DUKE COGEMA
STONE & WEBSTER

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555

18 July 2001
DCS-NRC-000054
Response Requested: *Yes*
By: *20 August 2001*

Subject: Docket Number 070-03098
Duke Cogema Stone & Webster
Mixed Oxide Fuel Fabrication Facility
Response to NRC Request for Additional Information on MOX Project Quality Assurance Plan (MPQAP) Revision 2

Reference: Letter, Johnson to Hastings, 19 June 2001, "Request for Additional Information on the Duke Cogema Stone & Webster (DCS) Mixed Oxide Project Quality Assurance Plan, Revision 2"

As requested in your 19 June 2001 letter, please find attached our response to your request for additional information on the Mixed Oxide (MOX) Project Quality Assurance Plan (MPQAP), Revision 2. DCS has committed in the attached responses to revise the applicable sections of the DCS MPQAP to incorporate the changes resulting from these responses. DCS will transmit the resulting revision after receiving notification of acceptance of the attached responses.

If you have any questions, please feel free to contact me at (704) 373-7820 or Jim Brackett at (704) 373-7841.

Sincerely,

/s/ RZ Hastings

for Peter S. Hastings, P.E.
Licensing Manager

Q004

PO Box 31847
Charlotte, NC 28231-1847

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

Enclosure: Responses to MPQAP Request for Additional Information

xc: Edward J. Brabazon, DCS
Ralph J. (Jim) Brackett, DCS
Sterling Franks, USDOE/SR
Lionel Gaiffe, DCS
Joseph G. Giitter, USNRC/HQ
Melton S. Glenn, USDOE/SR
Robert H. Ihde, DCS
James V. Johnson, USDOE/MD
Timothy C. Johnson, USNRC/HQ
B. Robert Justice, DCS
Eric J. Leeds, USNRC/HQ
John E. Matheson, DCS
Andrew Persinko, USNRC/HQ
Robert C. Pierson, USNRC/HQ
Donald J. Silverman, Esq., DCS
Jon H. Thompson, USDOE/MD
Luis A Reyes, USNRC/RII
Wilkins R. Smith, USNRC/HQ
Thomas E. Touchstone, DCS
Michael F. Weber, USNRC/HQ
PRA/EDMS: Corresp\Outgoing\NRC\Licensing\DCS-NRC-000054

RESPONSES TO NRC REQUEST FOR ADDITIONAL INFORMATION FOR THE DUKE COGEMA STONE & WEBSTER (DCS) MIXED OXIDE (MOX) QUALITY ASSURANCE PLAN (MPQAP), REV. 2

RAI Item 1: Provide a full description of the applicant's organization for construction. Identify the responsibilities and functions of all Duke Cogema Stone & Webster (DCS) and other quality assurance (QA), quality control (QC) or inspection organizations where construction activities are delegated.

The DCS Mixed Oxide Project Quality Assurance Plan (MPQAP) Section 2.1 commits to the requirements of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994 and Regulatory Guide 1.28 (Rev. 3), for describing a DCS QA program that meets the 10 CFR 70.23 requirement of meeting the 10 CFR Part 50, Appendix B QA criteria. NQA-1 Basic Requirement 1, Organization, states that the organizational structure, functional responsibilities, levels of authority and lines of communication for activities affecting quality shall be documented. The applicant's identification and functional description of the specific organizational groups responsible for constructing the facility should include contractors, consultants, and other outside service organizations in addition to the applicant. This should also include, but not be limited to, the process designers, architect engineering firm, and the construction contractor(s).

The MPQAP has brief descriptions relating to "construction management," but does not address the actual construction responsibilities and interfaces. Clarify if there will be major delegation of work such as to an architect/engineer, a mixed oxide (MOX) plant constructor, an integration contractor, system suppliers, or other on- or off-site organizations. Where work is delegated, the responsibilities and functions of the DCS QA, QC, inspection and/or construction management organizations and those of the subcontractors should be identified. The authorities and responsibilities among the organizational groups and the means of communication should be addressed, including the DCS design and engineering functions and interfaces and those of the various contractors during construction. Organization charts should reflect the lines of responsibility and authority. 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, should be identified. All key management positions for construction activities should be adequately addressed. Specific activities such as inspection and testing of construction activities, equipment, and structures, systems, and components (SSCs) should be adequately addressed as to what organization performs them, and what, how, and by whom, QA controls and management measures are applied.

