DUKE COGEMA
STONE & WEBSTER

Mr. William F. Kane, Director
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852-2738

29 January 2001
DCS-NRC-000035

Attention: Document Control Desk

Subject: Docket Number 070-03098
Duke Cogema Stone & Webster
Mixed Oxide (MOX) Fuel Fabrication Facility
Response to NRC Request for Additional Information on MOX Project Quality Assurance Plan (MPQAP) Revision 1 and Revision to MPQAP

Reference: Letter, Persinko to Hastings, 06 October 2000, "Acknowledgment for Acceptability of Review of Mixed Oxide Quality Assurance Plan and Request for Additional Information"

Dear Mr. Kane:

The referenced letter from your staff to Duke Cogema Stone & Webster (DCS) accepted DCS' Mixed Oxide Project Quality Assurance Plan (MPQAP) for review, and requested additional information associated therewith. Our responses to the NRC's questions are enclosed. These responses are reflected in Revision 2 of the MPQAP, 25 copies of which also are enclosed.

The MPQAP was originally submitted for your review in accordance with 10 CFR Part 70 in support of our pending request for construction authorization and eventual application for a license to possess and use special nuclear material. As you know, 10 CFR Part 70 requires satisfaction of criteria from 10 CFR Part 50 Appendix B for plutonium processing and fuel fabrication facilities [§§ 70.22(f) and 70.23(b)]. The results of the NRC review against these criteria, along with the addition of QA requirements associated with construction of the MFFF, are reflected in the revised MPQAP.

The revised MPQAP is being resubmitted in advance of our request for construction authorization to facilitate its timely review and acceptance for design and construction activities. As indicated in the enclosed plan, future updates to the MPQAP will address detailed operational requirements needed for the application for possession and use of special nuclear material for the facility.

PO Box 31847
Charlotte, NC 28231-1847

400 South Tryon Street, WC-32G
Charlotte, NC 28202

For your convenience, we also have enclosed a disk containing an electronic copy of the QA Plan (compiled in Adobe Acrobat format).

If you have any questions, please feel free to contact me at (704) 373-7820.

Sincerely,

Peter S. Hastings, P.E.
Licensing Manager

Enclosures:

(1) Response to NRC Request for Additional Information, MOX Project Quality Assurance Plan (MPQAP), Revision 1

(2) MPQAP, Revision 2 (25 copies)

(3) Compact Disk (1) containing MPQAP, Revision 2

xc (without enclosure):

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**Response to NRC Request for Additional Information**
**MOX Project Quality Assurance Plan (MPQAP), Revision 1**
**Letter Submittal dated June 22, 2000**
**Duke Cogema Stone & Webster (DCS)**
**Mixed Oxide Fuel Fabrication Facility**
**Docket: 70-3098**

**RAI Item 1:** The American Society of Mechanical Engineers (ASME) NQA-1-1994 (NQA-1), Basic Requirement 1, "Organization," requires that the organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. NQA-1, Basic Requirement 2, "Quality Assurance Program," requires that a documented QA program shall identify the activities and items to which it applies. Standard Review Plan (SRP) Section 15.1.4.3.A, "Organization," contains guidance for the applicant's description of the organizational structure and functional responsibilities, including principal contractors. The MPQAP Policy, Introduction, Section 1.0, "Organization," and Section 2, "QA Program," do not fully describe the organizational structure, functional responsibilities and activities to which the QA program applies. The MPQAP uses different functional and position titles without adequate identification or definition. It does not clearly identify who the actual MOX applicant will be. Clarify the authority of the DCS organization as an entity, its external interfaces, and to whom the DCS President & CEO/MOX Project Manager reports. The MPQAP sections require clarification to clearly show the overall DCS organization, the various functions, responsibilities, and internal and external interfaces, including all team members and major subcontracted functions. In particular, describe clearly how the SGN design and QA functions and organizations report to and interface with DCS and how SGN activities are controlled by the MPQAP.

**Item 1 Response:** Duke Cogema Stone & Webster (DCS) is the manager and licensee for the construction and operation of the MOX Fuel Fabrication Facility (MFFF). DCS Base Contract activities controlled by Revision 2 of the MPQAP include fuel qualification, design, and lead assembly fabrication; mission reactor modification identification and design, license amendment for use of MOX fuel, and lead assembly irradiation; and design and licensing of the MFFF. Option 1 (i.e., of the DOE-DCS contract) activities controlled by Revision 2 of the MPQAP include continuation of base contract fuel qualification activities, MFFF construction, and installation of mission reactor modifications. Revision 2 of the MPQAP contains the quality assurance requirements for both Base Contract and Option 1 activities.

Revision 2 of the MPQAP also details the organizational structure used to manage the MOX Project. Organizational management titles replace the "functional area" blocks in Figure 1.0-1 in Section 1, "Organization" for Base Contract and Option 1 activities. Management roles and responsibilities are summarized in Section 1.2, "Position Responsibilities," for each of the DCS managers and key Base Contract and Option 1 responsibilities for each manager are also noted in Figures 1.0-1 and 1.0-2. The organizational structure and responsibilities for the Quality Assurance organization are provided in new Figures 1.0-3 and 1.0-4 for Base Contract and Option 1 activities respectively. Managing the entire MOX Project for DCS is the DCS Project Manager who reports to the DCS Board of Governors. The members of the Board of Governors are corporate executives of the three corporate owners of Duke Cogema Stone & Webster (DCS), a Limited Liability Company (LLC), and Duke Power. The owners of the LLC are

Duke Engineering & Services, Cogema Inc., and Stone & Webster. The Project Manager also serves as President and Chief Executive Officer of DCS.

Subcontracted to DCS are:

> Framatome ANP, Inc. (formerly Framatome Cogema Fuels) for the design and qualification of the fuel;
>
> Nuclear Fuel Services (NFS) 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).

Additionally Cogema, Inc. has technical support subcontracts to:

> Electricité 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; and
>
> Packaging Technology, Inc. (PacTec) and Transnuclear, Inc. (TN) for fuel transportation package design and transportation integration.

