

December 12, 2003

MEMORANDUM TO: Joseph G. Giitter, Chief
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

THRU: Brian W. Smith, Chief **/RA/**
Special Projects Section
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards, NMSS

FROM: Wilkins R. Smith, Quality Assurance Scientist **/RA/**
Special Projects Section
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards, NMSS

SUBJECT: OCTOBER 29 - NOVEMBER 7 AND NOVEMBER 17-21 2003, IN-
OFFICE REVIEW SUMMARY: DUKE COGEMA STONE AND
WEBSTER QUALITY ASSURANCE PROGRAM FOR THE MIXED
OXIDE FUEL FABRICATION FACILITY

On October 29 - November 7 and November 17-21, 2003, U.S. Nuclear Regulatory Commission staff conducted an in-office review of the quality assurance program implementation for the Duke Cogema Stone & Webster (DCS) Mixed Oxide Fuel Fabrication Facility at DCS offices in Beaumont-LaHague and Bagnols-sur-Ceze, France, and Charlotte, North Carolina. A detailed summary of the meetings is attached.

Attachment: Meeting Summary

Docket: 70-3098

cc: P. Hastings, DCS	J. Conway, DNFSB
L. Zeller, BREDL	D. Curran, GANE
G. Carroll, GANE	D. Silverman, DCS
J. Johnson, DOE	H. Porter, SCDHEC

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**MEETING SUMMARY
IN-OFFICE REVIEW
DCS MOX FUEL FABRICATION FACILITY**

Executive Summary

The Nuclear Regulatory Commission (NRC) conducted an in-office review of the Duke Cogema Stone and Webster (DCS) project activities and quality assurance (QA) program implementation, for the proposed Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) on October 29 - November 7 and November 17-21, 2003. The purpose of the in-office review was to verify the adequate implementation of the DCS MOX QA program for the current programmatic, design, and procurement activities and that a QA program is in place, or planned, to support construction of the MFFF. The review assessed the DCS implementation of the NRC approved MOX Project QA Plan (MPQAP), Revision 3, at the Cogema Mecachimie and Societe Generale pour les Techniques Nouvelles (SGN) offices in Beaumont - LaHague on October 29-30, 2003 and Bagnols-sur-Ceze, France, on November 3-7, 2003. NRC staff conducted an on-site review of DCS implementation of the MPQAP implementation at the DCS project offices in Charlotte, North Carolina, during the week of November 17-21, 2003.

QA issues addressed during the in-office review included QA organization and functional responsibilities, QA program, audits and assessments, design control, procurement, procedures, document and records control, incident investigation, and corrective action. The applicant's project procedures, management assessment and QA status reports, and selected management, project, QA, design, and procurement documentation were reviewed. The applicant responded to questions from NRC staff about the MPQAP, QA procedures, and interpretation and implementation of QA requirements for the MOX project activities. No significant deficiencies that raised a concern for the quality of the DCS MFFF activities or project document products were found. The reviewers concluded that the DCS MFFF QA program was adequate and was being effectively implemented for the activities reviewed in France and in Charlotte.

IN-OFFICE REVIEW DETAILS

A. REVIEW OF DCS MANUFACTURING DESIGN GROUP (MDG) AT COGEMA MECASHIMIE IN BEAUMONT-LaHAGUE AND SOFTWARE DESIGN GROUP (SDG) AND MDG AT SGN IN BAGNOLS-SUR-CEZE

Background and Purpose

Mecashimie and SGN are wholly owned subsidiaries of Arreva Cogema, a DCS consortium team member. DCS MDG is responsible for the manufacturing design integration and preparation of procurement packages for major systems of the MFFF. SDG is responsible for developing the complete MFFF software programs and systems to operate and control the MFFF, including instrumentation and control, manufacturing information systems, safeguards systems, and production control. The purpose of the in-office review was to assess the implementation of the DCS MFFF QA program. All DCS activities are to be performed in accordance with the NRC approved MPQAP. The designs of the MFFF processes are based on the designs of the Cogema MELOX and LaHague facilities.

A separate foreign travel report (**ML033440279**) has been issued, to address the NRC foreign travel documentation requirements for the October 29 - November 7, 2003, in-office review activities in France.

a. Scope

In order to verify that DCS has adequately implemented the appropriate QA program commitments in the MPQAP the review team audited the DCS design activities and procedure implementation in France. The in-office review of the DCS MDG and SDG activities in France was accomplished by observing an internal DCS audit and by performing independent reviews. The DCS auditors and NRC reviewer reviewed training, design control, configuration control, control of documents and records, responses to deficiency action requests and corrective action, and design analysis software QA.

b. Observations and Findings

Design products, including in-process and approved documents, were reviewed by the auditors and the NRC reviewer. These included basis of design documents, specifications, drawings, and component classification lists. The MDG offices in France are responsible for manufacturing integration of major MFFF systems and components. This involves taking the design requirements and bases, and the engineering design, translating these into procurement specifications and documents and preparing a complete procurement package for each item. The procurement package contents were still in the definition stage during the review, but the package would be reviewed and approved by a review team, and then given to the DCS Procurement Engineering Group (PEG) in Aiken, South Carolina. PEG would work with the procurement organization and use the procurement package to plan the procurement approach and strategy, and prepare the requisition, solicitation, and/or purchase orders.