Response:

Construction Management (CM) Organization

The CM organization has overall responsibility for the construction and construction acceptance of the MOX Fuel Fabrication Facility (MFFF) construction project. The CM organization relies upon personnel from project support organizations that provide specialized services and

expertise. This is accomplished through a matrix organization representing all aspects of the construction process. The Construction Management organization provides oversight and management of the subcontractors and vendors that are subcontracted to execute specific construction work scopes. The organizational structure of the MOX Fuel Project during the construction phase is shown in Figures 1-1 and 1-2.

The CM organization is headed by the Construction Manager who reports to the Deputy Project Manager – Engineering & Construction. The MFFF Construction Manager is responsible for management and coordination of all site construction related activities. This is accomplished through a line construction organization supported by matrix personnel. Specifically, matrix support is provided in the areas of project control, QA, ES&H, contracts, and procurement. The direct report and matrix staffs are under the operational control and direction of the MFFF Construction Manager. The matrix staff is under the administrative and technical control of its respective project support organization manager.

Oversight and management of the construction subcontractors and vendors is the responsibility of the construction area management teams. Each construction area management team will be managed by a CM Area Superintendent who has the overall responsibility to (1) monitor and coordinate area construction work-in-progress and (2) ensure that it meets the requirements of the plans and specifications and good work practices. Daily oversight and direct coordination with the subcontractor QA/QC organization are the responsibility of the QA member of the construction area team (reports through the site assigned DCS QA supervisor to the DCS QA Manager). Results of QA oversight activities will be reported to both the MFFF Construction Manager and the DCS QA Manager. The construction engineers and discipline specialists will interface directly with their assigned subcontractors providing a point of contact for technical oversight and management. They also perform subcontractor/equipment vendor submittal reviews, construction acceptance of in progress and completed work, payment and schedule approval, coordination between subcontractors, issue resolution, change coordination, and corrective action resolution.

The Resident Engineering group supports the construction area management teams directly and indirectly at the site level. It provides construction acceptance and other miscellaneous support to the area management teams as required. It serves as a point of contact between CM and Title III Design Engineering for engineering changes and as-built drawing information. It provides site level survey control establishing site control points for subcontractor survey crew use and performs checks of subcontractor survey work as required. It performs the site materials management function for coordination and control of material/equipment warehouses and outside storage.

The Site Office group provides administrative support to the construction area management teams and the site level support groups. It is also the contact for the site security and building maintenance contracts and is the contact on matters related to document control, records management, internal security, training and personnel.