MPQAP Section 2.1.2, "Use of Subcontractor QA Programs," identifies the applicable QA programs authorized for use. Contract scope assigned to Packaging Technology, Inc. (PacTec) and Transnuclear, Inc. (TN) for fuel transportation package design and transportation integration is managed by the DCS Deputy Project Manager – Technical & Project Integration. DCS coordination with Duke Power for irradiation services is managed by the DCS MOX Fuel Irradiation Manager. Framatome ANP fuel qualification activities are managed by the DCS Project Manager. SGN activities are managed by the Deputy Project Manager – MFFF Engineering and Construction.

Initially SGN was authorized to perform assigned design activities to their 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 review of the acceptability of the SGN QA Manual that verified application of 10CFR50, Appendix B QA controls on SGN nuclear design. Once DCS design engineering procedures were approved and issued, SGN personnel were trained to these procedures. All SGN design output documents for the APD were then 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. SGN process design activities for Final Preliminary Design (FPD) and presently being performed for Final Design are being performed to the DCS QA Program and its applicable implementing engineering procedures.

**MPQAP changes as a result of RAI Item 1:**

1. The 1st paragraph of the Quality Assurance Program Policy Statement has been revised to identify that Base Contract and Option 1 (construction) activities are controlled by Revision 2 of the MPQAP.
2. The first paragraph of the "Introduction" has been revised to state that DCS manages the DCS MOX Fuel Project and is the licensee for the construction and operation of the MFFF.
3. The "Introduction" has been revised in the section titled "DOE Mixed Oxide (MOX) Fuel Project" to include a note that states that this revision of the MPQAP covers the requirements for Base Contract and Option 1 quality affecting activities.
4. The "Introduction" has been revised in the section titled "Duke Cogema Stone & Webster (DCS)" to clarify the makeup of DCS and to better identify the contract assigned rolls and responsibilities for the major subcontractors to DCS and technical support contractors to Cogema, Inc.
5. The "Introduction" has been revised in the section titled "MOX Project Quality Assurance Plan (MPQAP)" 1st sentence to state that this plan as written establishes the QA requirements for both DCS Base Contract and Option 1 quality affecting activities.
6. Section 1.1, "General," through section 18.1, "General," for each of the 18 major sections of the MPQAP have been revised to include applicability of each section to Option 1 (construction) activities on the MOX Fuel Project.
7. All of section 1.2, "Position Responsibilities," has been revised to include Option 1 activities and to provide applicable specific roles and responsibilities for each DCS manager.
8. Section 1.2.1, Duke Cogema Stone & Webster (DCS) Project Manager in Section 1.0, "Organization," has been revised to include the reporting relationship of the DCS Project Manager to the DCS Board of Governors and the makeup of the DCS Board of Governors.
9. Section 1.2.4.4, MOX Fuel Qualification Manager," in Section 1.0, "Organization," was revised to better detail Base Contract responsibilities and state that the qualification program is managed as a scope of the Base Contract.
10. Section 1.3, "Organizational Interfaces," in Section 1.0, "Organization," has been revised to clarify that internal and external interfaces are documented in the appropriate plans, work task agreements, basic ordering agreements, subcontracts, and implementing procedures. This section also now includes a description of the interfaces between DCS and DOE and the NRC with regard to approval of the MPQAP.
11. Figure 1.0-1 of Section 1.0, "Organization," has been revised to reflect management titles for the Base Contract that match with the titles provided in section 1.2, "Position Responsibilities."
12. Figure 1.0-2 of Section 1.0, "Organization," has been added to identify the DCS organizational structure for Option 1 activities.
13. Figures 1.0-3 and 1.0-4 of Section 1.0, "Organization," have been added to identify the DCS QA organizational structure for Base Contract and Option 1 activities respectively.
14. Section 2.1.2, "Use of Subcontractor QA Programs" in Section 2.0, "Quality Assurance Program," was revised to clarify which project participants are authorized by DCS QA to use their QA program, and in the 1st paragraph at the top of page 4 of 9 of Section 2.0 to clarify how the work of SGN for MFFF process design is controlled under the DCS QA Program.

**RAI Item 2:** NQA-1, Basic Requirement 1, "Organization," states that persons or organizations responsible for QA program establishment and verification of quality affecting activities must not only have direct access to responsible management at a level where appropriate action can be effected, but also report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations. The QA function/QA manager reports to the Project & Technical Integration function/Executive Vice President, which is responsible for project scheduling, finance and accounting. The QA Manager's reporting level is also a level lower than that of the MFFF Manufacturing, Licensing and Engineering & Construction Managers. It is not clear from the current MPQAP narrative and DCS functional organization chart that the QA persons or organizations have the appropriate management reporting level and independence from cost and schedule considerations. This appropriate reporting level and independence must be assured and implemented accordingly, and be reflected in the MPQAP organization description and functional organization chart. Please clarify how the appropriate reporting level and independence of the QA organization and QA Manager is assured.

**Item 2 Response:** DCS concurs that the organization in Revision 1 of the MPQAP was misleading and did not accurately represent the access that the DCS Quality Assurance Manager has (and has had) to the Project Manager. Accordingly, the reporting of the DCS QA Manager and the DCS QA organization has been changed to report to the DCS Project Manager. This change codifies the QA Manager's direct access to the same level of management as the line organization, and provides organizational reporting in compliance with Basic Requirement 1, "Organization," of NQA-1-1994.

**MPQAP changes as a result of RAI Item 2:**

1. Section 1.2.1, "Duke Cogema Stone & Webster (DCS) Project Manager," in Section 1.0, "Organization," has been changed to show that the DCS QA Manager reports to the DCS Project Manager.
2. Section 1.2.2, "Deputy Project Manager –Technical and Project Integration," in Section 1.0, "Organization," has been changed removing the QA Manager from reporting to that position.
3. Section 1.2.4.2, "QA Manager," in Section 1.0, "Organization," 1st paragraph has been revised to show that this position reports to the DCS Project Manager.
4. Figure 1.0-1 in Section 1.0, "Organization," has been changed to reflect the reporting of the QA Manager to the DCS Project Manager.