The SDG activities in France will involve several scores of software designers, engineers, and analysts in Bagnols-sur-Ceze to develop the software programs and systems to operate and control the MFFF. Aiken will also have a large SDG contingent, and some personnel will be in the LaHague and Charlotte offices. The SDG activities for principal, structures, systems and components (PSSCs) or items relied on for safety (IROFS) are not expected to begin before late 2004. IROFS-related work is estimated to be approximately 5% of the total SDG effort.

DCS has committed to an extensive software (and hardware) QA program for PSSC instrumentation and Controls (I&C) systems by compliance with numerous Institute of Electrical and Electronics Engineers (IEEE) standards. These include IEEE Standards 1012-1998, 828-1998, 1228-1994, 1028-1997, 830-1998, 1074-1997, and 1042-1987. The reviewer examined the SDG "Software QA Plan," the "Software Configuration Management Plan," and the "Software Verification and Validation Plan." These and other SDG QA planning documents are in various stages of review, testing, and approval. The actual development of MFFF software was just beginning with some sub-component or repetitive action software standards being started. The plans and documents appeared to be adequate, in accordance with nuclear industry practice, and the MPQAP commitments.

The DCS audit of MDG and SDG appeared to be thorough and in accordance with the MPQAP and project procedure requirements. The DCS audit team followed up on prior audit issues from 2002 and 2003, and verified the status of implementation of corrective actions. The SDG software QA plans had been reviewed by DCS technical personnel with software experience before the audit, and the issues raised in that review were discussed with the SDG personnel in France. Numerous activities, documents, and procedures and their implementation were reviewed by the DCS auditors.

Several observations for improvement of DCS U.S. or France activities, procedures, or documentation were identified by the DCS auditors. In particular, training implementation for design personnel and training records control were not in accordance with all project procedure requirements.

C. Conclusions

There were no significant deficiencies found by the DCS auditors or the NRC reviewer that raised a concern for the adequate quality of the design activities and products. The NRC reviewer noted that the DCS QA program was effective and adequately implemented for the MDG and SDG activities reviewed.

B. REVIEW OF DCS PROJECT ACTIVITIES AT DCS OFFICES IN CHARLOTTE, NORTH CAROLINA

Background/Purpose

NRC staff conducted an on-site review of MFFF activities at the DCS project offices in Charlotte, North Carolina, during the week of November 17-21, 2003. DCS senior project management, QA, administration support, and engineering are currently based in the Charlotte

offices. The purpose of the review was to confirm that the DCS commitments in the NRC approved MPQAP were adequately implemented for the DCS MFFF activities, and that the DCS project and QA procedures, and their implementation, were adequate for current and planned MOX activities.

The in-office review of the DCS Charlotte project activities was accomplished by conducting an audit of the implementation of the MPQAP implementation for current design and procurement activities. The NRC staff reviewed the QA organization and program implementation, audits and assessments, procurement, procedure control and compliance, training, design control and control of design analysis software, control of documents and records, and incident responses and corrective action.

1.0 REVIEW AREA: ORGANIZATION/QUALITY ASSURANCE PROGRAM

a. Scope

The review team examined the DCS project policies and procedures and QA program implementation to verify compliance with the QA program commitments in the MPQAP Sections 1.0, "Organization," and 2.0 "Quality Assurance Program." The review team examined the organization structure, personnel assignments and training, implementing project procedures, and the project document hierarchy; reviewed pertinent records; and discussed the program requirements and implementation with selected DCS management and staff.

b. Observations and Findings

At the review team's request, the current DCS organization and document hierarchy charts were provided. Presentations were also made by DCS senior management to explain the organization structure, functions and assignments, and the complete project documentation structure and hierarchy. The presentations combined with the organizational and document hierarchy charts were reviewed, and they indicated that significant effort has been put into development of a reasonable working organization and document structure for this project. This effort was also evident in the interviews of various DCS personnel. Each of the personnel knew their function, and the functions of the various project documents, and how to accomplish it according to the MPQAP and the implementing procedures.

