

October 1, 2001

Mr. Peter Hastings, Licensing Manager
Duke Cogema Stone & Webster
P.O. Box 31847
Charlotte, NC 28231-1847

**SUBJECT: DUKE COGEMA STONE & WEBSTER QUALITY ASSURANCE PROGRAM FOR
CONSTRUCTION OF THE MOX FUEL FABRICATION FACILITY**

Dear Mr. Hastings:

We have completed the technical review of the Duke Cogema Stone & Webster (DCS) Mixed Oxide (MOX) Project Quality Assurance Plan (MPQAP), Revision 1, submitted by letter dated June 22, 2000, and Revision 2, submitted by letter dated January 29, 2001. The enclosed Safety Evaluation Report (SER) approves MPQAP, Revision 2, which describes the DCS quality assurance (QA) program for construction activities, including design, procurement and fabrication, for the proposed MOX Fuel Fabrication Facility (MFFF). Subsequent revision(s) of the MPQAP, to be submitted in support of the 2002 application for a 10 CFR Part 70 license for the MFFF, will address startup testing and operation. Consequently, the SER approval of the MPQAP covers only construction activities, including design, procurement and fabrication.

Our technical review was based on NUREG-1718, "Standard Review Plan (SRP) for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," dated August 2000. The staff review of the MPQAP, Revision 2, included the methods, process and criteria for implementing graded quality assurance, categorization of, and definitions for Quality Levels, and identification of QA controls for structures, systems, and components (SSCs). By approving Revision 2 of the MPQAP, the staff is not making any conclusion as to Quality Level categorization or the applicability of graded QA controls for any specific SSC mentioned or referenced in the MPQAP.

The draft SER forwarded to you by letter dated August 17, 2001, noted that the MPQAP, Revision 2 was acceptable for construction-related activities with the exception of two issues. These issues related to the applicability of the QA program to all SSCs and to the grading of QA controls. DCS provided clarification and commitments regarding these two issues by letter dated September 4, 2001, as summarized below.

The first issue pertained to the paragraph on page 1 of 6 of the Introduction Section of the MPQAP that begins with the words "For MFFF design during..." which was not acceptable to the staff in that it indicated that the MPQAP requirements for design and construction apply to only principal SSCs prior to completion of the Integrated Safety Analysis (ISA), and items relied on for safety (IROFS) after completion of the ISA. DCS, in its response to the draft SER, clarified the applicability of the MPQAP to all SSCs, and committed to revising this section to make it clear

that all applicable QA requirements apply to Quality Level 2 SSCs, and that all applicable QA requirements, in particular, design and configuration control, among others, apply to all SSCs.

The second issue pertained to the MPQAP, Revision 2 description for graded application of QA controls to QL-1 SSCs/IROFS, contained in Sections 2.2, "Graded Quality Assurance" (GQA), and 2.2.2, "Identification of QA Controls," which was not acceptable to the staff, as it did not adequately define the process for identifying the SSC functions and characteristics relied on for safety and did not adequately identify the criteria and methods for applying specific GQA controls to individual and/or types of SSCs. DCS, in its September 4, 2001, response to the draft SER, clarified the process by which the SSC functional requirements are identified and stated the criteria for grading the MPQAP requirements that are associated with the 18 criteria of Appendix B. The DCS response identified the process for assignment of SSC Quality Levels commensurate with the SSC function and safety significance. It presented the process and the basis for application of GQA controls to adequately identify clear, definite, supportable, and verifiable methods, criteria and standards of performance. The DCS response also specifically stated that the applications of QA controls must be sufficient to reasonably ensure the design integrity and ability of the SSC to successfully perform its safety function. The DCS response presented an adequate definition of the process, methods, and criteria for identifying the SSC functional requirements and grading of QA controls. DCS also committed to revising the MPQAP to incorporate the process, methods and criteria for determining SSCs safety functions, safety significance, and the GQA controls to be applied to specific SSCs, as stated in the September 4, 2001, response. The DCS response and its commitment to revise the MPQAP are adequate and resolve the two issues with the MPQAP, Revision 2.

