DCS provided DCS QA confirms these QA programs meet NQA-1-1994 Part I Supplement 11S-2 and NQA-1-1994 Part II Subpart 2.7 requirements as revised by NQA-1a-1995 addenda.

H. COMPUTER PROGRAM TESTING

1. Test Requirements

Test requirements and acceptance criteria shall be provided in the applicable test procedure. Appropriate required tests including verification tests, hardware integration tests and in-use tests shall be procedurally controlled. Test requirements and acceptance criteria shall be based upon the applicable program design or other pertinent technical documents.

(a) Verification Tests

Verification tests shall demonstrate the capability of computer programs to produce valid results for test problems encompassing the range of permitted usage defined by program documentation. Test problems encountered during verification testing maybe solved using the following:

(i) hand calculations; and/or
(ii) data and information from comparable proven programs and technical literature.

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

Computer program testing shall vary with the complexity of the program. Single tests or a series of tests (as applicable) at various points during program development shall be performed followed by an overall computer program test. Test(s) shall verify proper performance of modules and correct translation between development stages. 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.

(b) In-Use Tests

When an approved QA computer program is installed on a different computer or when significant hardware or operating system configuration changes are made, in-use tests using pre-established test problems shall be run to confirm acceptable computer program performance. Periodic in-use manual or automatic self-check routines shall also be used for those applications where computer failures or drift can affect required performance. In-use tests shall be procedurally controlled.

2. Test Procedures

Test procedures shall specify the following, as applicable:

(a) required tests and test sequence;
(b) required ranges of input parameters;
(c) identification of the stages at which testing is required;
(d) criteria for establishing test cases;
(e) requirements for testing logic branches;
(f) requirements for hardware integration;
(g) anticipated output values;
(h) acceptance criteria; and
(i) reports, records, standard formatting and conventions.

3. Test Results

Test results shall be documented in the applicable QA procedure and reviewed to assure acceptable test results have been achieved.

4. Test Records

(a) Verification test records shall identify the following:

(1) computer program and hardware tested

(2) test equipment and calibrations, where applicable

(3) date of test, tester or data recorder

(4) simulation models used, where applicable

(5) test problems, results and acceptability

(6) action taken in connection with any deviations noted

(7) person evaluating test results

(b) In-use test results shall identify items below.

(1) computer program and hardware tested

(2) test equipment and calibrations, where applicable

(3) date of test, tester or data recorder

(4) acceptability

4.1 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 4 Procurement Document Control of 10CFR50, Appendix B, and Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994 as applicable to DCS Base Contract and Option 1 workscope.

Applicable design bases and other requirements necessary to assure adequate quality are included or referenced in DCS procurement documents for procurement of Quality Level 1 (IROFS) and 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 DCS hold points for witness/inspection activities during manufacturing, supplier documentation and record retention, requirements for processing and approving work stoppage and nonconformances and spare and replacement parts. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original procurement documents.

DCS procurements shall be issued only to those suppliers that have been evaluated and qualified as acceptable for the particular scope of material, equipment and services to be procured. The material, equipment and services shall be procured from approved suppliers by procurement requisitions and/or specifications, approved by the DCS Project Manager and QA Manager or their qualified designees. To the extent necessary, procurement documents require suppliers to have a quality assurance program consistent with the applicable requirements of 10CFR50 Appendix B. The requirements of 10CFR 21 (Part 21) are invoked during design, construction, testing and operations on all Quality Level 1 (IROFS) procurements.

4.2 REQUIREMENTS

4.2.1 PROCUREMENT DOCUMENT PREPARATION

DCS Procurement documents issued for Quality Level 1 (IROFS) and 2 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 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.

C. Quality Assurance Program Requirements including:

1. A requirement for the supplier to have a documented quality assurance program that implements applicable requirements of 10 CFR 50, 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. The supplier shall also incorporate the appropriate requirements into any subtier supplier issued procurement documents.

2. A requirement invoking NRC reporting requirements of 10CFR21 for Quality Level 1 procurements only.

   Note: If a supplier, or subtier supplier discovers a defect or non-compliance determined to be a substantial safety hazard, they shall be required to report the item to the NRC under 10CFR21 and notify the DCS QA Manager in writing. If the supplier or subtier supplier is unable to determine if the defect/non-compliance is a substantial safety hazard then the supplier or subtier supplier has the option to report the item to DCS for determination of reportability.

D. Right of access to supplier, including subtier, 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 without DCS QA Manager authorization. The DCS Project Manager may also establish hold points indicating work that cannot proceed without authorization by the Project Manager.

F. Documentation required to be submitted to DCS for information, review or acceptance 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.

G. Requirements for the supplier to report to DCS in writing adverse quality conditions resulting in work stoppages and nonconformances. DCS approval of partial and full work releases and disposition of nonconformances is required.

H. Identification of any spare and replacement parts or assemblies and the appropriate technical and quality assurance data required for ordering. Commercial Grade procurements shall also be identified in procurement documents.

