October 6, 2000

Mr. Peter Hastings, Licensing Manager
Duke Engineering and Services
COGEMA Inc. and Stone & Webster
P.O. Box 31847
Charlotte, NC 28231-1847

SUBJECT: ACKNOWLEDGMENT OF ACCEPTABILITY FOR REVIEW OF MIXED OXIDE PROJECT QUALITY ASSURANCE PLAN AND REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Hastings:

We have completed the initial administrative review of the Duke Cogema Stone & Webster (DCS) Mixed Oxide (MOX) Project Quality Assurance Plan (MPQAP), Revision 1, transmitted by letter dated June 22, 2000. We have found it acceptable for detailed technical review. We note that your submittal of Revision 1 of the MPQAP in advance of your request for construction authorization is to facilitate its early review and acceptance for design activities. It is our understanding that the current revision is intended to address the design activities associated with the MOX project, and that subsequent revision(s) will address other activities, including procurement, construction, startup testing, and operation. Consequently, we have reviewed it for design activities only.

Our technical review of the MPQAP for acceptability for MOX design activities and design-related quality assurance (QA) activities has identified additional information or clarification that is needed to determine its acceptability for the current MOX project activities. During our reviews, we are using NUREG-1718, “Standard Review Plan (SRP) for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility,” dated August 2000. We note that the SRP was published after your MPQAP was submitted.

If the additional information, specified in the enclosure, results in a revision of the MPQAP, DCS should submit the revised MPQAP for design activities to the Nuclear Regulatory Commission for review. DCS may respond separately to information requested in the enclosure that does not result in a revision to the MPQAP. The additional information requested should be provided by the planned DCS submittal of the request for construction authorization.

If you have any questions regarding these actions, I can be reached at (301) 415-6522.

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

cc: J. Johnson, DOE
H. Potter, SC Dept. of HEC
J. Conway, DNFSB

If you have any questions regarding these actions, I can be reached at (301) 415-6522.

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

cc: J. Johnson, DOE
H. Potter, SC Dept. of HEC
J. Conway, DNFSB

DISTRIBUTION: (Control Nos.) ML: Template:
Docket: 70-3098 ADAMS PUBLIC DAyres, Region II
SSSB SPB r/f OGC TJohnson EMcAlpine, RII

ADAMS Accession Number: ML003759431
G:\SPB\WRS\MOXQAPRAIDRAFT.WPD (* See previous concurrence)

OFC	SPB		SPB		SPB		SPB			
NAME	WSmith:cc*		DPersinko*		DHoadley*		MGalloway*			
DATE	10/4/00		10/4/00		10/6/00		10/6/00			

OFFICIAL RECORD COPY

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

GENERAL COMMENTS

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.

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 organization 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.

3. SRP Section 15.1.4.3.C, "Applicant's Provisions for Continuing QA," identifies guidance for the applicant's provisions for 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.

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, 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.

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.

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.

SPECIFIC COMMENTS

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.

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.

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.

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.

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.

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.

13. MPQAP Section 3.2.4, "Design Verification," states that design verification is required for 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.

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.

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

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.

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.”