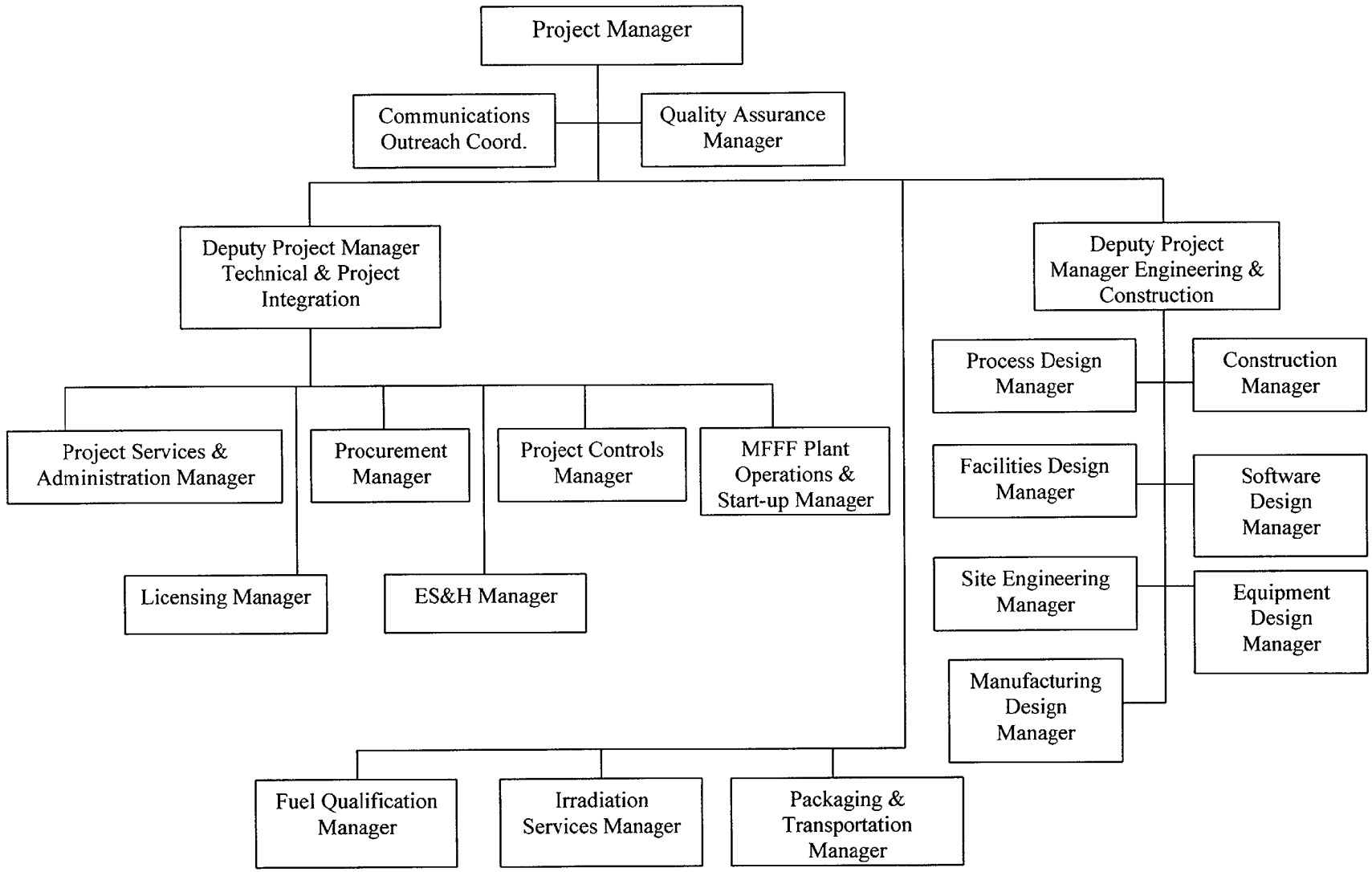

Figure 1-1: MOX Project Organization for Base Contract and Option 1

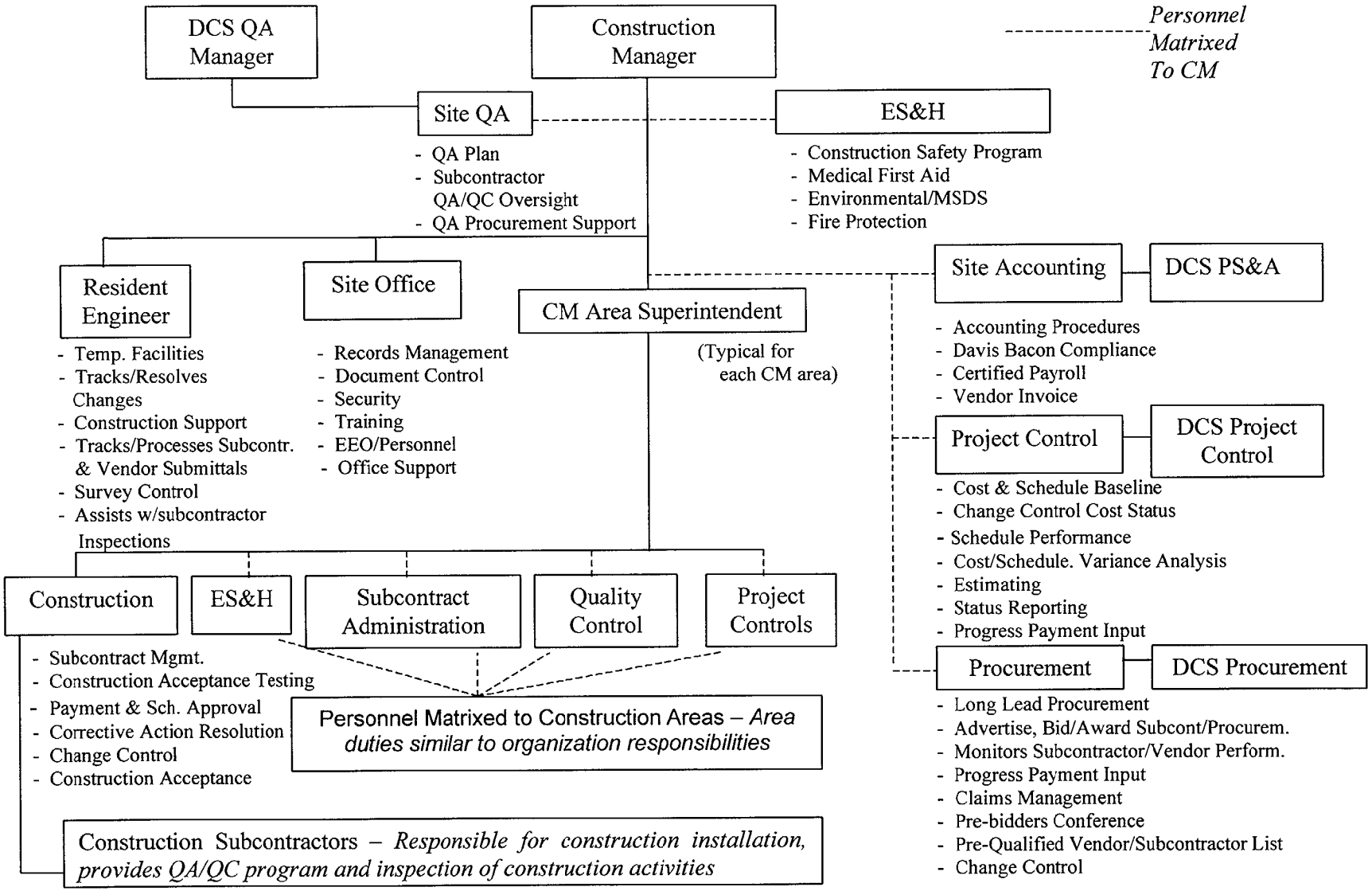

Figure 1-2: MOX Construction Management Matrixed Organization (Functional Chart)

Support Groups

Quality Assurance

The conduct of work in accordance with the requirements of the DCS Quality Assurance (QA) Program is the responsibility of the line organization conducting the work (flowdown of QA requirements to subcontractors is discussed below and in the response to question 3). The overall administration of the DCS QA Program and verification of quality achievement at the construction site is the responsibility of the DCS QA Manager and the site assigned QA personnel. QA audit, oversight and direction for quality functions will be the responsibility of the DCS QA Manager. Construction subcontractors and equipment suppliers responsible for 10 CFR 50, Appendix B installations shall provide a Quality Assurance program that complies with the applicable requirements of NQA-1-1994 as revised by NQA-1a-1995 and Regulatory Guide 1.28 (Rev.3). Audit and approval of subcontractors' Quality Assurance Programs for placement on the DCS Approved Supplier's List (ASL) is the responsibility of the DCS QA Manager.

The execution concept for the CM organization is to award competitive, fixed price subcontracts to construction contractors who will procure and install all construction materials and equipment. The construction installation will be subcontracted to the maximum extent possible. The major subcontracts in the MOX building will require NQA-1 Quality Assurance programs. Equipment identified as long lead-time will be procured by DCS and will be provided to the construction subcontractors for installation. The majority of the long lead-time equipment procurement vendors will require NQA-1 programs.