**RAI Item 3:** SRP Section 15.1.4.3.C, "Applicant's Provisions for Continuing QA," identifies guidance for the applicant's provisions to review and updates based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA changes. Describe the DCS provisions for continuing QA, including notification of the NRC of changes in the implementation of the QA program from that described in the MPQAP. The MPQAP should include appropriate provisions for the resubmittal of the MPQAP for minor changes and for significant modifications, both prior to approval of a license and after.

**Item 3 Response:** The MPQAP is required to be updated and maintained as necessary to support project options (e.g., MFFF construction, operations, and deactivation). It is a living document that has to be revised for: changes in the phases of the project; changes as a result of

NRC review of the MPQAP for the Construction Authorization Request (CAR) and License Application; and changes in organization, regulatory commitments, work scope changes, or corrective actions that warrant changes to the DCS QA Program. Major and minor revisions to the MPQAP will be submitted to the NRC. These changes will be submitted to the NRC, either 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 will be submitted with written justification to the NRC for approval prior to implementation.

**MPQAP changes as a result of RAI Item 3:**

1. The 1st paragraph of the Quality Assurance Program Policy Statement has been revised to state that the MPQAP is a living document that shall be revised for each phase of the project.
2. The "Introduction" has been revised to include the last section titled "Provisions for Continuing QA." This section addresses how DCS will maintain the MPQAP and submit minor and major changes to the NRC, consistent with the discussion above.

**RAI Item 4:** SRP Section 15.1.4.3.D, "Management Measures," states that the applicant's QA program should describe how the applicable QA criteria contained in (SRP) Sections 15.2, 15.3, 15.4, 15.5, 15.6, 15.7, and 15.8 of this review plan will be met. Please describe how, and to what degree, the MPQAP, Revision 1, is intended to address these management measures. Also describe how the MPQAP will relate to or interface with the integrated safety assessment (ISA) summary, items relied on for safety (IROFS), and management measures. Clarify that the integrated safety analysis (ISA) is performed with appropriate QA program controls applied.

**Item 4 Response:** The "Management Measures" in SRP 15.1.4.3.D were not addressed in Revision 1 of the MPQAP as "Management Measures," yet the QA controls needed to ensure compliant application of these measures was contained in the applicable sections of the MPQAP. Revision 2 of the MPQAP now addresses these management measures and summarizes how each management measure implements the applicable MPQAP sections in order to achieve compliance with committed requirements (see the section titled "NUREG 1718 SRP Section 15 Management Measures" in the "Introduction" section of the MPQAP). The implementation of these management measures are used to ensure that principal SSCs (before completion of the ISA) and items relied on for safety (IROFS – confirmed by the ISA) are available and reliable in performing their designed functions. The ISA is controlled by these management controls as the MPQAP and its implementing procedures are used to develop, review, verify, approve, and control the design output documentation that provides the technical input for the ISA. The output of the ISA is controlled and documented; review comments are resolved; documents are internally approved, placed under document control, and maintained in the DCS Records Management System. Results are submitted in the Integrated Safety Assessment Summary.

**MPQAP changes as a result of RAI Item 4:**

1. The 1st paragraph of the "Quality Assurance Program Policy Statement" was revised to introduce the use of management measures to control DCS Base Contract and Option 1 activities.

2. MPQAP section titled "NUREG 1718 SRP Section 15 Management Measures" has been added to the "Introduction" addressing how the SRP management measures are implemented. Table I-1.0, "NUREG 1718 Management Measures," was added to list the applicable MPQAP sections that implement each management measure. This section also summarizes how each of the management measures implements the applicable requirements of the MPQAP.

**RAI Item 5:** MPQAP Section 2.2, "Graded QA," defines DCS quality levels QL-1 through QL-4; however, it does not describe the DCS methodology for classifying systems, structures, and components (SSCs) and their associated activities, and states that this methodology is detailed in the applicable QA procedure. Clarify the methodology for designation of quality levels and identify the methodology for application of QA controls to all SSCs, principal SSCs, and IROFS. Also clarify why QL-2 SSCs should not be considered IROFS. Please also describe how the DCS quality level definitions, methodology, and applications address the defense-in-depth requirement of 10 CFR Part 70. Note that SRP Section 15.1.4.3, "Regulatory Acceptance Criteria," contains guidance concerning graded QA. If DCS chooses to apply graded QA to SSCs, its QA Program should describe four essential elements of the graded QA process, including categorization of SSCs; identification of QA controls; feedback mechanisms; and reassessment of safety significance.

**Item 5 Response:**

DCS has provided more details in the MPQAP regarding general methodology for SSC classification (including updated quality levels) and grading (see section 2.2). Specific details of that methodology are being developed for detailed design as part of the applicable DCS QA procedures.

In general, the methodology for SSC categorization and subsequent QA classification involves determination of SSCs' fundamental functional safety requirements associated with the two primary safety functions for the facility: confinement and criticality control. This determination is based initially on traditional engineering (i.e., deterministic) methods. An SSC functional classification list has been prepared to reflect the results of this effort. This list reflects three fundamental levels of safety significance: SSCs that are or are anticipated to become Items Relied On For Safety (IROFS), SSCs that are not IROFS that nonetheless provide additional protection of or limit challenges to SSCs[1], and SSCs that perform neither of these functions. Risk-informing the SSCs' QA classifications will occur during detailed design and based in part on this risk information, SSCs will be graded accordingly.
This grading will be based on the safety significance of SSCs. The safety significance, as reflected in the SSC's QA classification (i.e., quality level), will determine which 10 CFR 50 Appendix B criteria apply to an SSC's design, construction, and operation. (Note that, additionally, within the framework of those controls, the functional requirements of the SSC, either as a result of deterministic evaluation or as a result of the conduct of the Integrated Safety Analysis [ISA], will determine the need for an SSC to be redundant, isolated, separated, supported by emergency power, seismically restrained, etc.)