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. A review of the procurement documents and any changes thereto shall be made to verify that documents include all 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. Review by the QA Manager (or designee) shall assure compliance to quality assurance requirements.

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 and replacement 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/bid 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 contract 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. The analysis will identify any impact these changes might have on the procurement.

5.1 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 5 Instructions, Drawings, And Procedures of 10CFR50, Appendix B, and Basic Requirement 5 of NQA-1-1994 Part I as applicable to DCS Base Contract and Option 1 workscope.

Quality affecting activities are prescribed by and performed in accordance with documented DCS QA procedures and other implementing documents (drawings, specifications, etc.) appropriate to the MOX Project workscope. Quality Assurance procedures are reviewed by affected managers for definition of work controlling processes. QA Procedures are approved by the DCS QA Manager to ensure compliance with QA program requirements/commitments and by the DCS Project Manager for line management approval. Supplementary workplace procedures/instructions/guidelines may be used and controlled by Functional Area Managers to provide additional guidance over quality affecting activities; however, these documents shall not conflict with the MPQAP and completed work shall meet the requirements of the applicable MOX QA procedures for the task or activity. Use of procedures for quality affecting activities is an important management measure implemented to ensure consistent application of requirements.

5.2 REQUIREMENTS

5.2.1 TYPES OF IMPLEMENTING DOCUMENTS

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Implementing documents include Project QA procedures, drawings and specifications. Work controlling QA procedures may also 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 of this document.

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 DCS Corrective Action Process- see Section 16.0).

6.1 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 6 Document Control of 10CFR50, Appendix B, and Basic Requirement 6 and Supplement 6S-1 of NQA-1-1994 as applicable to DCS Base Contract and Option 1 workscope.

DCS Document Control distributes all DCS quality affecting documents. Applicable QA procedures provide controls over DCS generated QA documents as well as QA documents received from suppliers. QA procedures describe methods for preparing, reviewing, and approving documents, maintaining master list of controlled documents, controlling document distribution, receipt acknowledgment, maintenance of record copies, correction and deletion of documents, and control and retention of supplier generated documents. Documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel in accordance with the applicable implementing QA procedures.

6.2 REQUIREMENTS

6.2.1 TYPES OF DOCUMENTS

Implementing documents and documents specifying applicable technical and/or quality requirements shall be controlled in accordance with this section. DCS quality affecting documents controlled under the DCS QA Program include, project procedures, Design Requirements Document, Basis of Design Documents, Engineering Specifications, System Descriptions, drawings, calculations, procurement documents, and documents that need to be controlled due to being input to other DCS design documents or used for manufacturing and construction.

6.2.2 PREPARING DOCUMENTS

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

6.2.3 REVIEWING DOCUMENTS

Implementing documents and documents specifying applicable technical and/or quality requirements, shall be reviewed in accordance with applicable QA procedures for adequacy, correctness and completeness prior to approval and issuance.

6.2.4 APPROVING DOCUMENTS

The organizational position(s) responsible for approving the document(s) for release shall be identified in the applicable QA Procedures.

6.2.5 CONTROLLING THE DISTRIBUTION AND USE OF DOCUMENTS

Documents needing to be placed under document control are transmitted to DCS Document Control with the distribution list for document holders. Document control shall enter the document into the Document Control electronic database and master list of controlled documents, make the required copies, assigned document control numbers, complete transmittal forms and mail the documents and transmittal form to the document holders. Document holders shall acknowledge receipt on the transmittal and send the acknowledgement to DCS Document Control.

The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled as described below:

A. Documents used to perform work, hard copy and electronic media, shall be distributed to, and used at, the work location.

B. Effective dates shall be established for approved implementing 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 shall be controlled. Controlling instructions are contained in the applicable project procedures for document control and records management.

D. The DCS Electronic Data Management System (EDMS) shall be used to identify the current status of each document that is required to be controlled.

6.2.6 CHANGES TO DOCUMENTS

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. Implementing QA Procedures shall define the method used to incorporate changes. If the defined method is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.

E. Implementing 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 and maintained by DCS QA each time additional changes to the procedures are proposed. For other quality affecting documents the document history shall be maintained by the organization responsible for the documents.

6.2.7 EXPEDITED CHANGES

If an activity cannot be performed as described in a document and the change process would cause unreasonable delay, a temporary, expedited change may be made at the work location by responsible management. The applicable QA procedure shall control the documentation and approval of the expedited change.

A. After making the authorized expedited change, the change shall be processed through the normal change process in a timely manner consistent with the type and nature of the document being changed.

B. Implementing documents shall describe the process to control expedited changes according to the following requirements:

1. The level of management authorized to make expedited changes shall be identified,

2. Changes in work resulting from the expedited process shall be evaluated by the QA organization to assure QA Program compliance, and

3. Time limits for processing expedited changes through the normal change process shall be specified.

6.2.8 EDITORIAL CORRECTIONS

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:

A. Correcting grammar or spelling

B. Renumbering sections or attachments

C. Changing the title or number of the document

D. Updating organizational titles.
Note: A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.

7.1 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 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 of NQA-1-1994 and Regulatory Guide 1.28 Rev. 3 as applicable to DCS Base Contract and Option 1 workscope.