The review team determined from a sample of DCS personnel training and certification records that individuals performing activities affecting quality are properly trained and qualified to perform their intended function. The inspection team identified that though the records reviewed to support training were appropriate, some of the DCS training records were misfiled. A separate sample check by DCS staff confirmed that additional records were also misfiled. DCS management identified that an evaluation of the extent of the condition needed to be determined and corrective action identified. The inspection team also determined that adequate procedures exist for the training of personnel performing activities affecting quality. Procedure PP1-3, Rev. 4, "Project Training," applies to all personnel on the DCS project. The training records reviewed by the inspection team

reflected this training had been completed for the review samples for both QA and non-QA activities.

The responsibilities of the organizational members are well described in the MPQAP and implementing procedures and the descriptions of the position responsibilities appear reasonable as described throughout the program for the projected project activities.

It was noted during the audit that the MPQAP requirements to control and identify IROFS are adequately implemented in accordance with the project procedure PP9-1, "SSCS Quality Levels and Marking Design Documents," which requires specific designation and marking of all structures, systems, and components (SSCs). Compliance with the procedural requirements was noted in review of DCSO1-RAJ-DS-ANS-H-38335-A, "Hazard and Operability Analysis (HAZOP)," for the dissolution unit in KDB Table 4.2.

The review team examined the implementation of the procedural requirement in PP3-2, "QA Reporting to Management," Step 3.1.1, for the DCS QA manager to perform a review/analysis every six months. These reviews/analyses are summarized in "DCS MOX QA Program Status Reports," which are issued by the QA manager and distributed to senior management. The review team reviewed the last three reports numbered 06, 07, and 08. The QA Program Status Reports reviewed were detailed and pointedly informative, clearly indicating weaknesses and opportunities for improvement as well as strengths. Deficiency action requests, external audit reports, surveillance reports, management assessment reports, employee quality concerns, stop work notices, and reportable items are required to be reviewed for adverse trends. The inspection team noted that Deficiency Action Request (DAR) 04-002 recently resulted from the trend review for the QA Program Status Reports and the resulting identification of deteriorating trends in two areas: self identified deficiencies and timely completion of corrective actions. This DAR provided an indication that the quality review for the QA Program Status Reports is appropriate and sufficiently rigorous to provide results which should be helpful to DCS management and staff in improving the MOX project activities. The review team concluded that the reports to be a good tool for communication of the quality and management status of the ongoing project.

c. Conclusions

The review team concluded that DCS has established, and adequately implemented, an organization and QA program for the current activities, in accordance with its commitments in MPQAP Sections 1.0, "Organization," and 2.0, "Quality Assurance Program." The development and implementation of training and the qualification and certification of personnel is adequate, however, a need for improvement in the documentation and records of training was noted. Since the efforts of DCS has been primarily on the design phase of the project, the review team noted that additional development and definition of the organization and project and QA procedures will be required as the MOX project continues.

2.0 AUDITS AND ASSESSMENTS

a. Scope

In order to verify that DCS has established, and adequately implemented, the appropriate QA program commitments in the MPQAP Sections 2.0, "Quality Assurance Program," and 18.0, "Audits," the review team examined the DCS procedures for, and implementation of, QA audits and management assessments. The applicable project procedures were reviewed, pertinent records were examined, and discussions were held with selected DCS management and staff on the program requirements and implementation methods. The review was to verify that the applicant has established and implemented procedures to require and perform internal audits, assessments, and reviews, and that the results are effectively tracked and utilized by management to improve program effectiveness and performance. The adequacy and effectiveness of management oversight and involvement in the implementation and control of the QA Program and the mechanism to update the facility's quality program audit and assessment results was also examined.

b. Observations and Findings

The review team reviewed DCS's annual internal audit schedules for fiscal years 2003 and 2004. From this review and the review of completed audits and management assessments it appears that oversight of the QA program and activities affecting the IROFS are scheduled on a reasonably periodic basis.

For some of the audits reviewed, the associated audit plan was also reviewed. The reviewer noted that the plans were complete and well prepared. As an example, the checklist for audit MFE-03-A07 was reviewed and found to include the audited QA program criterion, the specific evaluation criteria, the results of the audit of the criterion, and ample space for remarks about the audit and associated activities, as well as the identities of the audit team members.

Audits reviewed:

<u>Audit ID</u>	<u>Audited Organization</u>	<u>Audit Dates</u>
MFE-03-A03	Manufacturing Design Group	4/28-5/9/03 6/23-24/03
MFE-03-A06	Facilities Design Group	5/12-16/03
MFE-03-A07	Systems Engineering Group	5/5-9/03
PSA-03-A08	Project Services and administration	6/16-24/03
ESH-03-A09	Environ Safety and Health Department	9/8-12/03

The reviewer noted that audit results, findings, and recommendations are documented, readily accessible, and disseminated to relevant personnel including management, and that identified deficiencies are tracked by the DCS Quality Manager. Though timeliness of corrective action is improving, the average time required for corrective action completion is still higher (as noted in the DCS Quality Status Reports) than DCS procedures allow. A Deficiency Action Request (DAR)-04-002 resulted from review of QA Program Status

reports and identification of trends, which indicated that self identification of deficiencies was declining and timely completion of Corrective Actions was also declining.

