

October 6, 2006

MEMORANDUM TO: Joseph Giitter, Branch Chief
Special Projects Branch
Division of Fuel Cycle Safety
and Safeguards

THRU: Stewart Magruder, Section Chief
Mixed Oxide Facility Licensing Section **/RA/**
Special Projects Branch, FCSS

FROM: Paul Bell, Lead Quality Assurance Engineer
Mixed Oxide Facility Licensing Section **/RA/**
Special Projects Branch, FCSS

SUBJECT: SEPTEMBER 11 - SEPTEMBER 15, 2006, OBSERVATION OF DUKE
COGEMA STONE & WEBSTER MIXED-OXIDE FUEL FABRICATION
FACILITY QUALITY ASSURANCE AUDIT OF PROCUREMENT
ACTIVITIES

On September 11 - September 15, 2006, U.S. Nuclear Regulatory Commission (NRC) staff conducted an onsite observation audit of Duke Cogema Stone & Webster's (DCS) performance of a Quality Assurance audit of procurement activities for the Mixed-Oxide Fuel Fabrication Facility (MFFF) project, which is proposed to be located at the Savannah River Site in Aiken, South Carolina. The review took place in the Duke Cogema Stone & Webster Savannah River Site engineering office. I am attaching a meeting summary for your use.

Docket: 70-3098

Duke Cogema Sone & Webster Mixed-Oxide Fuel Fabrication Facility

Quality Assurance Program Onsite Review of Procurement Activities

Dates: September 11- September 15, 2006

Place: Duke Cogema Stone & Webster Engineering Office
Savannah River Site Office, Aiken, SC

NRC Attendees: Paul Bell

Purpose:

The purpose and objective of this NRC Onsite Review was to observe and determine if the DCS audit of procurement activities is effectively being implemented in accordance with the Mixed-Oxide Fuel Fabrication Facility (MFFF) MOX Project Quality Assurance Plan.

The DCS auditors identified two findings, and one observation. The auditors also identified and issued 2 recommendations regarding quality improvement of processes, procedures and technical activities.

The audit team determined that, overall, the Quality Assurance Program and associated procedures had been developed, however procedures and processes used to manage procurement activities and to address their impact upon quality affecting activities were in need of improvement. The audit team did identify significant quality-affecting issues related to receipt and testing of software, work processes used for requisitioning items and services, procedural controls for the development of offer/proposal evaluations and award recommendations, and an ineffective quality assurance grading evaluation process. The NRC observers agreed with the audit team's findings, recommendations, and conclusions. Staff determined that if uncorrected, the programmatic importance and regulatory significance of the identified adverse conditions may have a direct impact upon the quality of items purchased, tested and installed in safety-related applications.

Staff evaluated the adequacy of the DCS audit process and the effectiveness of QA Program implementation, in meeting the QA requirements of the MOX Project Quality Assurance Plan. Staff determined that, overall, the DCS audit team achieved their purpose and obtained their objectives in completion of Internal Audit DCS-06-A07.

Discussion:

NRC staff and DCS auditors interviewed various representatives of the DCS Procurement Engineering Group at the DCS Savannah River Site engineering offices and reviewed QA programmatic and procurement procedures. The auditors and staff paid particular attention to the development and implementation of procurement actions for items relied on for safety. DCS auditors identified five discrepant issues and which are summarized below:

DCS Audit Issue Summary

- A process to manage receipt and initial testing of software is not controlled. Only a few software discs used for design based calculations could be located. A Software Baseline List or Analytical Software Library List used to control the issuance and release of safety-related software did not contain the software description, software platform, and restrictions or limitations on use. The auditors also noted that Software Program Managers, who are designated as custodians of safety-related software and records attesting to custodianship, were not current.
- Procurement packages involving the procurement of Quality-Level 2 (QL-2) components lacked attention to detail. Technical documents, specifications, drawings, and QA requirements were not referenced in various requisitions.
- Project administrative control procedures used to implement requirements for developing offer/proposal evaluations and award recommendations did not fully utilize the controlled forms specified for use in project procedures. The offer/proposal evaluation and award recommendation process is not being applied consistently to all procurement packages.
- Project Managers have not developed a ratification log for unauthorized supplier and subcontractor actions. The infrastructure Procurement Manager created a Ratification Log with the current ratification data, during the course of the audit.
- The DCS process for performing technical evaluations for Items Relied on for Safety (IROFS) and the corresponding quality assurance grading evaluations are unclear and ambiguous. DCS auditors expressed concerns regarding the application, implementation, and execution of the grading evaluation process. Additional audit team concerns, also included the inadequate communication of clearly defined control points and the inadequate application and appropriation of QA programmatic controls imposed on sub-suppliers, during design and manufacturing. Discussions with DCS procurement personnel indicated that late development of procurement specifications has had major impact on the procurement process. The DCS audit team also expressed concern that the current grading process does not apply the appropriate controls and control points to reasonably ensure safety, reliability, and performance of IROFS during the design, procurement, and the manufacturing process.