DCS procurement of QL 1 (IROFS) and 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 suppliers' QA programs, annual evaluations, periodic audits/source inspections and surveillance. Suppliers with an approved QA program are placed on the DCS Approved Suppliers List (ASL) prior to award of contract. 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 evaluations, annual evaluations, audits, surveillances, source inspections and receipt inspections shall be documented.

Note: This section does not apply to direct-support services used for staff augmentation or to DCS subcontractors that are allowed to work to their QA Programs for the scopes of work identified in section 2.1.2.

7.2 REQUIREMENTS

7.2.1 PROCUREMENT PLANNING

DCS procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the base contract schedule. 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 needed to effectively complete the procurement.

C. Provide for the integration of the following activities:

1. Procurement document preparation, review and change control according to the requirements of Section 4
2. Selection of procurement sources, proposal/bid evaluation and award
3. Purchaser evaluation of supplier performance
4. Purchaser verifications including any hold and witness point notifications
5. Control of nonconformances

6. Corrective action
7. Acceptance of the material, equipment or service
8. Identification of quality assurance records to be provided to DCS.

D. Be accomplished as early as possible, and no later than at the start of those procurement activities which are required to be controlled.

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

F. Include the involvement of DCS QA.

7.2.2 SOURCE EVALUATION AND SELECTION

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

B. The functional area needing the procurement shall request that DCS QA evaluate the potential supplier for placement on the DCS ASL. (See Section 7.3 for control and maintenance of the ASL)

C. Measures for evaluating and selecting procurement sources are detailed in the applicable QA procedure and include one or more of the following methods for evaluating potential suppliers:

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

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

3. Evaluation of the supplier's technical and quality capability based on an evaluation of supplier 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.

E. Supplier's currently on the Duke Energy or Duke Engineering & Services (DE&S) ASL may be placed on the DCS ASL provided review by QA of the latest supplier evaluation qualified the supplier to provide the same type of items or services needed by DCS.

7.2.3 PROPOSAL/BID EVALUATION

A. For Quality Level 1 & 2 designated proposals and bids, technically qualified personnel from the QA, procurement and technical organizations shall perform an evaluation to determine if the proposal/bid 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 personnel qualifications
4. Supplier production capability and past performance
5. Alternatives and exceptions.

B. Before the contract is awarded, DCS shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.

C. Supplier quality assurance programs shall be evaluated before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to these requirements.

D. Supplier quality assurance programs shall be accepted by the DCS QA Manager based on these MOX Project Quality Assurance Program (MPQAP) requirements before the supplier starts work.

7.2.4 SUPPLIER PERFORMANCE EVALUATION

A. The DCS Procurement Manager shall establish measures to routinely interface with the supplier and to verify supplier performance. The measures shall include:

1. Establishing an understanding between DCS and the supplier of the requirements and specifications identified in procurement documents.

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

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

4. Identifying and processing necessary change information.

5. Establishing the method to be used to document information exchanges between purchaser and supplier.

6. Establishing the extent of source surveillance and inspection.

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

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

7.2.5 CONTROL OF SUPPLIER GENERATED DOCUMENTS

A. Supplier generated documents shall be controlled, processed and accepted by DCS in accordance with the requirements established in the applicable implementing QA procedures.

B. Measures shall be implemented to ensure that the submittal of supplier 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 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 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 shall verify that furnished material, equipment or services comply with DCS' procurement requirements before offering the material, equipment or services for acceptance and shall provide to DCS 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's quality assurance function and whose responsibilities and position are described in the supplier's quality assurance program.

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

F. Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier 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.

7.2.8 SOURCE VERIFICATION

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

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

B. Documented evidence of acceptance of source verified material, equipment or services shall be furnished to the receiving destination of the item, to DCS, and to the supplier.

C. Personnel qualified in accordance with the applicable requirements for the material, equipment or service being procured shall perform source verification.

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.

B. The inspection shall be performed in accordance with established inspection implementing 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.

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

7.2.10 POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance, DCS and the supplier shall mutually establish test requirements and acceptance documentation.

7.2.11 CONTROL OF SUPPLIER NONCONFORMANCES

The DCS Procurement Manager and the supplier 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 shall evaluate nonconforming items according to the applicable requirements of Section 15.0 and submit a report of nonconformance to DCS including supplier recommended disposition (for example, use-as-is or repair) and technical justification.