The review of the sample of completed audit reports, and observation of the QA audit of MDG and SDG activities in France, indicates that the audits are sufficiently comprehensive. The review team determined that, for the audits reviewed or observed, they were performed by personnel trained in auditing techniques, practices, and procedures. The auditors did not have direct responsibility in the areas being audited and at least one member of each audit team was experienced and knowledgeable in the processes involved.

The commitments and implementation of MPQAP, Rev. 3, Section 2.4, "Management Assessments," and the following completed DCS management assessment reports were reviewed:

FY-03-M-LIC-008	(Licensing activities, performed July 8-18/03)
FY-03-M-QA-001	(QA activities, performed 6/3-12/03)
FY-03-M-PRO-003	(Procurement activities performed 7/9-24/2003)
FY-003-M-CON-003	(Construction-related activities performed 7/31/03)
FY-003-M-ESH-005	(Environmental, safety, and health activities, performed 7/16/03)

Also reviewed during the audit was the roll up assessment from the DCS President, Chief Executive Officer, and Project Manager, Robert H. Ihde, for FY-03, "Project Assessment Report, FY-03-P-09." This assessment identified positive project actions and identified three performance objectives for which improvement is needed. These were implementation of a MOX project integrated schedule, improvement of the interface between the engineering and integrated safety analysis (ISA) organizations, and completion of an action/commitment data base. The review team noted that the Project Assessment Report did not contain an overall evaluation statement regarding the effectiveness of the QA program, and suggested that DCS consider making such a statement in future reports. The review team also noted that the MPQAP states that the Project Performance Assessment will be performed by a team of DCS managers and/or supervisors, however, the FY-03 assessment was performed by external management consultants working with the DCS senior department managers and supervisors. When the review team noted this difference, the DCS QA Manager reviewed the issue and documented the deviation from the MPQAP wording in an interoffice memorandum, noting the qualifications of the assessors and the assessment performance approach and stating that the approach met the intent of the MPQAP requirement. The NRC review team concurred that the assessment met the MPQAP intent and that the approach ensured active management involvement and provided an objective assessment.

All reports were comprehensive and provided detailed recommendations and findings and indicated where a DAR was issued. The reviewer noted that the assessment reports provided opportunities for input by personnel through a questionnaire requesting responses to specific questions for each area assessed. The reviewer compared some of the assessments performed to the requirements of Procedure PP-3-11, Revision 2, "Assessments," and found that the procedural requirements had been met for the

performance of the sampled assessments. The Management assessments were very comprehensive, properly performed, and informative.

The review team questioned the DCS Quality Manager in regard to the deletion of the surveillance procedure from the project listing of quality procedures. The DCS Quality Manager indicated that the procedure had been combined with the DCS Procedure PP3-11, "Assessments." Since much of the work activity thus far by DCS has been design efforts, future consideration might be given to performing surveillance of work activities, as the MOX project matures. This would separate work surveillance activities from management assessments which might be more appropriate for an accurate indication of the quality of physical work on a performance based level. The results of the surveillance should then be added to the list of items reviewed for the development of DCS QA Program Status.

c. Conclusion

The review team concluded that DCS has established, and adequately implemented, an organization and QA program for audits and assessments, in accordance with its commitments in MPQAP Sections 2.0, "Quality Assurance Program," and 18.0, "Audits."

3.0 DESIGN CONTROL

a. Scope

NRC staff audited the design control activities at the DCS project offices in Charlotte, North Carolina, to confirm that the design control commitments contained in the MPQAP, Section 3.0, "Design Control," were being adequately implemented. The team reviewed various project procedures that addressed the QA commitments at the engineering design level. Interviews were held with the Responsible Engineers (REs) for the acid recovery, plutonium dissolution, and offgas systems to confirm the flow down of those commitments through the engineering organization to the working level. In addition, a "vertical slice" review was conducted for the design activities related to the acid recovery evaporator, plutonium dissolution electrolyzer, and the offgas system to determine whether the design requirements were being adequately implemented and confirm that various revised construction authorization request (RCAR) commitments were adequately communicated and tracked through the engineering organization.

b. Observations and Findings

The design control commitments contained in Section 3 of the MPQAP flow down to the engineering organization through about 20 MOX project procedures (PPs) contained in Section 9 of the QA Program Policy Statement. The project procedures address the input from various regulatory requirements and DOE contractual commitments into design requirements; the performance of plant level analyses; development of bases of design documents; use of other design documents such as calculations, drawings, technical documents, and engineering specifications; and SSC and/or system description documents.