[1] Note that, while this description (which, as will be discussed later, is associated with *QL-2* SSCs) is consistent with the 10 CFR §70.64(b) discussion of *defense-in-depth*, and these SSCs in fact afford a similar type of protection, they are referred to as *additional protection features* to avoid the perception that they are credited with specific performance in the ISA. These SSCs are not intended or expected to become IROFS.

The methodology for applying 10 CFR 50 Appendix B criteria is being documented in a DCS procedure for use during detailed design and currently under development/review.

DCS' Quality Level 1 (QL-1) is identical to 10 CFR 70's definition of IROFS; that is, the highest QA classification is reserved for those SSCs that are required to demonstrate performance requirements of 10 CFR §70.61. QL-2 includes SSCs that are not (or not expected to be) credited in the ISA for meeting these performance requirements, but which nonetheless are important enough to warrant inclusion in the QA program. These include SSCs that may limit risk to IROFS, or SSCs required to demonstrate compliance with other regulatory requirements. This is an elective application of the QA program, and because QL-1 SSCs are by definition IROFS (and vice versa), then including QL-2 SSCs as IROFS is neither necessary nor prudent.

The version of the QA classification procedure in force at the time of Revisions 0 and 1 of the MPQAP described QLs-1, -2, -3, and -4. This procedure presumed that all IROFS (QL-1 SSCs) would require application of all 10 CFR 50 Appendix B criteria, unless justification was provided (on a case-by-case basis). A revision to this procedure currently under review provides for grading of QL-1 SSCs based on their safety significance within the IROFS category as measured by an accident's sensitivity to the failure of that SSC.

Simply speaking, IROFS which are the single SSC preventing or mitigating a postulated confinement or criticality accident are defined as QL-1a and (by default) all 10 CFR 50 Appendix B criteria will continue to apply to these SSCs, except where justified on a case-by-case basis (e.g., in SSC-specific grading analyses).

Other QL-1 SSCs are credited (or expected to be credited) in the ISA, but their failure would constitute a loss of only one of two or more such protection features. DCS QA procedures will provide a certain predetermined set of 10 CFR 50 Appendix B criteria that are not applicable – or rather, require no justification to consider inapplicable – to these SSCs (to be designated QL-1b). These include criticality controls which are one of a pair of double contingency features, and controls whose sole function is worker protection, to which programmatic controls, operator training, and self-protection assumptions apply. (Note that the graded QL-1 approach does not preclude application of additional criteria, where determined necessary by the ISA.)

The definition of QL-2 SSCs has been clarified in the MPQAP. QL-2 SSCs are not IROFS and are not required to meet 10 CFR 70.61 performance requirements. However, QL-2 SSCs support normal operations of the facility (e.g., occupational exposure, radioactive waste management) and also function to further reduce public, worker, and environmental risks (e.g., physical interaction protection, radiological and criticality alarms). These SSCs have selected (graded) QA controls applied to the extent they are needed consistent with their intended function.

QL-3 SSCs are only internally subject to QA controls, and are not intended to be subject to NRC oversight or enforcement. They are defined based on financial or facility performance (e.g., throughput) considerations. QL-4 SSCs are simply those that are not defined as QL-1, -2, or -3, are subject only to conventional quality, and are similarly not intended to be subject to

NRC oversight or enforcement (QL-4 was selected as a label – for completeness – in lieu of "non-Q").

DCS' classification and grading definitions, methodology, and applications support the concept of defense-in-depth in several ways. The graded quality levels focus the most rigorous set of QA controls on those SSCs with the greatest safety significance. The definitions also recognize the importance of providing multiple layers of control, by providing for grading primarily when at least two such sets of IROFS controls exist, or when the SSC's function is not IROFS. Further emphasis on the importance of defense-in-depth is demonstrated through the allocation of "safety significance" – as indicated by the applicability of the QA program – not only to IROFS, but also to certain SSCs that are not IROFS.

Discussion of feedback mechanisms and reassessment of safety significance has also been added to the MPQAP.

**MPQAP changes as a result of RAI Item 5:**

1. The 1st paragraph of the "Quality Assurance Program Policy Statement" was revised to limit the applicability of "quality affecting activities" to Quality Level 1 and 2 SSCs only.
2. The 2nd paragraph of section titled "MOX Project Quality Assurance Plan (MPQAP)" in the "Introduction" was revised to limit the applicability of the MPQAP to Quality Level 1 and 2 SSCs.
3. Section 2.1.1, Program Basis, 2nd paragraph revised the definition of "quality affecting" to be limited to Quality Level 1 and 2 SSCs only.
4. MPQAP section 2.2, "Graded Quality Assurance," was entirely revised to include expanded definitions of the Quality Levels and to describe the methodology for determining quality level categorization, identification of needed QA controls for each quality level, feedback mechanisms, and reassessment of safety significance.

**RAI Item 6:** The SRP was published after your MPQAP was submitted. A number of changes to the QA subchapter were made, including changes to review criteria for NQA-1-1995a, Regulatory Guide 1.28, "QA Program Requirements (Design and Construction)," and graded QA. DCS should review the MPQAP to update and clarify the requirements in these areas. In particular, the MPQAP should be reviewed in comparison to the SRP guidance, NQA-1, and 10 CFR Part 21 requirements for reporting of defects and noncompliance.

**Item 6 Response:** The MPQAP was reviewed against NUREG 1718 SRP Section 15.1 Quality Assurance, NQA-1-1995a, Regulatory Guide 1.28, and 10 CFR Part 21 for needed changes to ensure compliance of the MPQAP with committed requirements. For each of the applicable 18 sections of the MPQAP, the "X.1 General" section was appropriately revised to include references to the applicable committed standards that affected that section. Additional quality assurance requirements imposed by these QA standards were added to the text of the applicable sections.