The staff has determined that the MPQAP, Revision 2, with the DCS clarifications and commitments in response to Nuclear Regulatory Commission (NRC) Requests for Additional Information (RAIs) and the draft SER, is acceptable for application to the construction of the MFFF, including design, procurement, and fabrication of the SSCs for the MFFF. For the reasons discussed in the attached SER, the NRC staff concludes that DCS has adequately described its QA program, and that this program meets the requirements of 10 CFR Part 50, Appendix B. The staff therefore finds, pursuant to 10 CFR 70.23(b), that the DCS QA program, as applied to the SSCs of the MFFF, will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The scope of this finding pertains to the construction of the MFFF's SSCs, and includes all related design, procurement and fabrication activities, but does not include any start-up testing or operation of the MFFF. In this regard it should be noted that MPQAP Section 12, "Test Control," is acceptable for construction activities, but has not been reviewed for acceptability for start-up testing.

P. Hastings

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If you have any questions regarding this letter or the enclosed SER, please contact me at (301) 415-6522, or Wilkins Smith at (301) 415-5788.

Sincerely,

/RA/

Andrew Persinko, Project Manager
Enrichment Section
Special Projects Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-3098

Enclosure:
Safety Evaluation Report

cc: J. Johnson, DOE, MD-12
H. Porter, SC Dept. of HEC
J. Conway, DNFSB
Don Moniak, BREDL
Glenn Carroll, GANE
Ruth Thomas, Environmentalists, Inc.

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DATE	9/27/01	10/1/01	9/27/01	10/1/01	10/01/01

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DOCKET NUMBER: 70-03098

APPLICANT: Duke Cogema Stone & Webster
Charlotte, North Carolina 28231

SUBJECT: SAFETY EVALUATION REPORT: QUALITY ASSURANCE
PROGRAM FOR CONSTRUCTION OF MOX FUEL FABRICATION
FACILITY

BACKGROUND

By letter dated June 22, 2000, Duke Cogema Stone & Webster (DCS) submitted the Mixed Oxide (MOX) Project Quality Assurance Plan (MPQAP), Revision 1, for Nuclear Regulatory Commission (NRC) review in accordance with 10 CFR Part 70. Section 70.23 (b) of 10 CFR Part 70 requires, in part, that an applicant's quality assurance (QA) program for construction of a plutonium processing and fuel fabrication facility be found to provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The QA program must adequately describe how the criteria of 10 CFR 50 Appendix B will be met.

Revision 1 of the MPQAP described the DCS quality assurance program for MOX Fuel Fabrication Facility (MFFF) design activities only, and was submitted in support of the DCS submittal of a construction authorization request (CAR). The initial staff review of MPQAP, Revision 1, identified a number of issues which required additional information or clarification. NRC requested additional information by letter dated October 6, 2000. DCS responded by letter dated January 29, 2001, and submitted MPQAP, Revision 2. Revision 2 added provisions applicable to apply to MFFF construction, as well as to design activities. The NRC staff review of Revision 2 of the MPQAP identified issues that required further information and clarification. The staff forwarded a Request for Additional Information (RAI) to DCS by letter dated June 19, 2001. DCS responded to this RAI by letter dated July 18, 2001, and committed therein to revise Revision 2 of the MPQAP. The NRC staff completed its technical review of Revision 2 of the MPQAP, and determined that this QA program, as supplemented by the DCS July 18 RAI response, was acceptable, with two exceptions described below in Section 2. By letter dated August 17, 2001, the staff forwarded to DCS a draft Safety Evaluation Report (SER) for comment. By letter dated September 4, 2001, DCS submitted additional information, clarifications and commitments resolving the two exceptions referenced above.

DISCUSSION

The technical review of the MPQAP was based on the guidance in NUREG-1718, "Standard Review Plan (SRP) for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," dated August 2000. Revisions 1 and 2 of the MPQAP were reviewed, as were the DCS commitment and clarifications in responses to the two staff RAIs and the draft SER. The MPQAP, Revision 2, was submitted as the required description of a QA program that meets the requirements of 10 CFR Part 50, Appendix B ("Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," referred to hereafter as Appendix B). DCS has committed itself to comply with the provisions of 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). These ASME NQA-1 and Regulatory Guide provisions are hereafter referred to as NQA-1. The staff's review compared and evaluated the MPQAP against the Appendix B requirements and the NQA-1 provisions.