PP-14 provides an overview of the design hierarchy showing the flowdown of design requirements and feedback mechanisms. The QA program commitments reviewed were adequately addressed in the project procedures.

The vertical slice review for the design activities related to the acid recovery evaporator, plutonium dissolution electrolyzer, and the offgas system and was conducted by reviewing the basis of design document, drawings, and related design documents, tracking the design requirements and RCAR commitments through the engineering organization, interviewing the REs, and examining records utilizing the Documentum system.

Interviews with the REs indicated that the HAZOP (hazard and operability evaluations used to perform the Integrated Safety Assessments required by 10 CFR 70.62) for their systems were complete and approved. However, substantial design work remained to be performed. The team noted that the HAZOP process generates action requirements that are used to develop the Nuclear Safety Evaluation (NSE). An adequate HAZOP cannot be performed until the design is completed. Subsequent discussions were held with the ISA manager concerning safety and design integration. The review team was informed that the initial HAZOP was performed to identify initial IROFS and action items. The proposed resolutions for these items would be part of the design input process and their actual implementation would be fed back into the HAZOP. Additionally, lessons learned and other design changes from COGEMA, in the form of design rules reflected in the piping and instrumentation diagrams (P&IDs), would also be fed into the design process. At a future date, the design would be frozen and a final HAZOP performed, and any future design changes would be handled under the configuration management system. The team identified no other concerns with the design process.

Several preliminary HAZOPs for the vertical slice SSCs were reviewed. The HAZOPs were documented in detail and each generated an extensive list of IROFS. The team identified no concerns with the methodology or content of the HAZOPs reviewed.

The status of various PSSCs and related controls identified by the applicant in the RCAR and subsequently docketed submittals were reviewed for the acid recovery evaporator, electrolyzer, and offgas treatment system. The team noted that while some of the open issue commitments were not incorporated into the preliminary HAZOPs, they were being tracked in a computer-based action tracking system. Resolution would be completed prior to conducting the final HAZOP. The team identified no concerns with the tracking of regulatory commitments and their feedback into the design process.

The project procedures and systems for control of software used in design analysis and engineering calculations were reviewed. The DCS management approach and project procedures for control of this software were significantly revised in October 2003. Training on the new procedures was conducted in October and November. No discrepancies were noted with the analytical software documentation reviewed.

Conclusions

The review team concluded that DCS was adequately controlling the design process in accordance with the commitments in Revision 3 of the NRC approved MOX Quality Assurance Plan. Implementing project procedures had been developed and approved. A vertical slice review of selected components and systems found that the commitments had flowed down to the working level and regulatory commitments were being adequately tracked. No safety concerns or open items were identified.

The review team concluded that DCS has established, and adequately implemented, an organization and QA program for the current activities, in accordance with its commitments in MPQAP Section 3.0, "Design Control."

4.0 PROCUREMENT

a. Scope

In order to verify that DCS has established, and adequately implemented, an organization and QA program with defined responsibilities and functions to administer the appropriate technical and QA program commitments in the MPQAP Sections 4.0, "Procurement Document Control," and 7.0, "Control of Purchased Material, Equipment and Services," the review team examined the organization structure, personnel assignments and training, and the implementing QA and project procedures. The review team also examined pertinent records and discussed the program requirements and implementation with selected DCS management and staff. The staff reviewed selected aspects of the procurement program to determine whether a process was established to ensure that PSSCs, would be procured and fabricated in accordance with the commitments and requirements specified in the CAR, 10 CFR Part 70, and the applicant's QA procurement procedures.

b. Observations and Findings

The staff reviewed the DCS organizational structure for engineering and procurement services. In addition, the staff interviewed applicant representatives, reviewed selected sections of the MPQAP, and reviewed selected portions of the implementing procedures and long lead-time plans associated with the procurement program. Finally, the staff reviewed a request for the procurement of preliminary design services for the sintering furnace.

The staff interviewed the procurement manager to discuss the responsibilities for managing the procurement process for equipment and materials supporting the construction of the proposed MFFF. The procurement manager was also responsible for coordinating supplier evaluations, developing procurement packages, and review of contract terms and conditions. The staff verified that the procurement manager met the minimum qualifications specified in Section 4.1.4 of the MFFF CAR, which included a Bachelors degree (or equivalent) and two years of related experience. In addition, the staff verified that DCS had established an engineering organization that would provide for the integration and coordination between the manufacturing, facilities, software, and equipment design groups, and the procurement engineering group. Equipment engineering and procurement activities are expected to occur in Aiken, SC, Denver, CO, La Hague, France, and Bagnols, France.