B. Reports of nonconformances to procurement document requirements, or documents approved by DCS, shall be submitted to DCS for disposition by the procuring technical organization whenever one of the following conditions exists:

1. Technical or material requirements are violated

2. A requirement in supplier 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.

C. DCS shall disposition the supplier's recommendation and verify implementation of the disposition.

7.2.12 COMMERCIAL GRADE ITEMS (For IROFS Only)

A. Commercial grade items are items that are:

1. Not subject to design or specification requirements that are unique to MOX Fuel Fabrication facilities or activities;

2. Used in applications other than MOX Fuel Fabrication facilities or activities; and

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

B. Critical characteristics for Commercial Grade material, equipment and services are determined and approved by the DCS Project Manager designee based on the manufacturer's published specifications and the intended Quality Level 1 (IROFS) safety function for the items and services. Specific characteristics used for acceptance or dedication of the material, equipment and services are selected based on providing reasonable assurance that the material, equipment and services will meet their catalog or manufacturer specifications and will perform the specified functions as intended. Verification of acceptance requirements will be by manufacturer/supplier evaluation, manufacturing surveillance, receipt tests or inspections or post-installation testing. Historical data, when documented, may be used to supplement other acceptance methods.

C. Where the design utilizes commercial grade material and/or equipment, the following requirements are an acceptable alternate to other requirements of this Section:

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

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

3. Commercial grade items shall be identified in the 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:

   (a) special test(s) or inspection (s) or both;
   (b) commercial grade survey of the supplier;
   (c) source verification;
   (d) acceptable supplier/item performance records.

5. Prior to acceptance of a commercial grade item, DCS shall determine that:

   (a) damage was not sustained during shipment;
   (b) the item received was the item ordered;
   (c) inspection and/or testing is accomplished, as required, to assure conformance with critical characteristics; and
   (d) documentation, as applicable to the item, was received and is acceptable.

7.3 APPROVED SUPPLIER LIST

The DCS Quality Assurance Manager is responsible for the development and maintenance of the DCS Approved Suppliers List. The ASL contains those suppliers with acceptable Quality Assurance Programs that have been evaluated and accepted by the DCS Quality Assurance Manager in accordance with approved procedures.

The DCS QA organization shall perform and document an evaluation of each supplier every 12 months. Satisfactory results will maintain the supplier on the ASL. Additionally, suppliers will be evaluated by means of an audit at least triennially, if initial approval was by audit or survey. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in 3 years will be removed from the ASL.

8.1 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 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 as applicable to DCS Base Contract and Option 1 workscope.

The DCS QA Program procedures establish the necessary controls to assure that only correct and accepted material, parts and components are used or installed. In addition, procedures require that identification is maintained on the items or in documents traceable to the items in a manner that assures that adequate identification and controls are established and maintained.

8.2 REQUIREMENTS

8.2.1 IDENTIFICATION

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

B. Items 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 at all times 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.

9.1 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 9 Control of Special Processes of 10CFR50, Appendix B, and Basic Requirement 9 and Supplement 9S-1 of NQA-1994 Part I as applicable to DCS Base Contract and Option 1 workscope.

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 5.0. 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 2.5 of Section 2.0 of this document.

10.1 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 10 Inspection of 10CFR50, Appendix B, and Basic Requirement 10 and Supplement 10S-1 of NQA-1-1994 Part I as applicable to DCS Base Contract and Option 1 workscope.

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be employed are specified in implementing QA procedures. Inspection results are documented. Persons other than those who performed or directly supervised the work being inspected shall 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

Inspection planning shall be performed, documented and include:

A. Identification of each work operation where inspection is necessary to ensure quality and implementing documents that shall be used to perform the inspections;

B. Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed;

C. Identification of inspection or process monitoring methods to be employed;

D. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements;

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

F. Identification of acceptance criteria;

G. Identification of sampling requirements;

H. Methods to record inspection results; and

I. 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 Section 2.6.

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 item being inspected and are independent of the organization directly responsible for the work. 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 implementing 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.

10.2.8 INSPECTION DOCUMENTATION

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 nonconformances, as applicable.

11.1 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 11 Test Control of 10CFR50, Appendix B, and Basic Requirement 11 and Supplement 11S-1 of NQA-1-1994 Part I as applicable to DCS Base Contract and Option 1 workscope. The requirements in Supplement 11S-2 are addressed in section 3.2.7.

The test controls for certain DCS activities are specified in this section. Tests required to verify conformance of an item or computer program 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 implementing 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. Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment/instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions and provisions for data acquisition;

E. 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 level of personnel performing tests.

11.2.2 PERFORMING TESTS

Tests shall be performed in accordance with implementing QA procedures that address the following requirements 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. Include or reference 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, supplier manuals or other related documents containing acceptance criteria) may be used instead of preparing special test implementing procedures. If used, then they shall incorporate the information directly into the approved test-implementing procedure or shall be incorporated by reference in the approved test-implementing procedure.

B. Implementing 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 14.0.

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. Identification of 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. Identification of the 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

Personnel who perform testing shall be qualified according to the requirements of Section 2.6.

12.1 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 12 Control of M&TE of 10CFR50, Appendix B, and Basic Requirement 12 and Supplement 12S-1 of NQA-1-1994 Part I as applicable to DCS Base Contract and Option 1 workscope.

This section establishes DCS control for tools, gages, instruments and other M&TE used for quality affecting activities. M&TE is controlled and 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.

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 THE 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 or replaced.