1. Organization

Section 1.0 of the MPQAP, "Organization," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 1, and Basic Requirement 1 and Supplement 1S-1 of NQA-1-1994 Part I. Criterion 1 of Appendix B requires that the applicant shall be responsible for the establishment and execution of the QA program. The applicant may delegate to others such as contractors, agents, or consultants the work of establishing and executing the QA program, or any part thereof, but shall retain responsibility therefor. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components (SSC) shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the QA functions. The QA functions are those of (a) assuring that an appropriate QA program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing QA functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Such persons and organizations performing QA functions shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the QA program may take various forms provided that the persons and organizations assigned the QA functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the QA program at any location where activities subject to this appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the organization responsible for the establishment and execution of the QA program for the MFFF in accordance with NUREG-1718, and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions.

Initially, the staff's review of Section 1.0 of the MPQAP did not adequately describe the actual construction organization responsibilities and interfaces. DCS, in its July 18, 2001, response on this issue, clarified the actual construction responsibilities and interfaces. This response also identified and clarified the responsibilities and functions of the DCS QA, quality control (QC), inspection and construction management organizations, and the construction organization including subcontractors. The authorities and responsibilities among the organizational groups and the means of communication were addressed, including the DCS design and engineering

functions and interfaces and those of the various contractors during construction. Additional organization charts were provided by DCS in its July 18, 2001, response that reflected the lines of responsibility and authority. DCS's commitments to clear and unambiguous controls and communications, and responsibility and authority between the construction, equipment and system suppliers and DCS design, engineering, project management, procurement, construction management and QA, were identified. The key management positions for construction activities were adequately addressed. Performance of specific activities such as inspection and testing of construction activities, equipment and SSCs were addressed as were what, how, and by whom the QA controls and management measures are to be applied.

As revised, the MPQAP description of the organization and DCS's commitments to revise Section 1.0 (incorporating additional information provided in its RAI response dated July 18, 2001) together meet the requirements of 10 CFR Part 50, Appendix B and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description, and requirements for DCS's organization for implementation of the QA program are adequate and acceptable for use on the MFFF construction activities, including design, procurement and fabrication.

2. QA Function/Program

Section 2.0 of the MPQAP, "Quality Assurance Program", commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 2, "Quality Assurance Program", and Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, 2S-4 and Appendix 2A-1 of NQA-1-1994 Part I, as revised by NQA-1a-1-1995 Addenda, and Regulatory Guide 1.28 (Rev.3). DCS did not request to be excepted from any of these requirements.

MPQAP Section 2.0 describes and presents the overall DCS QA program for the MFFF activities in accordance with 10 CFR Part 50, Appendix B, and ASME NQA-1. It states DCS policies, assigns responsibilities, and specifies requirements governing implementation of QA requirements on the MOX Project. All 18 criteria of 10 CFR Part 50, Appendix B, are to be addressed to identify the total set of QA requirements required for the MFFF construction activities, including design, procurement, and fabrication. Applicable QA criteria are to be applied to subcontractors as delineated in procurement documents controlled under Section 4.0 of the MPQAP.

Section 2.0 also states that specific processes and controls, which implement 10 CFR Part 50, Appendix B and NQA-1 commitments, are to be specified in QA procedures contained in the DCS Project Procedures Manual. Development, review, approval and training of QA implementing procedures shall be done prior to performance of the activities controlled by the procedures. The QA Program is required to provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions, including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and with assurance that prerequisites for the given activity have been satisfied. The DCS QA Program is to provide 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. Furthermore, this section requires that, 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 to be stopped until the procedures are changed. Requirements for stop work are further discussed in Section 16.

The DCS requirements for use of subcontractor programs, graded QA, categorization of SSCs, identification of QA controls and training, and management assessments are described in the MPQAP, Revision 2 and in the DCS responses and commitments to the NRC RAIs and the draft SER. The MPQAP categorization of SSCs provides four Quality Level (QL) categories and definitions for SSCs. IROFS are classified as QL-1 and are further defined as QL-1a and QL-1b.

The MPQAP Introduction Section, states that MPQAP describes the QA requirements, implementing procedural controls and documentation requirements that apply to management measures, including configuration management, maintenance, training and qualification of plant personnel, plant procedures, audits and assessments, incident investigations, and records management for the MFFF construction activities. It further addresses the DCS commitments for provisions for continuing QA and revision of the MPQAP.