Selected portions of the following approved procurement related procedures and long lead-time procurement plans were reviewed:

- PP3-6, Corrective Action Process, Revision 5
- PP3-12, Supplier Evaluation, Revision 4
- PP3-13, Supplier Quality Assurance Source Surveillance, Revision 2
- PP3-16, Bid/Proposal Evaluations, Revision 1
- PP9-9, Engineering Specifications, Revision 5
- PP9-14, Design Process, Revision 2

- PP9-16, Basis of Design Documents, Revision 4
- PP10-1, Procurement Requisition, Revision 2
- Long Lead-Time Procurement Plan, Revision 2
- DCS Procurement/Subcontracting System for Federal Government Procurement, Rev. 1

Based on a review of the above procedures and plans, the staff did not identify any apparent procurement related issues with the reviewed procedures. The staff did note that the applicant's process for handling non-conforming materials, parts, or components had not been developed. Discussions with the DCS QA, procurement, and senior project management indicated that procedures for documentation and evaluation of non-conforming items, identifying non-conforming items, segregating non-conforming items, and disposition of non-conforming items were expected to be completed during the first quarter of 2004.

The staff also reviewed selected aspects of the applicant's procurement process by reviewing the records associated with the request for the procurement of preliminary design services for the sintering furnace that is planned to be used in the proposed MFFF. At the time of this audit, the procurement process for the design services was in the review and evaluation stage. The staff reviewed the following: (1) "Request for Proposal, Preliminary Design Services," dated October 2, 2003; (2) DCS procurement plan checklist; (3) engineering, procurement, quality assurance, and safety reviews; and (4) pre-award supplier evaluations. The staff verified that the potential supplier for the design services was on the DCS Approved Supplier List (ASL). The staff did note that, on an in-process procurement requisition, #0333, "Preliminary Design of Sintering Furnace," dated September 15, 2003, Section 10, "Supplies or Services," Note 4, stated that since the supplier (ECM) was a foreign entity, the requirements of 10 CFR 21 would not be invoked on the supplier because it is not legally binding. The requisition further stated that a clause that addresses deficiency reporting would need to be included in the subcontract terms and conditions to contractually bind the supplier to DCS for deficiency reporting. The reviewers discussed the wording pertaining to 10 CFR 21 reporting requirements in the procurement requisition with applicant representatives and noted that MPQAP, Sections 4.1 and 4.2.1.c.2 specified that the requirements of 10 CFR 21 would be invoked during design, construction, testing, and operations of all Quality Level 1 procurements. The DCS QA and Procurement managers stated they will take measures to assure that the wording in completed procurement requisitions involving foreign entities is consistent with the requirements specified in the MPQAP.

A project organization and procurement process had been established that would provide for the integration and coordination between the manufacturing, facilities, software, equipment design, and procurement engineering groups and the procurement and QA organizations. The process and procedures needed for handling supplier nonconformances, receipt inspection, and non-conforming materials, parts, or components, in general, had not been completed. These will be necessary for major procurement, receipt, and construction activities. DCS management stated that they are on the DCS QA and project management issue tracking schedules, and are in the developmental stage.

c. Conclusions

The review team concluded that DCS has established, and adequately implemented, an organization and QA program for the current activities, in accordance with its commitments in MPQAP Sections 4.0, "Procurement Document Control," and 7.0, "Control of Purchased Material, Equipment, and Services." The review team also noted that additional project procedures would be needed for major procurement, PSSC receipt, and construction activities.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

a. Scope

The review team audited the implementation of the DCS MPQAP Section 5.0, "Instructions, Procedures, and Drawings," to determine if the applicant has established and implemented governing policies for the development and implementation of instructions, procedures, and drawings, including the use of only approved and current procedures, and that approved procedures exist for MOX project functions associated with IROFS.

b. Observations and Findings

The review team interviewed eight individuals from seven technical or administrative disciplines supporting the DCS MOX project. Those interviewed were asked questions concerning the controls and availability of the procedures needed to perform their daily activities, as well as the controls for the types of document products developed by these members of the DCS staff. The DCS MOX project utilizes Documentum, a computer based document and records control and storage system, for essentially all of its document and records control requirements, including instructions, procedures, and drawings. The results indicated that, overall the DCS staff members interviewed were very knowledgeable in the use of the Documentum system to find the appropriate documents needed for their daily work. The observation of each individual's use of the Documentum system during the interviews provided overall evidence that DCS had developed multiple quality procedures to control the MOX project work activities, and that current and approved documents could easily be accessed for use at each work location.