**MPQAP changes as a result of RAI Item 6:**

1. The 1st paragraph of the "Quality Assurance Program Policy Statement" was revised to add the following to the basis of the MPQAP: ASME NQA-1a-1995 Addenda and Regulatory Guide 1.28 (Rev.3).
2. The 1st paragraph of section titled "MOX Project Quality Assurance Plan (MPQAP)" in the "Introduction" was revised to add ASME NQA-1a-1995 Addenda and Regulatory Guide 1.28 (Rev.3) to the statement of what requirements the MPQAP meets.
3. Section 2.1, General," of Section 2, "Quality Assurance Program," was revised to include ASME NQA-1a-1995 Addenda and Regulatory Guide 1.28 (Rev.3) being applicable to the Base Contract and Option 1 workscope controlled by Section 2. Also added Appendix 2A-1of NQA-1-1994 Part I as being applicable with a footnote that RG1.28 (Rev.3) requires that NQA-1-1983 version of the appendix be used and DCS has compared this with the NQA-1-1994 version and found no lessening of requirements. DCS elects to use the later version to be consistent with using the NQA-1-1994 standard.
4. Section 2.1, "General," of Section 2, "Quality Assurance Program," was revised to include list of applicable NQA-1-1994 Part II subparts.
5. Section 2.6, "Qualification/Certification of Inspection and Test Personnel," if Section 2, "Quality Assurance Program," was revised to include applicability of Appendix 2A-1.
6. Section 3.1, "General," of Section 3, "Design Control," was revised to include applicability of NQA-1a-1995.
7. Section 3.2.3.D of Section 3, "Design Control," was revised to include applicability of NQA-1a-1995.
8. Sections 3.2.7.C.3 (d) & (e), 3.2.7.C.5 (e), 3.2.7.G.1, and 3.2.7.G.3 & 4 of Section 3, "Design Control," had text added from NQA-1-1a-1995 for software design and documentation.
9. Sections 4.2.1.C.2 of Section 4, "Procurement Document Control," was revised to include 10 CFR Part 21 requirements.
10. Section 7.1, "General," of Section 7, "Control of Purchased Material, Equipment and Services," was revised to include applicability of NQA-1a-1995 and Regulatory Guide 1.28 (Rev.3).
11. Sections 7.2.12 A & C.4 of Section 7, "Control of Purchased Material, Equipment and Services," had text added from NQA-1a-1995 for commercial grade items.
12. Section 7.3, Approved Suppliers List," of Section 7, "Control of Purchased Material, Equipment and Services," was added to detail requirements for control of the approved suppliers list and to address the frequency of evaluations from Regulatory Guide 1.28 (Rev.3).
13. Section 8.1, "General," of Section 8, "Identification and Control of Material, Parts and Components," was revised to include applicability of NQA-1a-1995.
14. Section 9.2.3, "Qualification of Nondestructive Examination Personnel," of Section 9, "Control of Special Processes," was revised to replace "eddy current" with "electromagnetic" in order to stay inline with terminology used in NQA-1a-1995 Supplement 2S-2.
15. Section 16.2.1.2.D in Section 16, "Corrective Action," was revised to allow supplier's to report 10 CFR Part 21 items to DCS for determination of reportability if the supplier is unable to determine if the item is a substantial safety hazard.
16. Section 17.1, "General," of Section 17, "Quality Assurance Records," was revised to include applicability of Regulatory Guide 1.28 (Rev.3).

17. Section 17.2.2.1.B 2nd paragraph of Section 17, "Quality Assurance Records," was revised to add retention requirements for non-permanent records from Regulatory Guide 1.28 (Rev.3).
18. Section 18.1, "General," of Section 18, "Audits," was revised to include applicability of NQA-1a-1995 and Regulatory Guide 1.28 (Rev.3).
19. Section 18.2.1.A of Section 18, "Audits," was revised to reflect Regulatory Guide 1.28 (Rev.3) requirements for scheduling audits.
20. Section 18.2.9.2.C.4 of Section 18, "Audits," was revised to add details from NQA-1a-1995 Supplement 2S-3.

**RAI Item 7:** The scope and applicability of the MPQAP is described in various areas, including Policy, Introduction, Section 1.0, "Organization," and Section 2, "QA Program." Clarify that the MPQAP scope includes all IROFS, and that this scope includes not only principal SSCs, but all items and activities determined to be relied upon for safety. Such items include not only structures, systems, and components but also materials (including consumable materials), parts, measuring and test equipment, computers, and computer programs (software and firmware), as appropriate.

**Item 7 Response:** The MPQAP applies to all Quality Level 1 (IROFS – Items Relied on for Safety) and Quality Level 2 structures, systems and components (SSCs) and their associated activities as defined in section 2.2, "Graded Quality Assurance," in Section 2, "Quality Assurance Program." Applicability to IROFS also includes "principal SSCs" as these are SSCs that have a high potential of being credited in the ISA as demonstrating compliance with 10 CFR §70.61 requirements.

**MPQAP changes as a result of RAI Item 7:**

1. The 1st paragraph of the "Quality Assurance Program Policy Statement" was revised to limit the applicability of the MPQAP to Quality Level 1 and 2 SSCs only.
2. The 2nd paragraph of section titled "MOX Project Quality Assurance Plan (MPQAP)" in the "Introduction" was revised to limit the applicability of the MPQAP to Quality Level 1 and 2 SSCs.
3. The 2nd paragraph of section titled "MOX Project Quality Assurance Plan (MPQAP)" in the "Introduction" was revised to state that the MPQAP also applies to materials, parts, components, measuring and test equipment and computer software and hardware associated with principle SSCs and IROFS.
4. Section 2.1.1, Program Basis, 2nd paragraph revised the definition of "quality affecting" to be limited to Quality Level 1 and 2 SSCs only.
5. MPQAP section 2.3, "Graded Quality Assurance," was entirely revised to include expanded definitions of the Quality Levels and to describe the methodology for determining quality level categorization, identification of needed QA controls for each quality level, feedback mechanisms, and reassessment of safety significance.