Staff Observations:

- Procurement Planning is currently in the proposal and reply stage. Duke Cogema Stone & Webster has categorized procurement activities into 3 Basic Groups:
 - (1) Basic Ordering Agreements - Suppliers of Products or Design Features
 - (2) Long Lead Items - items that require extended manufacturing lead time
 - (3) Process Units - French designed Machining Systems manufactured using the French Platform

The applicant stated that Basic Ordering Agreements, long lead items, and the procurement of process units from some sole source foreign suppliers have encountered problems. The problems encountered include foreign suppliers lack of understanding of U.S. technical and quality assurance requirements. The staff was informed that in some cases, sole source vendors of IROFS have been reluctant to bid on long lead items, due to their lack of understanding of QA and technical requirements.

To maintain the validity of the DCS procurement process from design through procurement, staff informed the applicant that a vertical slice of the QA Program will be performed of the QA Program and is contemplated early in FY-07.

- Currently, grading evaluations have been completed for two IROFS, the Pelletizing Presses and Pellet Grinders. DCS auditors and staff informed the applicant that quality level grading determinations lack a standard approach and the application of QA requirements were not being consistently applied. The Staff determined that control points and the appropriate quality criteria established through the grading process and imposed on foreign suppliers through technical specifications was not clearly defined and communicated in procurement documents, to ensure reliability and performance throughout the manufacturing process. The applicant is in the process of determining the adequacy of grading evaluations. The DCS audit team recommended that a management assessment be conducted of the QA Grading Process.
- The applicant has evaluated some foreign suppliers of IROFS. DCS has stated that many long lead items and process units will be procured from and manufactured by sole source suppliers. However, DCS has stated that in many cases, foreign supplier/subcontractors do not have documented QA Programs that implement the requirements of 10 CFR 50 Appendix B nor 10 CFR Part 21. Staff discussions with DCS Procurement Engineering indicate that foreign suppliers and their sub-tier suppliers have expressed their reluctance or inability to comply with contractual flow-down requirements of 10 CFR Part 21 "Reporting of Defects and Noncompliance". Staff review of procurement specifications and QA Grading Evaluations indicate that DCS has not implemented nor applied the appropriate methods for commercial grade dedication, functional testing, and identification of the critical characteristics to support the procurement of IROFS.
- DCS will be developing procedures and processes for oversight of manufacturing and hardware acceptance tests. The applicant has stated, that each IROFS will be functionally tested at vendor facilities, prior to shipment. As part of oversight of hardware acceptance, pre-established hold point inspections of the hardware phase of manufacturing will be verified through "Engineering Hold Points" and "Quality Assurance Hold Points", which will be performed down to the component level.

Additionally, IROFS and select SSCs will also include the verification of the application of specific graded QA controls. Staff informed the DCS that since “defense-in-depth” IROFS are not credited in the Integrated Safety Analysis, the process used to apply the “graded approach” for defense-in-depth IROFS should be clearly defined in procedures, drawings, and design documents.

- Staff discussed with the applicant their “Build to Print” approach to procurement. Feedback provided by DCS indicate that the methodology on how this approach will be implemented has not been finalized. There is uncertainty by DCS regarding the path forward in procurement of Quality Level 1b (QL-1b) “defense-in-depth” IROFS. DCS has questioned their choice to verify adequacy of design and material compatibility through the use of grading or commercial dedication. DCS stated that awards to sole source vendors have been impeded, due to noncompliant quality assurance programs, language barriers, and the lack of understanding of U.S. technical specifications and the possible use of third party oversight for prospective vendors. Since these logistics impact the procurement process involving the development of basic ordering agreements and long lead items, DCS has requested staff feedback regarding their application and flow-down of 10 CFR Part 21, “Reporting of Defects and Noncompliance” to foreign suppliers and their proposed use of commercial dedication and/or quality assurance grading. Staff informed DCS that upon receipt and acceptance review of the license application, staff will provide feedback of QA programmatic issues, during the vertical slice that will be performed in FY-07.

October 6, 2006

MEMORANDUM TO: Joseph Giitter, Branch Chief
Special Projects Branch
Division of Fuel Cycle Safety
and Safeguards

THRU: Stewart Magruder, Section Chief
Mixed Oxide Facility Licensing Section /RA/
Special Projects Branch, FCSS

FROM: Paul Bell, Lead Quality Assurance Engineer
Mixed Oxide Facility Licensing Section /RA/
Special Projects Branch, FCSS

SUBJECT: SEPTEMBER 11 - SEPTEMBER 15, 2006, OBSERVATION OF DUKE
COGEMA STONE & WEBSTER MIXED-OXIDE FUEL FABRICATION
FACILITY QUALITY ASSURANCE AUDIT OF PROCUREMENT
ACTIVITIES

On September 11 - September 15, 2006, U.S. Nuclear Regulatory Commission (NRC) staff conducted an onsite observation audit of Duke Cogema Stone & Webster's (DCS) performance of a Quality Assurance audit of procurement activities for the Mixed-Oxide Fuel Fabrication Facility (MFFF) project, which is proposed to be located at the Savannah River Site in Aiken, South Carolina. The review took place in the Duke Cogema Stone & Webster Savannah River Site engineering office. I am attaching a meeting summary for your use.

Docket: 70-3098

ML062760418

OFC	MOX	MOX		
NAME	PBell	SMagruder		
DATE	10/ 5 /06	10 / 6 /06		

OFFICIAL RECORD COPY