The review team was able to witness use of the DCS system (Documentum), which, if used and maintained properly, ensures the use of only approved and current procedures. The review team noted that the Documentum system is broadly available and relatively user friendly. The reviewer noted that during the audit, the backlog for entering newer information into the Documentum system was averaging about 23 days. Though the Documentum system worked very well during the audit, any type of backlog could be an impact on the availability of information and, in-turn impact MOX project progress. At the time of the audit, the processing group had two open positions for employment for additional documentation personnel and that some personnel, on a rotating basis, and were continuing to work overtime to try to maintain or reduce the backlog. The DCS

management indicated that information awaiting input into Documentum that is identified as “rush” by managers is currently addressed first, as needed.

The review team reviewed project procedure PP1-2, “Preparation Of Project Procedures,” Rev. 5, Step 3.1.1.2, which required that procedures designated “QA” be used to implement the QA requirements, and specifically that if the work cannot be accomplished per procedure, the work will stop until adequately proceduralized. From an explanation of the process by the quality manager, review of procedures and records, and discussions with DCS staff, the review team was able to verify the implementation of PP1-2, Rev. 5, Step 3.1.4.1, which requires review in accordance with PP1-5, “Review of Documents,” and the follow-on approval under PP1-2, “Preparation of Project Procedures,” Rev. 5, Step 3.1.5.1, by the responsible manager, the QA manager, and the DCS president or other personnel, as applicable.

c. Conclusions

The review team concluded that DCS had established and adequately implemented policies and procedures in accordance with its commitments in MPQAP Sections 5.0, “Instructions, Procedures, and Drawings.” The reviewer verified that approved procedures exist for current activities. The review team, was also able to verify through a sampling process, that adequate and current instructions, procedures, and drawings, are available at the work location and implemented properly by the personnel using them. As stated in Section 5.0, “Procurement,” above, the review team also noted that additional project procedures would be needed for major procurement, PSSC receipt, and construction activities.

6.0 INCIDENT INVESTIGATIONS AND CORRECTIVE ACTION

a. Scope

The review team examined the DCS MOX project policies and procedures for addressing incident investigation and corrective action and commitments contained in Revision 3 of the MPQAP Sections 2.0, “Quality Assurance Program,” and 16.0, “Corrective Action.” The team reviewed the implementation of these policies and procedures, conducted interviews with DCS staff, and examined selected QA reports and deficiency action requests (DARs) to verify that conditions adverse to quality were promptly identified, corrected, and trended.

b. Observations

The three main project procedures that implement the commitments of Section 16 of the QAP are PP3-6, “Corrective Action Process,” PP3-20, “Trend Evaluation Analysis,” and PP3-25, “Root Cause Analysis.” These procedures covered the elements of a corrective action program applicable to the design phase of the project and were reviewed by the review team. The review team reviewed a listing of the DARs opened to date and selected several to confirm that the program commitments were adequately implemented and that the proposed resolution appeared adequate. The selected DARs covered

procurement, software control, and application submittals. The DARs addressed a wide range of deficiencies on activities, document, and procedures. The conditions identified were appropriate and adequately described and the DAR appeared to be timely in comparison to the activity addressed. Proposed corrective actions on DARs were tracked and received appropriate management attention. The DARs were in compliance with the DCS project procedure requirements.

As noted in the review of audits and assessments in Section 2.0 above, DAR-04-002 was issued by DCS QA based on the review of QA Program Status Reports, which showed a trend indicating that self identification of deficiencies was declining and completion of Corrective actions was becoming less timely. Reviews of recent QA Program Status Reports indicate that completion of corrective actions was improving. However, the time to complete corrective action still averages over the 100 day limit allowed by the DCS program requirements.

As noted in Section 2.0 above, DCS reviews and analyzes deficiencies and adverse trends and the QA manager prepares a QA Program Status Report every six months. The review team reviewed the last three reports numbered 06, 07, and 08. The reports are distributed to senior management. Deficiency action requests, external audit reports, surveillance reports, management assessment reports, employee quality concerns, stop work notices, and reportable items are required to be reviewed for adverse trends. DCS was placing emphasis on self-identification of problems and conducted trending reviews on a 6 month frequency. DCS has applied a graded approach for root cause analysis and the proposed corrective actions appeared adequate.

c. Conclusions

The review team concluded that DCS has established, and adequately implemented, an incident investigation and corrective action program for the current MOX activities in accordance with its commitments in MPQAP Sections 2.0, "Quality Assurance Program," and 16.0, "Corrective Action."