**RAI Item 8:** MPQAP Section 2.1.1, "Program Basis," last sentence on page 1 of 5, states that "To the extent necessary, requirements contained in this MPQAP are also invoked on all DCS subcontractors. Clarify what is intended by "to the extent necessary," and what QA program requirements are applied to subcontractors.

**Item 8 Response:** The MPQAP applies to all levels of the DCS organization, including subcontractors, who perform quality affecting activities. The use of the phrase "to the extent necessary" was not clear for the intent of the sentence. What was meant at the time Revision 0 and 1 were issued for the design phase of the MFFF was that "applicable" requirements would be invoked on all DCS subcontractors based on their assigned scope of work. As an example, for process design activities, the requirements of Section 13, "Handling, Storage and Shipping," would not be necessary. Only those requirements needed to control design activities would be necessary. This ambiguous wording has been corrected in section 2.1.1 of the revised MPQAP.

**MPQAP changes as a result of RAI Item 8:**

1. The NOTE in the section titled "DOE Mixed Oxide (MOX) Fuel Project" in the "Introduction" was added to stress that requirements apply as appropriate to ensure installed SSCs are available and reliable to perform their intended function.
2. 5th paragraph in Section 2.1.1, "Program Basis" in Section 2, "Quality Assurance Program," was revised to state "Applicable QA requirements contained in this MPQAP are also invoked on DCS subcontractors for their contracted scope of work.

**RAI Item 9:** MPQAP Section 2.1.1, "Program Basis," third paragraph, fifth sentence states "Although all 18 criteria will not be fully implemented during the base contract..." Clarify the intent of this wording and that DCS will apply all applicable QA criteria for all appropriate activities.

**Item 9 Response:** DCS will apply all 18 criteria of the MPQAP for Base Contract and Option 1 activities as appropriate for the particular scope of work. The intent at the time Revisions 0 and 1 were issued was to indicate that not all18 criteria would be required for the Base Contract. The ambiguous wording has been corrected in Revision 2 to the MPQAP.

**MPQAP change as a result of RAI Item 9:**

1. 3rd paragraph in Section 2.1.1, "Program Basis" in Section 2, "Quality Assurance Program," was revised to delete the referenced first part of the sentence. It now simply states "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."

**RAI Item 10:** MPQAP Section 2.1.2, "Use of Subcontractor QA Programs," first sentence of last paragraph, notes the requirement that the DCS QA Manager be kept apprised of changes to other DCS team members' QA plans via controlled distribution prior to implementation. Clarify how this is accomplished and how it assures effective control of QA programs.

**Item 10 Response:**

The DCS QA Manager keeps apprised of subcontractors' use of their QA programs through frequent audits of subcontractor activities to access compliant implementation and effectiveness of their authorized QA programs for use on assigned DCS Base Contract and Option 1 workscope. The DCS QA Manager's review of controlled copies of subcontractors' QA plans does not necessarily result in complete evaluation of performance for compliance with project requirements. The use of audits also affords evaluation of QA plans and procedures in use, as

well as providing the opportunity for evaluation of effective implementation. This point has been clarified in the revised MPQAP.

**MPQAP change as a result of RAI Item 10:**

1. Last paragraph in Section 2.1.2, "Use of Subcontractor QA Programs," in Section 2, "Quality Assurance Program," was entirely revised to state "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."

**RAI Item 11:** MPQAP Section 2.3, "QA Training," states that "QA training is provided to all personnel performing quality affecting activities as determined by supervision." Clarify what is intended by "as determined by supervision," and identify why this is not determined by management or procedure.

**Item 11 Response:**

The referenced MPQAP section in Revision 1 was intended to mean that each supervisor would determine what training was needed for each of his or her employees based on assigned duties. All personnel would get QA Indoctrination Training in accordance with the applicable project procedure on training and then each employee would get training in the specific project procedures needed for their assigned position. For clarification, the paragraph has been revised to require training on job-specific project procedures, as assigned by the cognizant supervisor responsible for identification and oversight of efforts needed to carry out each assignment. The applicable QA project procedure requires the applicable manager or supervisor of DCS personnel doing quality affecting work to designate the required training and determine if the training is conducted by classroom training, self-study, or in a briefing.

**MPQAP changes as a result of RAI Item 11:**

1. 1st paragraph in section 2.3, "Quality Assurance Training," in Section 2, "Quality Assurance Program," was revised to delete the referenced sentence.
2. 1st paragraph in section 2.3, "Quality Assurance Training," in Section 2, "Quality Assurance Program," was also revised to include the following: "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."

**RAI Item 12:** NQA-1, Supplement 2S-2, "Supplementary Requirements for the Qualification of NDE Personnel," Section 2.3 requires that the records of personnel qualification be established and maintained. Clarify that the MPQAP incorporates this requirement.

**Item 12 Response:**

Originally section 2.5, "Qualification/Certification of Nondestructive Examination (NDE) Personnel," of Section 2, "Quality Assurance Program," made no reference to Supplement 2S-2; however, section 2.1, "General," did commit to implementing this supplement. Section 2.5 did

invoke ASNT Recommended Practice SNT-TC-1A (December 1988 Edition) as required by the supplement, yet there was no mention of maintaining certification records for NDE personnel. Section 2.5 of the MPQAP has been revised to meet Supplement 2S-2 requirements, including records requirements.

**MPQAP change as a result of RAI Item 12:**

1. Section 2.5, "Qualification/Certification of Nondestructive Examination (NDE) Personnel," of Section 2, "Quality Assurance Program," was revised to commit to meeting NQA-1a-1995 Part 1 Supplement 2S-2, "Supplementary Requirements for the Qualification of NDE Personnel," including records requirements.

**RAI Item 13:** MPQAP Section 3.2.4, "Design Verification," states that design verification is required by QL-1 IROFS. Clarify why design verification is not required for other Quality Level SSCs and how DCS assures the proper classification of these SSCs without verification.