The staff reviewed the DCS commitments and the description of the QA program in accordance with NUREG-1718, and compared them to the applicable requirements of 10 CFR Part 50, Appendix B and the NQA-1 provisions. Initially, the staff's review of Section 2.0 of the MPQAP, and the MPQAP's Introduction section, determined that DCS did not adequately commit to putting all SSCs into the QA program's scope. DCS, in its September 4, 2001, response to the draft SER, clarified the applicability of the MPQAP to all SSCs, and committed to revising the MPQAP to make it clear that all applicable QA requirements apply to Quality Level 2 SSCs, and that all applicable QA requirements (for example, design and configuration control), apply to all SSCs.

Additionally, the staff's initial review of Section 2.0 of the MPQAP determined that Sections 2.2 (Graded Quality Assurance (GQA)) and 2.2.2 (Identification of QA Controls) were not acceptable. DCS had not adequately defined the process for identifying the SSC functions and characteristics relied on for safety, and had not adequately identified the criteria and methods for applying specific graded QA controls to individual and/or types of SSCs. DCS, in its September 4, 2001, response to the draft SER, committed to revising the MPQAP to adequately describe the process for determining the safety functions and safety significance of SSCs. DCS, in its September 4, 2001, response to the draft SER, clarified the process by which the SSC functional requirements are identified and stated the criteria for grading the MPQAP requirements that are associated with the 18 criteria of Appendix B. The DCS response identified the process for assignment of SSC Quality Levels commensurate with the SSC function and safety significance. It presented the process and the basis for application of GQA controls to adequately identify clear, definite, supportable, and verifiable methods, criteria and standards of performance. The DCS response also specifically stated that the applications of QA controls must be sufficient to reasonably ensure the design integrity and ability of the SSC to successfully perform its safety function. The DCS response presented an adequate definition of the process, methods, and criteria for identifying the SSC functional requirements and grading of QA controls. DCS also committed to revising the MPQAP to incorporate the process, methods and criteria for determining SSCs safety functions and safety significance, and the GQA controls to be applied to specific SSCs, as stated in the September 4, 2001, response. The DCS

response and its commitment to revise the MPQAP are adequate and resolve the two issues with the MPQAP, Revision 2.

The staff review of the MPQAP documented QA program determined that it meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Based on its review, as discussed above, the staff concludes that the MPQAP commitments, description, and requirements for the QA program, as supplemented by DCS in its September 4, 2001, letter, are adequate and acceptable for use on the MFFF construction activities, including design, procurement and fabrication.

3. Design Control

Section 3.0 of the MPQAP, "Design Control," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 3, and Basic Requirement 3 and Supplement 3S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda. Section 3.0 also commits DCS to adhere to Part II American Society of Mechanical Engineers (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." DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the QA program for design control in accordance with NUREG-1718, and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that MPQAP Section 3.0 meets the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. Therefore, the staff concludes that the MPQAP commitments and requirements for design control are adequate and acceptable for use on the MFFF design and construction activities, including procurement and fabrication. Section 3.0 of the MPQAP is briefly summarized below.

MPQAP Section 3.0 describes the DCS design control program, established to meet the requirements of 10 CFR Part 50, Appendix B, Criterion 3. Section 3.0 states that measures will be established in the DCS QA implementing procedures to assure that applicable requirements are correctly translated by DCS into design documents. Design inputs are to be specified on a timely basis to support base contract milestones, and controls 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 are required to detail the controls for design input, design process, design verification, design changes and approval. These procedures must include appropriate quantitative and/or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. DCS design documents are required to be prepared, reviewed, and approved by qualified individuals. Designs are required to be verified by design reviews, alternate calculations or qualification tests, and the method of verification used and the results of the verification must be documented. Design changes are to be governed by control measures commensurate with those applied to the original design.

Computer software to be used by DCS will be verified and validated in accordance with the applicable ASME requirements specified above. 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 SSCs relied on for safety. The application of specific requirements is required to be prescribed in plans for computer software quality assurance and written policies and procedures. Configuration management and changes to the various types of design documents are to be maintained in accordance with the applicable QA project procedure. Section 3.0 incorporates the applicable requirements of Appendix B and NQA-1, and includes requirements for the design process. Section 3.0 addresses requirements for design input, analyses, verification, reviews, interface and change control, documentation and records.