7.0 **RECORDS AND DOCUMENT CONTROL**

a. Scope

In order to verify that DCS has established, and adequately implemented, the QA program commitments in the MPQAP Sections 6.0, "Document Control," and 17.0, "Quality Assurance Records," the review team examined project procedures, reviewed pertinent records, and discussed the program requirements and implementation with selected DCS management and staff. The reviewers verified whether the applicant had established and implemented a method for identifying and controlling appropriate records and documentation in support of the MOX project.

b. Observations and Findings

Through interviews and observance of procedural use, the reviewer verified that current documents are available at each work location. The review team noted the hard copies of sample documents, which had been distributed according to the requirements of PP7-4, "Document Control," Step 3.2, and were at the work areas of those interviewed, matched the controlling identification numbers and revision numbers as each document was identified in Documentum. As new technical documents are prepared for use, the reviewer verified that the associated document controlling criteria is also included. During the interviews performed by the review team it became evident that the DCS staff recognized their responsibility to use the Documentum system to verify current documents were in use at each of their respective work areas. In addition, each person knew how to obtain a copy of the latest revision of the instruction, procedure, or drawing that they are using to perform their work activity.

During the interviews with DCS personnel, the reviewer reviewed multiple copies of transmittal sheets at work locations which had been signed and returned to the Project records center in accordance with PP7-4, "Document Control," Step 3.3. The reviewers witnessed a variety of documents in preparation during interviews with DCS personnel. On each document there was sufficient identifiable and retrievable evidence for that record to be maintained and to furnish evidence of compliance with project procedure PP3-4, "Records Management."

Documents reviewed included the following:

Calculations:	DCSO1-XGA-DS-CAL-B_01072-D DCSO1-RRA-DS-CAL-Z-35403-A DCSO1-RRA-CG-CAL-H-06682-A
Specification:	DCSO1-BAA-DS-SPE-b-09101-A
Drawing:	GAH-K-14855-A& B

The review of records and document control activities determined that the appropriated project procedures were in place, were adequate for the current activities, and were being implemented. No deficiencies were noted during this review activity.

c. Conclusions

The review team concluded that DCS has established, and adequately implemented, its commitments in MPQAP Sections 6.0, "Document Control," and 17.0, "Quality Assurance Records." The review team verified that the applicant has established and implemented adequate procedures for identifying and controlling appropriate records and documentation in support of the MOX project.

C. RESULTS OF IN-OFFICE REVIEWS AND AUDIT OF DCS MOX QA PROGRAM

The NRC in-office review team determined that the DCS commitments for QA approved by NRC in the MPQAP, Revision 3, are adequate for the current activities of design, advance procurement, and construction planning. The team also determined that the MPQAP commitments have been adequately implemented for the current activities. It was noted by the review team that additional policies, procedures, and training will need to be implemented as the project progresses into detailed system integration, software and hardware design, and major procurement and when construction and receipt of procured material, components, and services begins. The MOX Project QA program adequacy and implementation should be periodically reviewed, and should include evaluation at each location where major Mox project activities are being performed.

LIST OF IN-OFFICE REVIEW PARTICIPANTS AND PERSONNEL CONTACTED

[FRANCE]

NRC	Wilkins Smith
DCS QA	Donald Dalton
	Robert Justice
SGN QA	Amelia Jennequin
QA LHDO	Bernard Janssens
MDG FPC	Serge Claraz
MDG BDO	Eric Belton
MDG TR	Laurence Bourachat
MDG LHDO	Eric Lestournel
	Stephane Meslin
	David Audonnet
	David Lohier
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	Jean-Marc Belmont
SDG	Gary Bell
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[CHARLOTTE]

NRC Reviewers:	
NMSS	Wilkins Smith, Team Lead, Quality Assurance Scientist
RII/DFFI	William Gloersen, Senior Fuel Facility Project Inspector
NMSS	William Troskoski, Senior Chemical Safety Inspector/Technical Reviewer
SFPO	James Pearson, Transportation and Storage Safety Inspector

DCS Personnel:
James Cassidy
Sonya Chapman
Tanya Cyree
Don Dalton
Bob Eble

Dick Getz
Phil Hammond
Jody Hartsell
Michael Hunter
Wayne Love
Scott Matheny
Naresh Jain
Judy Justice
Robert Justice
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Mindy Singleton
Roger Alley,
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Robert Ihde
F. Kania,
Joe King
Mitchell Laney
Tommy Touchstone
Ed Brabazon
Earl Friend
Department of Energy
Mosi Dayani (NNSA)
Gene Langston (SAIC),

LIST OF ACRONYMS USED

ASL	Approved Supplier List
CAR	Construction Authorization Request
DCS	Duke, Cogema, Stone & Webster
DFFI	Division of Fuel Facility Inspection
DOE	Department of Energy
IROFS	Items Relied On For Safety
ISA	Integrated Safety Analysis
MFFF	MOX Fuel Fabrication Facility
MOX	Mixed Oxide
MPQAP	MOX Project Quality Assurance Plan
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
RII	Region II
SFPO	Spent Fuel Project Office