**Item 13 Response:**

Section 3.2.4, "Design Verification," of Section 3, "Design Control," requires design verification for Quality Level 1 (IROFS) SSCs. The use of design verification only for IROFS is consistent with industry practice (e.g., at commercial reactors, where safety-related SSCs undergo design verification but SSCs that are not safety-related do not, as their safety significance is of lesser or no concern with regard to nuclear safety). In the case of the MFFF, SSCs that are classified as QL-2 (and QL-3 and -4) are not IROFS and are not required to meet 10 CFR 70.61 performance requirements; therefore a graded approach to checking the validity and completeness of their design is appropriate and consistent with industry practice.

Design verification is not the mechanism used to determine or validate the proper classification of SSCs. The methodology used by DCS for initial SSC categorization and subsequent QA classification involved a deterministic approach based on review of applicable regulations and MELOX and La Hague experience; all SSCs were identified at the functional level as IROFS (or potential IROFS) or designated as Quality Level 2, 3 or 4. This initial categorization involved all SSCs and is documented in the Functional Classification List in the Design Requirements Document, which underwent review and approval under DCS QA procedures. The Integrated Safety Analysis (ISA) will then compare the SSCs with their functions and postulated events with established criteria. The ISA will evaluate all SSCs for potential inclusion as IROFS. Further, for programmatic efficiency, DCS conducts design of all SSCs (including QL-2, -3,
and -4) in accordance with the same QA procedures (even though QL-3 and -4 SSCs are not subject to the QA program), which includes review and approval of SSC classifications. Section 2.2, "Graded Quality Assurance," has been revised to better detail this process.

**MPQAP change as a result of RAI Item 13:**

1. Section 2.2, Graded Quality Assurance," in Section 2, "Quality Assurance Program," is revised in response to RAI item 5 to better describe the process DCS uses to categorize Quality Levels and determine the applicable controls from the DCS MPQAP that are needed to ensure MFFF SSCs are reliable and perform their intended functions.

**RAI Item 14:** In MPQAP Sections 1.0, "Organization;" 4.0, "Procurement Document Control;" and 7.0, "Control of Purchased Material, Equipment, and Services, " clarify the organizational responsibilities for the various procurement activities covered by Section 4.0 and 7.0. In particular, clarify the project and QA management responsibilities for preparing and controlling the Approved Suppliers List (ASL), supplier selection, procurement document preparation and approval, bid evaluation, review of supplier-generated documents, acceptability of items in-work, delivered items and services (activities), resolution of supplier nonconformances and procurement and supplier records. Also describe QA, design engineering, and procurement organization interactions for controlling these activities. DCS should also review MPQAP Section 7.0 and clarify that it appropriately incorporates all applicable NQA-1 QA controls for procurement of commercial grade items and services.

**Item 14 Response:** The required actions to implement the DCS procurement process for quality affecting procurements for services for MFFF design, and items and services for construction of the MFFF, and for the balance of the MOX Fuel Project are performed by several different functional areas within the DCS organization according to their assigned project responsibilities.

DCS' MFFF engineering organization identifies in the final design of the MFFF the structures, systems and components needed to construct the facility. Engineering develops the procurement specifications to the applicable requirements of Section 3, "Design Control," Section 4, "Procurement Document Control" and Section 7, "Control of Purchased Material, Equipment and Services" for needed equipment and materials to construct the facility. Procurement of items and services for the balance of the MOX Fuel Project are also initiated by the responsible functional area manager to the requirements of sections 4 and 7 of the MPQAP.

For Quality Level 1 (IROFS) and Quality Level 2 procurements, the DCS QA organization reviews the procurement specifications for appropriate identification of QA requirements.

The DCS Procurement Manager manages the planning and execution of the procurement proposal process according to the requirements of Section 7 and the applicable procurement QA procedure. The Procurement Manager identifies for all Quality Level 1 procurements and for selected Quality Level 2 procurements the potential suppliers that are to be evaluated by QA for compliance with 10 CFR 50 Appendix B requirements.

Potential suppliers of Quality Level 1 (IROFS) and management selected Quality Level 2 services or items are evaluated at the supplier's facility by the DCS QA organization in accordance with section 7.2.2, "Source Evaluation and Selection" and the applicable QA supplier evaluation procedure. DCS QA coordinates with the suppliers on resolving any problems identified during the supplier evaluation. Suppliers that meet the applicable requirements are placed by DCS QA on the DCS Approved Suppliers List (ASL) prior to contract award. The ASL is maintained by DCS QA in accordance with section 7.3, "Approved Supplier List," and the applicable QA supplier evaluation procedure.

The Procurement Manager manages the proposal/bid evaluation process in accordance with Section 7.2.3, "Proposal/Bid Evaluation" and evaluates – with support from technical and QA personnel as appropriate – whether the proposal/bid meets procurement document requirements.

Once supplier selection is made, the Procurement Manager manages the generation of the contract and purchase order to the selected supplier in accordance with the requirements of the applicable QA procurement procedure. The manager responsible for the item or service being procured, the Procurement Manager, and the QA Manager are required to approve the procurement requisition.

The appropriate technical manager (e.g., MFFF Engineering for design of the MFFF) and DCS QA review and approve the disposition of any supplier-generated nonconformances that are identified by the supplier during performance of the contract in accordance with the requirements of section 7.2.11, "Control of Supplier Nonconformances" and implementing QA procedures. This review will result in acceptance or rejection of the supplier's recommended disposition to "use-as-is, repair, or discard" the item. DCS QA performs all required QA hold points and the procuring organization performs all technical hold points during manufacturing that are identified in the procurement documents issued to the supplier. DCS QA performs any required source inspections at the supplier's facility prior to shipment.

Procured QL-1 and QL-2 items are also received at the MFFF in accordance with the applicable QA receiving inspection procedures. MFFF Engineering and Construction and QA approve all required supplier generated documents in accordance with the applicable QA procedures ensuring that procurement document requirements have been met. Receiving inspections and required QA documentation for the procurement are maintained in the DCS Records Management System in accordance with the requirements of Section 17, "Quality Assurance Records."