12.2.4 LOST M&TE

When M&TE is lost, 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.

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 implementing document (including revision level) used in performing the calibration.

13.1 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 13 Handling, Storage and Shipping of 10CFR50, Appendix B, and Basic Requirement 13 and Supplement 13S-1 of NQA-1-1994 Part I as applicable to DCS Base Contract and Option 1 workscope.

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 implementing 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.

14.1 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 14 Inspection, Test and Operating Status of 10CFR50, Appendix B, and Basic Requirement 14 of NQA-1-1994 Part I as applicable to DCS Base Contract and Option 1 workscope.

This section establishes requirements for DCS to identifying 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 or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified. Status indicators shall also 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, 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.

15.1 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 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 applicable to DCS Base Contract and Option 1 workscope.

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. 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.

16.1 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 16 Corrective Action of 10CFR50, Appendix B, and Basic Requirement 16 of NQA-1-1994 Part 1 as applicable to DCS Base Contract and Option 1 workscope.

All conditions adverse to quality (reference Section 16.2.1) shall be identified promptly and corrected as soon as practical. Such conditions shall be tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken.

During Option 1, when DCS is required by the Nuclear Regulatory Commission (NRC) to report nonconformances in accordance with Title 10 of the Code of Federal Regulations, Part 21, "Reporting of Defects and Noncompliance" (10CFR21), all significant conditions adverse to quality shall be evaluated for reportability and reported if conditions meet the 10CFR21 reporting criteria. Regardless of the reportability determination, the cause of the significant condition shall be determined, and corrective action to preclude recurrence shall be taken. The identification, cause and corrective action shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of this corrective action.

DCS implementing QA procedures shall be established to provide requirements and processes for the following activities:

A. Prompt identification, correction and trending of all conditions adverse to quality;

B. Evaluating significant conditions adverse to quality for reportability to the NRC (when required) under 10 CFR 21 requirements and reporting such conditions when warranted;

C. Stopping work, if applicable;

D. Determining root cause and preventive actions for significant conditions adverse to quality; and

E. 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 in one of two

categories in regard to their significance, and corrective actions shall be taken accordingly. The two categories of significance include:

A. Conditions adverse to quality

B. Significant conditions adverse to quality

16.2.1.1 Conditions Adverse to Quality

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

B. Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the DCS QA organization for tracking and trending.

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

D. Responsible management shall then utilize investigation results to determine and document corrective action (including remedial action and actions to prevent recurrence). Concurrence from the DCS QA Manager shall be obtained to ensure that MOX Project Quality Assurance Plan (MPQAP) requirements are satisfied.

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

16.2.1.2 Significant Conditions Adverse To Quality

A. Significant conditions adverse to quality are defined as:

1. A deficiency that would seriously impact an item from performing its intended function of assuring public health and safety;

2. A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;

3. 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;

4. 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;

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

6. Loss of essential data required for activities or items subject to MPQAP controls;

7. A deficiency, repetitive in nature, related to an activity or item subject to the MPQAP; and

8. A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to MPQAP controls.

B. Significant conditions adverse to quality shall be documented and reported to the management responsible for the condition, their upper management, and to the DCS QA organization for tracking.

C. When required by the NRC, significant conditions adverse to quality shall be evaluated for reportability under 10 CFR 21 to determine if the defects or noncompliances are reportable to the NRC. If found to be reportable, the responsible management shall immediately inform the DCS QA manager, Project Manager and other appropriate management within the organization, and report the condition to the NRC in accordance with established requirements.

D. When required by the NRC, if a supplier or subtier supplier discovers a defect or noncompliance which the supplier evaluates as a substantial safety hazard, then the supplier shall be required to report the item to the NRC under 10 CFR 21 and notify the DCS QA Manager in writing. If the supplier or subtier supplier is unable to determine if the defect/non compliance is a substantial safety hazard then the supplier or subtier supplier has the option to report the item to DCS for determination of reportability.

E. 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 implementing 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.

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

G. 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 the DCS QA Manager shall be obtained to ensure that MPQAP requirements are satisfied.

H. 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 QA Manager shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.

16.2.3 TRENDING

The DCS QA Manager 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.

17.1 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 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 Regulatory Guide 1.28 (Rev.3) as applicable to DCS Base Contract and Option 1 workscope.

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. The term *record(s)*, used throughout this Section, is to be interpreted as *QA Record(s)*.

DCS completed records that furnish documentary evidence of quality shall be specified, prepared and maintained in accordance with applicable regulatory requirements and DCS implementing QA procedures. Records shall be legible, identifiable, retrievable, and shall be protected against damage, deterioration and loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance and disposition shall be established and documented. Retention periods for the various types of records generated under the DCS QA Program shall be specified as Lifetime or Nonpermanent according to the criteria given in this Section. See Figure 17.0-1 for examples of Typical Lifetime QA Records.

17.2 REQUIREMENTS

17.2.1 RECORD MANAGEMENT SYSTEM

Project Development shall establish a record management system and the DCS QA Records Center at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the requirements of this Section. The QA record management system shall be defined, implemented and enforced in accordance with written procedures, instructions or other documentation.