4. Procurement Document Control

Section 4.0 of the MPQAP, "Procurement Document Control," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 17, "Procurement Document Control," and Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994 Part I. DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the QA program for procurement document control in accordance with NUREG-1718, and compared them to the requirements of 10 CFR Part 50, Appendix B and the NQA-1 provisions. The staff verified that MPQAP Section 4.0 meets the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. Therefore, the staff concludes that the MPQAP commitments and requirements for QA records are adequate and acceptable for use on the MFFF design and construction activities, including procurement and fabrication. Section 4.0 of the MPQAP is briefly summarized below.

Section 4.0 of the MPQAP states that applicable design bases and other requirements necessary to assure adequate quality be included or referenced in DCS procurement documents for procurement of QL-1 (IROFS) and QL-2 material, equipment, and services. Procurement documents must 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 are required to be subject to the same degree of control as utilized in the preparation of the original procurement documents.

Section 4.0 also provides that procurements 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. Material, equipment, and services are procured from approved suppliers by procurement requisitions and/or specifications that are approved by the DCS Project Manager and QA Manager or their qualified designees. To the extent necessary, procurement documents require suppliers to have a QA program consistent with the applicable requirements of 10 CFR Part 50, Appendix B, or NQA-1-1994. Section 4.0 states that for all QL-1 (IROFS) procurements, the 10 CFR Part 21 requirements will be invoked.

Section 4.0 identifies requirements for procurement document preparation including a statement of work, technical, QA program, nonconformances and documentation requirements, and right of access. Section 4.0 also describes the process for procurement document review, approval, and change, and is in agreement with those processes described in NQA-1.

5. Instructions, Procedures and Drawings

MPQAP, Section 5.0, "Instructions, Drawings and Procedures," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 5, "Instructions, Procedures and Drawings," and NQA-1, Basic Requirement 5. DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the QA program requirements for instructions, procedures and drawings in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix, and the NQA-1 provisions. The staff reviewed the MPQAP description of the requirements for instructions, procedures, and drawings and verified that MPQAP Section 5.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments and requirements for instructions, procedures, and drawings are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 5.0 of the MPQAP is briefly summarized below.

MPQAP Section 5.0 implements the Appendix B and NQA-1 requirements that quality- affecting activities be prescribed by, and performed in accordance with, documented QA procedures and other implementing documents (drawings, specifications, etc.) appropriate to the MOX Project. QA procedures are required to be reviewed by affected managers for definition of work controlling processes, and 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. Section 5.0 identifies the requirements for implementing document preparation, content, review, approval, issuance, control and change. The type of document used to perform work must be appropriate to the work being performed. Implementing documents must include responsibilities, technical and regulatory requirements, sequential description of the work to be performed, acceptance criteria, prerequisites and other conditions, quality verification and hold points, work completion methods, and identification of records. Section 5.0 adequately incorporates the applicable requirements of 10 CFR Part 50, Appendix B, and NQA-1.

6. Document Control

Section 6.0 of the MPQAP, "Document Control," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 6, "Document Control," and NQA-1-1994 Part I, Basic Requirement 6 and Supplement 6S-1. DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the QA program for document control in accordance with NUREG-1718, and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff reviewed the MPQAP description of the document control measures and has verified that MPQAP Section 6.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description, and requirements for measures to control the issuance of documents are adequate and acceptable for use on the MFFF design

and construction activities including procurement and fabrication. Section 6.0 of the MPQAP is briefly summarized below.

MPQAP Section 6.0 states that all DCS quality-affecting documents will be distributed by DCS Document Control. Applicable QA procedures are required to provide controls over DCS-generated QA documents as well as QA documents received from suppliers. QA procedures are required to describe the 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. Section 6.0 also states that documents, including changes thereto, are to be reviewed for adequacy and approved for release by authorized personnel in accordance with the applicable implementing QA procedures. Section 6.0 also identifies the types of documents that are required to be controlled, and the requirements for document preparation, review, approval, distribution, use and change. Section 6.0 adequately incorporates all of the applicable requirements of Appendix B and NQA-1.

7. Control of Purchased Items

Section 7.0 of the MPQAP, "Control of Purchased Material, Equipment and Services," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 17, "Control of Purchased Material, Equipment and Services," and Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994, Part I as revised by NQA-1a-1995 Addenda and Regulatory Guide 1.28 (Rev.3). DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the QA program for control of purchased material, equipment and services in accordance with NUREG-1718, and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff reviewed the MPQAP description of the MFFF procurement control program and has verified that MPQAP Section 7.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description, and requirements for control of purchased material, equipment, and services are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 7.0 of the MPQAP is briefly summarized below.