The construction subcontractors will be responsible to provide all labor, equipment and materials to complete the contracted scope of work. DCS QA has the responsibility for approval of the subcontractor QA programs and oversight and audit functions during the course of construction. DCS QA personnel will provide daily oversight of construction activities and the Quality Verification Group, who reports to the DCS QA Manager, will perform audits. Each construction subcontractor will have a defined scope of work, contract terms and conditions specifying the QA/QC requirements and technical specifications and drawings. Each subcontractor is required to perform the QA audits and QC inspections required by their DCS approved QA program. DCS QA personnel will perform surveillance of the subcontractors to assure that appropriate audit and inspection procedures have been established and that the subcontractor's QA audit and QC inspection personnel properly accomplish the audits and inspections. DCS audits and surveillance will be performed in accordance with DCS approved procedures. DCS Construction Management is responsible for management of the subcontract and DCS QA assures that the subcontractor conforms to the quality program approved for the subcontract work scope.

Engineering

The Engineering organizations (Process Design, Facilities Design and Site Engineering organizations) will be supporting construction with primary responsibilities in the areas of Title III engineering, equipment procurement and licensing. The Engineering organizations report to the Deputy Project Manager – Engineering & Construction responsible for overall engineering

organization performance meeting the engineering support requirements of the CM, ES&H, QA, Licensing, Purchasing and Operations organizations.

The Title III Engineering Support groups provide design engineering support to the CM organization. Title III engineering support activities include:

Resolution of technical issues
Review and approval of subcontractor technical submittals
Response to subcontractor technical questions
Interpretation of drawings and specifications
Review of corrective action disposition proposals
Technical evaluation of change requests
Correction of design errors/omissions
Assessment of subcontractor drawing/specification compliance

Configuration change control is managed through a formal process that authorizes and documents all changes to the design. Each subcontractor will be required to follow the DCS change control process to request field changes after subcontract award. Changes to the design will be controlled and must receive approval from design engineering, QA, and construction management. Safety evaluations for design changes are a part of the change control process. The construction management individual responsible for the affected construction subcontract is responsible for change implementation and coordinate formal approvals through the change control process. Configuration conformance is maintained during construction and verified prior to turnover for operations.

Manufacturing Design

The Manufacturing Design engineering group is responsible for the detailed design of the MFFF process equipment. This group provides subassembly and component details, layout configurations and geometrical interfaces. They also perform safety analysis and safety functions for the process equipment.

Equipment Design

The Equipment Design group provides engineering support to the DCS Procurement organization on the long lead-time process equipment and balance of plant equipment procurements, which are placed directly by DCS. Equipment procurement support engineering activities include the following:

Response to technical questions during the bid process
Technical evaluation of vendor proposal
Resolution of vendor comments through Procurement
Issuance of purchase specification
Review and approval of vendor design and submittals
Performance of shop verifications of compliance with technical requirements, acceptance of in process work and factory testing

Support to QA for vendor qualification and acceptance
Factory acceptance test criteria

Software Design

The Software Design engineering group provides the design of the software logic needed to operate the integrated control system for the MFFF. Software design, development, testing, and installation are performed meeting the requirements of Section 3.2.7 of the MPQAP for QA software.

Testing

As work is completed, construction acceptance testing (CAT) is performed in accordance with regulatory requirement and the terms and conditions of the construction subcontract. The subcontractors shall prepare the CAT procedures in accordance with specification requirements established by the Process and Facility Design organizations and approved by the CM, QA, ES&H and Operations organizations. The purpose of the CAT is to confirm proper installation of components and readiness for start-up testing prior to CM acceptance from the subcontractor. Coordination between CM and the Start-up organization for start-up testing and remediation of problems and final turnover is in accordance with the Functional and Operability Testing Plan. Each construction subcontract will have construction acceptance testing requirements specified as criteria for subcontract completion. DCS QA will provide oversight of the testing activities and witness specified testing.

Construction Acceptance is the completion status of construction at the point of turnover from the construction subcontractor to the CM and includes the following:

Completion of erection and assembly of facilities including erection of equipment, sub-assemblies and parts
Performance of non-operating adjustments, cold alignment checks
Performance of leak, pressure and other non-destructive testing
Instrument calibration and loop checks
Electrical continuity and motor rotation checks
Construction, construction punchlist and clean-up activities
Documentation turnover to DCS

Documentation includes as-built drawings, inspection records, completed test records, punch lists, startup and operating instructions and manuals from equipment/material suppliers, spare parts data etc.

DCS QA provides oversight witness of final testing and selected test activities and audits of test activities.