Procedure(s) describing the record management system shall include methods for controlling records withdrawn from storage that are required for the completion of work activities. Additionally, provisions shall be made for the capability to retrieve information stored on magnetic or optical media.

17.2.2 GENERATION OF QA RECORDS

Applicable DCS design specifications, procurement documents, test procedures, operational procedures or other documents and procedures shall specify the records to be generated, supplied or maintained. Documents that are designated to become records shall be legible, accurate and completed appropriate to the work accomplished. Retention classification shall be specified in accordance with the following section.

17.2.2.1 Classifications of QA Records

DCS records shall be classified for retention purposes as lifetime records or nonpermanent records in accordance with the criteria in this Section.

A. Lifetime Records

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

1. Those which would be of significant value in demonstrating capability for safe operation;

2. Those which would be of significant value in maintaining, reworking, repairing, replacing or modifying an item;

3. Those which would be of significant value in determining the cause of an accident or malfunction of an item; and/or

4. Those which provide required baseline data for in-service inspections.

Lifetime records are required to be maintained for the life of the particular item while it is installed in the facility or stored for future use. Examples of typical lifetime QA records are shown in Figure 17.0-1.

B. Nonpermanent Records

Nonpermanent records are those required to show evidence that 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. The retention period for nonpermanent records shall be documented in the applicable implementing QA procedure and the QA Records Retention Index.

QA 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 life of the item for product records.

17.2.2.2 Producing Valid QA Records

A. Implementing QA procedures shall identify those documents that will become QA records. The individual using the procedure is responsible for ensuring the QA records required by the procedure are submitted to the permanent record storage facility. 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.

B. Individuals creating records shall ensure the records are legible, accurate and complete, and shall protect them from damage, deterioration or loss during the time the records are in their possession.

C. 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. QA records may be originals or copies.

D. 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 base contract workscope.

E. DCS subcontractors shall submit to the DCS QA Records Center those records being temporarily stored by them that are subject to records turnover requirements. The timing of the submittal shall be as record packages become completed, or as items are released for shipment, or as prescribed by implementing QA procedures and procurement documents. Records shall be controlled and submitted to the records management system in accordance with implementing QA procedures.

17.2.3 RECEIVING QA RECORDS

A. A receipt control system shall be established for temporary and permanent storage of records in the DCS QA Records Center. The DCS 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 DCS receipt control system shall include the following:

1. A method for designating the required records;

2. A method for identifying records received;

3. Procedures for receipt and inspection of incoming records; and

4. A method for submittal of completed records to the storage facility without unnecessary delay.

B. The DCS QA Records Center under the administrative controls of PS&A shall receive records and protect the records from damage, deterioration or loss when received. Additionally, a current and accurate assessment of the status of the records shall be performed during the receiving process and legibility/completeness

of the records shall be verified (QA record correction and replacement processes are addressed later in this Section).

C. 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;

2. Identification of the item or related activity to which the records pertain; and

3. The retention classification of the record.

D. Records shall be submitted for permanent records storage after the records acceptance process has been completed.

17.2.4 STORING AND PRESERVING QA RECORDS

A. Records shall be stored and preserved in the DCS QA Records Center in accordance with an approved implementing 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. Approved filing methods shall require records to be firmly attached in binders, or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the record medium being stored.
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.

17.2.4.1 QA Record Repositories

Originating organizations shall store records in temporary storage while active and required for use; subsequently the records shall be transmitted for permanent storage in accordance with the requirements of this Section and associated implementing QA procedures.

A. Temporary Storage

DCS organizations shall provide for temporary storage of records during processing, review or use, until turnover to the DCS QA Records Center for disposition, according to implementing QA procedures and the following requirements:

1. Records shall 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.

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

B. Permanent Storage

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

1. Natural disasters (i.e., winds, floods or fires);

2. Environmental conditions (i.e., high and low temperatures and humidity); and

3. Infestation of insects, mold or rodents.

If the alternate single facilities provision is used, then DCS records shall be stored in the DCS QA Records Center in two (2) hour fire rated Class B file containers meeting the requirements of National Fire Protection Association (NFPA) 232-1986 or NFPA 232AM-1986 or both.

If the dual storage facilities provision is used for hard copies, then DCS records shall be stored with one copy in the DCS Records Center and the second copy stored in the Duke Engineering & Services records storage area at the Duke Energy Records Center. These facilities are sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

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

17.2.5 RETRIEVING QA RECORDS

A. The records management system shall provide for retrieval of records in accordance with planned retrieval times based upon the designated record type.

B. Access to records storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the records at both the DCS QA Records Center and the Duke Energy Records Center.