MPQAP Section 7.0 describes the implementing measures to assure that DCS procurement of QL- 1 (IROFS) and QL-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 required to be 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 to be performed by DCS, 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 are required to be documented.

Provisions for procurement planning, source evaluation and selection, bid evaluation, supplier performance, control of supplier documents, acceptance of items and services, and conformance certificates are described. Section 7.0 also addresses requirements for source

evaluation, receiving inspection, post-installation testing, control of nonconformances, and commercial grade items. This section adequately incorporates the applicable requirements of 10 CFR Part 50, Appendix B, and NQA-1 for control of procured items.

8. Identification and Control of Items

MPQAP, Section 8.0, "Identification and Control of Material, Parts and Components," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 8, "Identification and Control of Material, Parts and Components," and Basic Requirement 8 and Supplement 8S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda. Criterion 8 of Appendix B requires that identification and control measures be designed to prevent the use of incorrect or defective material, parts, and components. These measures include the identification and control of materials, parts, and components, including partially fabricated assemblies. The measures also must provide assurance that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the QA program for records in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 8.0 description of the measures for identification and control of material, parts and components meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description, and requirements for control of purchased material, equipment, and services are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 8.0 of the MPQAP is briefly summarized below.

The DCS MPQAP Section 8.0 contains procedures to establish the necessary controls to assure that only correct and accepted material, parts and components are used or installed at the MFFF. These 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. Section 8.0 also describes the measures and requirements for identification, physical markings, traceability and other applicable controls. DCS's description of its measures for identification and control of item is in full accord with the Appendix B Criterion 8 requirements, and incorporates the requirements of NQA-1.

9. Control of Special Processes

Section 9.0 of the MPQAP, "Control of Special Processes," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 9, "Control of Special Processes," and Basic Requirement 9 and Supplement 9S-1 of NQA-1-1994 Part I. Criterion 9 of Appendix B requires that measures be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications,

criteria, and other special requirements. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments for, and the description of, the control of special processes affecting the quality of items or services in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. (Note that, for processes other than “special processes,” the requirements for the content and generation of the procedures that control these processes are addressed in MPQAP Section 5.0, “Instructions, Drawings and Procedures,” and the staff review is discussed in the corresponding Safety Evaluation Report review area). The staff has verified that MPQAP Section 9.0 description of the methods for control of special processes meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description, and requirements for control of special processes are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 9.0 of the MPQAP is briefly summarized below.

DCS MPQAP Section 9.0 states that QA program procedures will 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. The requirements of NQA-1 for control of special processes are incorporated in Section 9.0

10. Inspection

Section 10.0 of the MPQAP, “Inspection,” commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 10, “Inspection,” and Basic Requirement 10 and Supplement 10S-1 of NQA-1-1994 Part I. DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the requirements for inspections in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff reviewed the MPQAP description of the MFFF inspection program and has verified that MPQAP Section 10.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description and requirements for inspection are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 10.0 of the MPQAP is briefly summarized below.

MPQAP Section 10.0 describes the DCS program and requirements for inspections. Inspections to verify conformance of an item or activity to specified requirements are required to be planned and executed. Characteristics of the item are to be inspected and inspection methods must be specified in implementing QA procedures. Inspection results are to be documented. Persons other than those who performed or directly supervised the work being inspected must perform the inspection. This section also addresses all the requirements of NQA-1 related to inspections, including inspection planning, selection of personnel, hold points, in-process inspections and monitoring, final inspection, item acceptance, and inspection documentation, with one exception. Section 10.2.4, “Statistical Sampling,” does not commit to the NQA-1 requirement that the sampling be based on recognized standard practices. The staff noted this

omission in the RAI forwarded to DCS on June 10, 2001. DCS, in its July 18 RAI response, committed to revising MPQAP Section 10.2.4 to incorporate the NQA-1 requirement.

11. Test Control

Section 11.0 of the MPQAP, "Test Control," commits DCS to adhere to the requirements of 10 CFR 50, Appendix B, Criterion 11, "Test Control," and Basic Requirement 11 and Supplement 11S-1 of NQA-1-1994 Part I, as revised by Regulatory Guide 1.28 (Rev.3). Criterion 11 of Appendix B requires that a test program shall be established to assure that all testing required to demonstrate that SSCs will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied. DCS did not request to be excepted from any of these requirements. (Note that the commitments and requirements of NQA-1-1994, Supplement 11S-2 for computer program testing are addressed in MPQAP Section 3.0, "Design Control").