Action:

Revise MPQAP Section 1.2 Position Responsibilities to describe changes for support of construction to the project management organizational chart and specifically adding the construction management organization details for the Construction Manager, Resident Engineer, and CM Area Superintendents including roles, responsibilities and interfaces as discussed above. Also revise section 1.2.4.2 QA Manager to describe the oversight of construction subcontractors. Figure 1.0-2 will be replaced with Figures 1-1 and 1-2 of this response. Functions for each of the positions will also be added to Figure 1-1 similar to what was done with Figure 1.0-2.

RAI Item 2: Discuss DCS' application, and implementation of, 10 CFR Part 21 requirements and procedures on the MOX project activities before operation, including MOX facility construction and design and MOX fuel design and qualification activities. Also, explain why only Items Relied on for Safety (IROFS) SSCs and not Quality Level (QL) 2 SSCs would be subject to Part 21 requirements.

NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," (SRP) Section 15.4.3.D states that the requirements of 10 CFR Part 21 should be addressed by the applicant.

Response:

CAR Section 15.1.8 erroneously identified that 10 CFR Part 21 would be implemented upon receipt of the license to possess and use SNM under 10 CFR Part 70. As an example of DCS' implementation of 10 CFR Part 21 during design, DCS has imposed 10 CFR Part 21 reporting requirements on suppliers of the geotechnical work performed at the MFFF Savannah River Site to provide input to the QL-1 (i.e., Items Relied On For Safety or IROFS) design of the MFFF. As this input was included in QL-1 seismic calculations, DCS required notification if the suppliers identified conditions which could possibly invalidate the results obtained. This requirement was placed on suppliers of QL-1 services through the DCS procurement procedures, specifications, and contracts for these procurements. 10 CFR Part 21 requirements will also be invoked on QL-1 long lead procurements for the glove boxes and process equipment for the MFFF. The controls for processing QL-1 procurements are identified in Section 4.0 *Procurement Document Control* in the MOX Project Quality Assurance Plan (MPQAP), DCS Project Procedure for procurement, procurement specifications and contracts. 10 CFR Part 21 requirements apply to all QL-1 procurements for the MFFF design, construction, testing, and operations. Framatome ANP also implements 10 CFR Part 21 on its DCS assigned MOX fuel design and qualification activities through Section 4 *Procurement Document Control* of the DCS QA approved Framatome ANP Quality Assurance Program.

The application of 10 CFR Part 21 requirements on QL-1 (IROFS) SSCs and not on QL-2 SSCs is based on the 10 CFR 21.3 definition of "basic component":

> "When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts, 30, 40, 50 (other than nuclear power plants), 60, 61, 70,71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that

affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation of this chapter, order, or license issued by the Commission could create a substantial safety hazard."

QL-1 SSCs are defined as Items Relied On For Safety as defined in 10 CFR 70.61; QL-1 SSCs (IROFS) are, by definition, those SSCs with a "safety function" as defined in 10 CFR Part 70. QL-2 SSCs as defined in Section 2.2 *Graded Quality Assurance* of the MPQAP are not relied on to satisfy 10 CFR 70.61 performance requirements. While DCS has elected to control these SSCs under the controls of the DCS MPQAP as an added conservatism for certain SSCs (see response to question 4), these SSCs do not meet the definition of items relied on for safety in 10 CFR 70.61, and thus are not basic components in 10 CFR 21.3.

Action:

Revise MPQAP Section 4.1 to clarify that 10 CFR Part 21 applies to QL-1 procurements for design, construction and operations activities. Also include in the answer to question 238 on the CAR that section 15.1.8 of the CAR incorrectly limited the application of 10 CFR Part 21 to after receipt of a license to possess and use SNM under 10 CFR Part 70. This was in error as it applies for QL-1 procurements for design, construction and operations.

RAI Item 3: Clarify the requirements and application of DCS QA program commitments for subcontractor QA Programs and activities.

SRP Section 15.1.5.2.A, Construction Approval, states that the review should result in a determination that there is reasonable assurance that the applicant's and the applicant's principal contractors' QA programs will provide reasonable assurance against natural phenomena and the consequences of potential accidents through the QA program's application to the design, fabrication, construction, testing, and operation of the applicant's SSCs.