Commercial grade items may be used for Quality Level 1 (IROFS) items provided the requirements of section 7.2.12, "Commercial Grade Items (For IROFS Only)" are met. These requirements include the applicable requirements of NQA-1a-1995.

**MPQAP changes as a result of RAI Item 14:**

1. Section 1.2.2.3, "Procurement Manager," was added as a new position reporting directly to the Deputy Project Manager – Technical and Project Integration in Section 1, "Organization." This organizational change was to elevate the importance of this activity to the project.
2. Section 7.2.2.B of Section 7, "Control of Purchased Material, Equipment and Services," was revised to include reference to section 7.3, "Approved Supplier List."
3. Sections 7.2.4.A and 7.2.11 of Section 7, "Control of Purchased Material, Equipment and Services," was revised to indicate Procurement Manager actions.
4. Section 7.2.12 "Commercial Grade Items (For IROFS Only)" was revised to reflect requirements from NQA-1a-1995.
5. Added section 7.3, "Approved Supplier List," to Section 7, "Control of Purchased Material, Equipment and Services.

**RAI Item 15:** Clarify the function and applicability of the Problem Investigation Process referred to in MPQAP Section 5.2.4.B.

**Item 15 Response:** This was an incorrect reference that has been corrected. The correct reference is the DCS Corrective Action Process that is described in Section 16, "Corrective

Action." The term "Problem Investigation Process" was taken from the current automated, online Duke Power process presently in use at Duke's nuclear stations. This sophisticated database program is not warranted at this time for the MFFF but maybe employed at a later date. Any such change would not require a change to the MPQAP but would require a change to the applicable implementing procedure.

**MPQAP change as a result of RAI Item 15:**

1. Section 5.2.4.B in Section 5, "Instructions, Drawings and Procedures," was revised to delete the reference to "Problem Investigation Process" and replace it with "DCS Corrective Action Process – see Section 16.0)."

**RAI Item 16:** MPQAP Section 6.0, "Document Control," states that this section and associated QA procedures implement the committed requirements for document control, but the types of documents controlled and the DCS document control methods and system are not identified. Clarify whether a master list or equivalent, updated and distributed to predetermined personnel in a timely manner, has been established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. Describe the DCS document control system or features such as a master list or equivalent, and the major types of document controlled, including instructions, procedures, and drawings. Identify and describe the key aspects of the DCS document hierarchy.

**Item 16 Response:** DCS QA documents (such as the MPQAP and implementing QA procedures) and engineering documents (such as the Design Requirements Document, Basis of Design Documents, SSC/Program Description Documents, and design output documents) specifying applicable technical and/or quality requirements, are controlled in accordance with the DCS document control system. For MFFF design, the DCS quality affecting document hierarchy controlled under the DCS QA Program include: the MPQAP; implementing project QA procedures controlling design activities; the Design Requirements Document; Basis of Design Documents; SSC/Program Descriptions; and design output documents (engineering specifications, drawings, calculations, procurement documents, and documents that need to be controlled due to being input to other DCS design documents or used for procurement, manufacturing and construction.)

DCS Document Control distributes all DCS quality affecting documents whose use requires hard copy distribution. 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 the 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. Documents needing to be placed under document control are transmitted by the responsible organization for the documents to DCS Document Control with the distribution list for hard copy document holders. Document Control enters the document into the Document Control Electronic Data Management System (EDMS) and the master list of controlled documents, makes the required copies, assigns document control numbers, completes transmittal forms, and

mails the documents and transmittal form to the document holders. (The copy placed in EDMS is also the official record copy of the document). Document holders acknowledge receipt on the transmittal and send the acknowledgement to DCS Document Control. The master list is used to identify current revision numbers for all controlled documents and the distribution list is maintained and used to distribute subsequent revisions of controlled documents to the document holders.

**MPQAP changes as a result of RAI Item 16:**

1. 2nd paragraph of section 6.1, "General," of Section 6, "Document Control," was revised to expand the discussion on describing all the elements involved in controlling the distribution of documents.
2. Section 6.2.1, "Types of Documents," of Section 6, "Document Control," was revised to list the types of documents that are controlled by DCS.
3. Section 6.2.3, "Reviewing Documents," of Section 6, "Document Control," was revised to state that reviews would be performed in accordance with the applicable QA procedures.
4. Section 6.2.5, "Controlling the Distribution and Use of Documents," of Section 6, "Document Control," was revised to include an expanded discussion of the necessary actions to control distribution of controlled documents to the work location.
5. Section 6.2.6.E of Section 6, "Document Control," was revised to require DCS QA to maintain document history files for QA procedures. The responsible organization for other quality affecting controlled documents are responsible for maintaining the associated document history files for those documents.

**RAI Item 17:** NQA-1, Basic Requirement 9, "Control of Processes," and Supplement 9S-1, "Supplementary Requirements for Control of Processes," have requirements for control of processes (not just special processes) affecting quality that do not appear to be in the MPQAP. Clarify how these requirements are addressed. Note that these requirements could be addressed under MPQAP Section 9.0 or Section 5.0, "Instructions, Drawings and Procedures."

**Item 17 Response:** Although all quality affecting activities are required to be controlled by procedures meeting the requirements of Section 5.0, "Instructions, Drawings and Procedures," there was no reference to how DCS controls processes other than special processes in Section 9, "Control of Special Processes." Work control is an example of such a process. This oversight has been corrected in Sections 9.1, "General" of Section 9, "Control of Special Processes," and 5.2.1, "Types of Implementing Documents," of Section 5.0, "Instructions, Drawings and Procedures."

**MPQAP changes as a result of RAI Item 17:**

1. Section 5.2.1, "Types of Implementing Documents," in Section 5, "Instructions, Drawings and Procedures," was revised to address work control processes and applicable control documents.
2. 2nd paragraph of section 9.1, "General," in Section 9, "Control of Special Processes," was revised to address how processes other than "special processes" are controlled. Paragraph was also changed to reference Section 5, "Instructions, Drawings and Procedures," as location for content and generation of procedures controlling these processes.