17.2.6 RETENTION OF QA RECORDS

A. Lifetime records shall be retained and preserved for the operating life of the item or facility.

B. Nonpermanent records shall be retained for a minimum of three (3) years or as specified by procurement documents. Nonpermanent records shall not be disposed of until the following conditions are met:

1. Regulatory requirements are satisfied;

2. Facility status allows document disposal; and

3. DCS MOX Project Quality Assurance Plan (MPQAP) requirements are satisfied.

17.2.7 CORRECTING INFORMATION IN QA 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 if desired (e.g., corrective action tracking number and audit number).

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

17.2.8 REPLACING QA RECORDS

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

ATTACHMENTS:

Figure 17.0-1 – Example of Typical Lifetime QA Records

Figure 17.0-1 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
- Purchaser 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 17.0-1 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

18.1 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 18 Audits of 10CFR50, Appendix B, and Basic Requirement 18 and Supplements 18S-1 and 2S-3 of NQA-1-1994 Part I as revised by NQA-1a-1995 and Regulatory Guide 1.28 (Rev.3) as applicable to DCS Base Contract and Option 1 workscope.

Quality Verification personnel shall verify DCS compliance with all aspects of the DCS MOX Project Quality Assurance Plan (MPQAP) and determine QA Program effectiveness by performing planned and periodic audits. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. DCS 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 reports to the DCS QA Manager and has the organizational independence and authority to execute an effective audit system to meet all requirements of the MPQAP.

18.2 REQUIREMENTS

Requirements for the preparation, performance, reporting and closure of audits, in addition to audit team qualification requirements are covered in this section. Controls for audits and surveillances, including the certification of auditors, have been established and shall be implemented through implementing QA procedures. Surveillances are a part of the audit program and are performed on a random basis at the direction of the QA Manager. Internal surveillances are intended to provide line managers with regular feedback on the implementation of the MPQAP within their area of responsibility.

18.2.1 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. Internal audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. As a minimum internal audits of DCS quality affecting activities shall be at least once per year or at least once during the life of the activity, whichever is shorter.

B. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of

compliance or effectiveness. Internal audits to determine quality assurance program effectiveness (performance based audits) shall be performed on selected work products.

C. The audit schedule shall be developed annually and revised as necessary to ensure that coverage is maintained current. Frequency of audits should be based upon evaluation of all applicable and active elements of the MPQAP applicable to DCS base contract workscope. These evaluations should include an assessment of the effectiveness of the applicable and active elements of the MPQAP based upon previous audit results and corrective actions, nonconformance reports, identified trends which are adverse to quality and the impact of significant changes in personnel, organization or the MPQAP.

18.2.2 AUDIT PLANS

Quality Verification shall develop and document an audit plan for each scheduled audit. This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used. Audits shall include technical evaluations of the applicable procedures, instructions, activities and items as directed by the DCS QA Manager.

18.2.3 AUDIT TEAMS

A. Quality Verification shall select and assign auditors who are 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 Quality Verification and any applicable technical 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. The Quality Verification Manager shall participate in the selection of qualified auditors, including auditors used in evaluating design activities.

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 by Quality Verification to assist in assessing the adequacy of technical processes.

D. Before commencing the audit, Quality Verification shall ensure the personnel assigned to the audit team collectively have experience and/or training commensurate with the scope, complexity or special nature of the work to be audited. Lead auditors, auditors and technical specialists shall be qualified

according to the requirements of this Section. The DCS QA Manager, according to the requirements outlined in this section, shall certify non-DCS auditors.

18.2.4 PERFORMING AUDITS

Quality Verification shall provide written notification of a planned audit to the involved organizations at a reasonable time before the audit is to be performed. The notification should include all 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 by Quality Verification and the audited organization shall correct the findings according to the requirements of Section 16.0. Minor audit findings shall be corrected by the audit process.

18.2.5 REPORTING AUDIT RESULTS

The audit report shall be prepared by the audit team leader, and issued to the management of the audited organization and participating organizations within 30 days of completion of the audit. 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 documents reviewed, persons interviewed and the specific results of the reviews and interviews (i.e., a summary of the checklist contents).

E. Statement as to the effectiveness of the implementation of the MPQAP elements audited.

F. A description of each reported adverse audit finding (i.e., condition adverse to quality) in sufficient detail to enable corrective action to be taken by the audited organization according to the requirements of Section 16.0.

G. A requested date for response by the audited organization.

18.2.6 RESPONDING TO AUDITS

Management of the audited organization shall:

A. Investigate adverse audit findings (conditions adverse to quality) in a timely manner;

B. Determine and schedule corrective action, including measures to prevent recurrence;

C. Prior to or by the requested response date, notify Quality Verification in writing of the actions taken or scheduled, according to the requirements of Section 16.0; and

D. Notify Quality Verification when scheduled corrective actions have been completed.

18.2.7 EVALUATING AUDIT RESPONSES

The adequacy of corrective actions for adverse audit findings (conditions adverse to quality) shall be evaluated by Quality Verification according to the requirements of Section 16.0. When corrective actions are considered inadequate, written notification of this determination shall be provided to the audited organization with a request for a revision to the corrective action plan.