MPQAP Section 1.4, Organization, states that, "All DCS quality affecting activities shall meet the requirements of this document except when work is performed under an approved subcontractor QA program as addressed in section 2.1." Describe how these requirements flow down, how they are implemented by the subcontractors' QA programs, and how DCS assures the adequacy and implementation of the DCS QA commitments. Discuss DCS's plans for submittal for review and/or approval by NRC of principal subcontractors' QA programs or the justification and adequacy for not submitting these programs.

Response:

In accordance with SRP Section 15.1 the DCS QA Program established in the MOX Project Quality Assurance Plan (MPQAP) is based on the requirements of 10CFR50 Appendix B, Parts I and II of ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications,* as revised by NQA-1a-1995 Addenda, and Regulatory Guide 1.28 (Rev.3), *Quality Assurance Program Requirements (Design and Construction).* These requirements are flowed to

DCS suppliers and subcontractors through the respective procurement documents for the particular scope of work being contracted. Flowdown of applicable QA requirements is applied both to procurements for QL-1 and QL-2 items and services (such as construction). Procurement documents are reviewed by DCS QA prior to issuance and QA requirements applicable to the specific contracted work are placed in the request for proposal and/or procurement specification. The applicable 10CFR50, Appendix B and NQA-1 QA Program elements required for the particular scope of work are first identified in the request for proposal and/or procurement specification.

Potential equipment and component suppliers/subcontractors are required to submit their QA Plans to DCS QA for review in accordance with the request for proposal/procurement specification. DCS QA performs an audit at the supplier's/subcontractor's facility of their QA program and its implementation verifying that the supplier's/subcontractor's QA program meets the requirements established in the request for proposal/procurement specification. If the audit is acceptable then the supplier/subcontractor is added to the DCS Approved Suppliers List (ASL) and a contract between DCS and the supplier/subcontractor may be issued. For procured items DCS may also require that DCS QA perform source inspections or witnessing of tests at the supplier's facility if the equipment/component warrants inspection due to safety significance and/or complexity. Such requirements are also identified in the procurement documents and/or contract.

Construction subcontractors for DCS QA Program controlled construction activities are also required to be placed on the ASL prior to contract award. Construction subcontractors are required to perform the QA activities required by their QA program including audits of their own activities as well as any required quality control (QC) inspections. DCS QA will provide oversight of these subcontractors in the form of audits and surveillances verifying that each subcontractor is properly implementing the subcontractor's QA program as approved by DCS QA. Contractually subcontractors will be required to correct DCS identified deficiencies. Deficiencies require investigation, root cause analysis (for Significant Level 1 findings), planned corrective actions, and completion of planned corrective actions and verification of completed corrective actions. Interfaces between DCS construction management, DCS QA and construction subcontractors are further discussed in the response to RAI Item 1.

DCS QA is responsible for qualifying suppliers/subcontractors prior to issuance of a contract. Initial supplier/subcontractor qualification audits, followed by yearly evaluations and triennial re-audits are requirements of the DCS QA Program. The records of these QA activities are continuously subject to NRC audits and inspections. The NRC has the authority to review any of the DCS supplier/subcontractor QA programs however DCS does not plan on submitting the supplier's/subcontractor's QA programs for NRC review and approval. DCS QA qualification and oversight of supplier/subcontractor activities is sufficient to ensure their QA programs will provide reasonable assurance against natural phenomena and the consequences of potential accidents through the proper implementation of the their QA programs. This will be verified as the NRC audits DCS MFFF construction activities and verifies that DCS QA is properly implementing its committed QA program.

Action:

Section 2.1.2 of the MPQAP will be revised to better clarify the flowdown of QA requirements to subcontractors and use of subcontractor QA Programs as discussed above.

RAI Item 4: Please amplify the application and definitions of QL-1, QL-2, and QL-3 presented in MPQAP Section 2.0, QA Program. Also, provide a full description of the methods for grading the application of QA controls for various QL levels.