The staff reviewed the DCS commitments and the description of the QA program for test control in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 11.0 description of the MFFF test control program meets the requirements of 10 CFR Part 50, Appendix B and NQA-1. Therefore, the staff concludes that the MPQAP commitments to, and description of, requirements for test control are adequate and acceptable for use on the MFFF construction and design activities including procurement, and fabrication. This finding does not include startup testing. Section 11.0 of the MPQAP is briefly summarized below.

Section 11 of the MPQAP describes the DCS test control program for construction activities, not including startup testing, and incorporates the applicable requirements of NQA-1. This section presents the QA program requirements for test planning, performing tests, use of other test documents, test results, and test documentation.

12. Control of Measuring and Test Equipment

Section 12.0 of the MPQAP, "Control of Measuring and Test Equipment," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 12, "Control of Measuring and Test Equipment," and Basic Requirement 12 and Supplement 12S-1 of NQA-1-1994 Part I. Criterion 12 of Appendix B requires that measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the measures for control of measuring and test equipment in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 12.0 description of the DCS controls for measuring and test equipment meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments to, and description of, the measures for control of measuring and test equipment are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 12.0 of the MPQAP is briefly summarized below.

MPQAP Section 12.0 describes the DCS controls for measuring and test equipment and incorporates the requirement of NQA-1 for this area. This section appropriately specifies requirements for calibration, use documentation, control of out-of-calibration and lost items, handling and storage, and documentation.

13. Handling, Storage, and Shipping

Section 13.0 of MPQAP, "Handling, Storage and Shipping," commits DCS to adhere to the requirements of and describes the measures for implementing, 10 CFR Part 50, Appendix B, Criterion 13, "Handling, Storage and Shipping," and Basic Requirement 13 and Supplement 13S-1 of NQA-1-1994 Part I. Criterion 13 of Appendix B requires that handling, storage, cleaning, packaging, shipping, and preservation of items be controlled to prevent damage or loss and to minimize deterioration, and that, when necessary for particular products, special protective environments such as inert gas atmosphere, specific moisture content levels, and temperature levels, be specified and provided. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the measures for controlling the handling, storage, cleaning, packaging, shipping and preservation of items in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 13.0 descriptions of the applicable measures (*i.e.*, for controlling the handling, storage, cleaning, packaging, shipping and preservation of items to prevent damage or loss, and to minimize deterioration) meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments to, and description of, the measures referenced above are adequate and acceptable for use on the MFFF construction and design activities including procurement and fabrication. Section 13.0 of the MPQAP is briefly summarized below.

MPQAP Section 13.0 describes the measures required to be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. Section 13.0 describes the DCS measures for handling, storage and shipping of items, incorporates all of the requirements of NQA-1 for these activities.

14. Inspection, Test and Operating Status

MPQAP, Section 14.0, "Inspection, Test and Operating Status," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 14, "Inspection, Test and Operating Status," and Basic Requirement 14 of NQA-1-1994 Part I. Criterion 14 of Appendix B requires that the QA program establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear facility. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of SSCs of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the relevant MPQAP requirements in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 14.0 description of the requirements for identifying the inspection, test, and operating status of MFFF items meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments and descriptions for identifying the inspection, test, and operating status of items are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 14.0 of the MPQAP is briefly summarized below.

Section 14 of the MPQAP describes the DCS measures for inspection, test, and operating status control during construction to meet the 10 CFR Part 50, Appendix B, requirements and includes the requirements of NQA-1. The section includes requirements for identifying items and for indicating the status of required inspections and tests of items and the authority for applying and removing status indicators.

15. Nonconformances

Section 15.0 of the MPQAP, "Nonconforming Materials, Parts or Components," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 15, "Nonconforming Materials, Parts or Components," and Basic Requirement 15 and Supplement 15S-1 of NQA-1-1994 Part I. Criterion 15 of Appendix B contains measures to be established to control materials, parts, or components which do not conform to requirements, in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the QA program for controlling nonconforming items in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff reviewed the MPQAP description of the process and requirements for controlling nonconforming items, and has verified that MPQAP Section 15.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description and

requirements for control of nonconforming material, parts or components, are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 15.0 of the MPQAP is briefly summarized below.