18.2.8 CLOSING AN AUDIT

A. Follow-up action shall be taken by Quality Verification to verify that corrective actions are accomplished as scheduled according to the requirements of Section 16.0. Written notification of audit closure shall be provided upon verification that all corrective actions have been satisfactorily completed.

B. Audit records shall include audit plans, audit reports, Corrective Action Reports (if applicable), written replies and the record of completion of any required corrective actions. These documents are QA records and shall be formally submitted by Quality Verification to the DCS QA Records Center for retention according to the requirements of Section 17.0.

18.2.9 AUDIT TEAM QUALIFICATION REQUIREMENTS

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:

A. MPQAP orientation to provide a working knowledge and understanding of this document and implementing documents used to plan and perform audits, report audit results and close audits;

B. Training programs to provide general and specialized training in audit performance;

C. General training shall include the fundamentals, objectives and techniques of performing audits;

D. 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) addressed by corrective action requests; and/or

E. 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.

18.2.9.1 Technical Specialist Qualifications

A. 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.

B. Technical specialists shall also have verifiable evidence as meeting the requirements for education and experience as provided in this Section (minimum of five credits).

18.2.9.2 Auditor Qualifications

A. 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.

B. Auditors shall have verifiable evidence that the requirements for education and experience have been met as provided in this Section (minimum of eight credits).

C. Auditors shall be trained to the extent necessary to ensure their competence in auditing skills as established by Quality Verification. One or a combination of the following methods shall be used to develop competence:

1. Knowledge and understanding of this document and other program-related procedures, codes, standards, regulations and regulatory guides;

2. General structure of quality assurance programs as a whole and the specific elements of this document;

3. Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying, providing audit finding follow-up and closing corrective action items;

4. Audit planning in functional areas (such as siting, designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, statistics, nondestructive examination, maintaining, repairing, operating, modifying, decommissioning, and safety) of nuclear facilities; and/or

5. On-the-job training to include applicable elements of the audit program.

18.2.9.3 Lead Auditor Qualifications

A. Lead auditors shall be capable of organizing and directing audits, reporting audit findings and evaluating planned and taken corrective actions. Lead auditors shall be current with training and all lead auditor requirements.

B. Lead auditors shall have verifiable evidence and be certified that the requirements for education and experience have been met as provided in this Section (minimum of ten credits).

C. 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.

D. 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.

E. 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.

F. Upon satisfaction of all the above requirements, lead auditors shall be certified by the Quality Verification as being qualified to lead audits

G. Lead auditors shall maintain their proficiency through one or a combination of the following:

1. Regular and active participation in the audit process;

2. Review and study of codes, standards, implementing documents, instructions and other documents related to the DCS QA Program and program auditing; and/or

3. Participation in training programs.

H. Quality Verification management 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. Lead auditors who fail to maintain their proficiency for a two-year period shall require re-qualification to the requirements of this section for a lead auditor.

18.2.9.4 Non-DCS Auditor Qualifications

Non-DCS certified auditors may be used to perform audits and surveillances provided the DCS QA Manager confirms and documents all DCS QA requirements have been met and the individual has been certified in accordance with the implementing QA procedure on auditor qualification and certification.

18.2.10 EDUCATION AND EXPERIENCE

The following credits shall be assigned to each auditor or lead auditor candidate in evaluating and determining qualification and certification level for performing audits:

18.2.10.1 Education Requirements (Four Credits Maximum)

A. An associate degree from an accredited institution: score one credit. If the degree is in engineering, physical sciences, mathematics or quality assurance: score two credits; OR

B. A bachelors degree from an accredited institution: score two credits, OR if the degree is in engineering, physical sciences, mathematics or quality assurance: score three credits.

C. In addition, for a master's degree in engineering, physical sciences, business management or quality assurance from an accredited institution: score one credit.

18.2.10.2 Experience Requirements (Nine Credits Maximum)

A. 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: score one credit for each full year (maximum of five credits for this aspect of experience).

B. Additionally:

1. If two years of this experience have been in the nuclear-related field: score one additional credit; OR

2. If two years of this experience have been in quality assurance: score two additional credits; OR

3. If two years of this experience have been in auditing: score three additional credits; OR

4. If two years of this experience have been in nuclear-related quality assurance: score three additional credits; OR

5. If two years of this experience have been in nuclear-related quality assurance auditing: score four additional credits.

(Maximum of four credits for this aspect of experience.)

18.2.10.3 Professional Competence Qualifications (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: score two credits.

18.2.10.4 Rights Of Management Qualifications (Two Credits Maximum)

When determined appropriate by Quality Verification 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). Justification for these credits shall be attested to in writing by the candidate's management.

18.2.11 LEAD AUDITOR EXAMINATION

The development and administration of the examination for a lead auditor is the responsibility of Quality Verification. The test shall be oral, written, practical or any combination. Quality Verification shall:

A. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations.

B. Develop and maintain objective evidence regarding the type and content of the examination.

18.2.12 LEAD AUDITOR CERTIFICATION

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

A. Duke Cogema Stone & Webster 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. Signature of the Quality Verification Manager.