MPQAP Section 15.0 describes the DCS methods for implementing the requirements of Criterion 15 of Appendix B, as set forth above. Section 15.0 contains the DCS requirements for documenting, evaluating, identifying, segregating, and dispositioning of nonconforming items. The requirements of this section incorporate all of the requirements of Appendix B and NQA-1 in this area.

16. Corrective Action

Section 16.0 of the MPQAP, "Corrective Action," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 16, "Corrective Action," and Basic Requirement 16 of NQA-1-1994 Part I. Criterion 16 of Appendix B requires that measures be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the MFFF corrective action program in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 16.0 description of the MFFF corrective action program meets the requirements of 10 CFR Part. 50, Appendix B and NQA-1. Therefore, the staff concludes that the MPQAP commitments and descriptions for corrective action are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 16.0 of the MPQAP is briefly summarized below.

MPQAP Section 16.0 includes commitments to and requirements for implementation of all of the 10 CFR Part 50, Appendix B, and NQA-1 requirements. This section describes the DCS measures for identifying and classifying conditions adverse to quality, including follow-up and closure action and trending nonconformances.

17. QA Records

Section 17.0 of the MPQAP, "Quality Assurance Records," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 17, "Quality Assurance Records," and Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 Part I, as revised by Regulatory Guide 1.28 (Rev.3). DCS did not request to be excepted from any of these requirements. The staff reviewed the DCS commitments and the description of the QA program for records in

accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff reviewed the MPQAP description of the MFFF QA records management system and has verified that MPQAP Section 17.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments, description, and requirements for QA records are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 17.0 of the MPQAP is briefly summarized below.

MPQAP Section 17.0 commits DCS to establish a records management system, which will include a QA Records Center. This management system will govern records quality, generation, identification, classification, legibility, retrievability and protection, at the MFFF. Section 17 identifies the specific requirements for record management, responsibilities and procedures, and describes the specific requirements for generation, receiving, storage, preservation, retrieval, and retention of QA records. DCS has also committed to requiring subcontractors to have a QA program that meets the records requirements of 10 CFR Part. 50, Appendix B, and NQA-1. Examples are included in MPQAP Section 17.0 of typical QA records which would be retained for the life of the item while installed or stored for use.

18. Audits and Assessments

Section 18.0 of the MPQAP, "Audits," commits DCS to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 18 "Audits," 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). Criterion 18 of Appendix B requires that a comprehensive system of planned and periodic audits be carried out to verify compliance with all aspects of the QA program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, shall be taken where indicated. DCS did not request to be excepted from any of these requirements.

The staff reviewed the DCS commitments and the description of the QA program for audits in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff has verified that the MPQAP Section 18.0 description of the MFFF audit program commitments and requirements meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1. Therefore, the staff concludes that the MPQAP commitments and description for audits are adequate and acceptable for use on the MFFF design and construction activities including procurement and fabrication. Section 18.0 of the MPQAP is briefly summarized below.

MPQAP Section 18.0 incorporates the applicable Appendix B requirements and the NQA-1 provisions for audits and assessments. This section describes the requirements for audit schedules, plans, team selection, performance and reporting of results, and describes the DCS implementation of requirements for audit responses, closure, and team qualification requirements. DCS will verify compliance with all aspects of the DCS MPQAP and determine the effectiveness of the QA program by performing planned and periodic audits. The DCS audits are required to be performed in accordance with written procedures or checklists, and by appropriately trained and qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results are to be documented and provided to the appropriate

management for review and corrective action. Follow-up actions are required to be 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.

CONCLUSION

Based on the review of the MPQAP, Revision 2, and the clarifications and commitments made by DCS in response to NRC RAIs and the draft SER, the NRC staff concludes that DCS has adequately described its QA program, and that this program meets the requirements of 10 CFR Part 50, Appendix B. The staff therefore finds, pursuant to 10 CFR 70.23(b), that the DCS QA program, as applied to the SSCs of the MOX Fuel Fabrication Facility, will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The scope of this finding pertains to the construction of the MFFF's SSCs, and includes all related design, procurement and fabrication activities, but does not include any start-up testing or operation of the MFFF.

Principal Contributor

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This review has been coordinated with NRC Region II.