SRP 15.1.4.3, Regulatory Acceptance Criteria, states that the applicant should describe, if used, the graded approach for application of QA. The methods for grading should be described, including how the QA program controls are applied or not. Amplify the discussion of the definitions of QL-1, QL-2 and QL-3. Discuss the relationship between the QL definitions and designations and the performance criteria of 10 CFR 70.61, and to what extent probability performance or failure rates are factored in the application of QLs and QA controls. Please explain the relationships and differences between the QL and applied QA controls and the engineering requirements and specifications for QL-1 and QL-2 SSCs.

Examples may be used for illustrative purposes. For example, specifically identify which MPQAP provisions will apply to criticality controls classified QL-1b. It would appear that most criticality safety controls would be graded QL-1b, on account of the double contingency principle. It is stated in the MPQAP that all MPQAP requirements pertain to controls graded QL-1a but, not necessarily QL-1b. Also, please identify the differences in the application of QA controls for SSCs that are produced routinely or to standard requirements and have a well-defined failure experience base such as thermocouples and those which may be customized with little or no failure rate data such as electrolyzer controls. Examples that compare the application of QA controls for a simple passive SSC to that for a complex active SSC would also be useful in providing a full description of the methods of defining QL categories and applying graded QA controls.

Response:

QA classification of SSCs and determination of applicable QA controls (grading) are controlled and documented by the MPQAP and applicable MOX Project procedures. The DCS QA Program categorizes structures, systems and components (SSCs) into four quality levels based on the definitions found in Table 2-1 of Section 2.2 *Graded Quality Assurance* in the MPQAP. Quality levels are assigned to SSCs commensurate with their safety significance as indicated by the performance requirements of 10 CFR 70.61, which define IROFS based on the likelihood and consequences of postulated design basis events. Reviews of the SSCs' functions, applicable regulations, and consideration of SSCs with the same functions at MELOX and La Hague were used to determine, at a functional level, the initial Quality Level designations. These designations will either be confirmed or changed upon completion of the Integrated Safety Analysis (ISA). Classifications of SSCs and determination of applicable grading are controlled and documented by the MPQAP and applicable MOX Project Procedures.

The approach to a graded application of QA requirements provides a safety benefit by allowing preferential allocation of resources to more safety-significant SSCs. Safety significance of the SSC affects the applicability of QA requirements to SSC design, purchase, fabrication, handling, shipping, storage, cleaning, construction, installation, inspection, testing, operation, maintenance, repair, and modification. Of these activities, those that are related to procurement, inspection, testing, and record keeping are key areas where graded controls may be appropriate for less safety-significant SSCs.

Quality Level 1 (QL-1)

QL-1 SSCs are defined in the MPQAP as those SSCs "that are items relied on for safety (IROFS) to prevent potential accidents such that high-consequence events are made highly unlikely and intermediate-consequence events are made unlikely, or to mitigate their potential consequences, or that are relied on to prevent criticality." These SSCs are required to meet the performance requirements of 10 CFR 70.61. QL-1 design and procurement specifications require design verification and QA approval. QL-1 SSCs have been divided into two classification levels in order to allow possible grading (i.e. the selected application of QA requirements) based on a justification documented in the form of an engineering analysis.

QL-1a is used for SSCs whose single failure could directly result in a loss of confinement leading to a release of radioactive material to the environment, a criticality accident, or in exceeding 10CFR70.61 public (offsite) performance requirements. These SSCs are subject to all of the applicable controls of the MPQAP. No grading applies to these SSCs except where justified on a case by case basis in a documented analysis conducted under DCS QA procedures with Engineering and QA approval (this should be rare).

QL-1b is used for SSCs whose failure in conjunction with the independent, unlikely failure of an additional item or administrative control, could result in exceeding 10 CFR 70.61 performance requirements. These are SSCs that have been determined to provide some opportunity for selective grading with justification since their single failure could not result in an accident as described in QL-1a. To date the following SSCs are expected to be classified as QL-1b (based on an in-progress analysis):

- Fire suppression and detection for Process Areas containing plutonium; and
- Controls and equipment that meet the double contingency principle for criticality control, except for geometry control (which is QL-1a).

Quality Level 2 (QL-2)

QL-2 is used for SSCs which are not relied on to satisfy 10 CFR 70.61 performance requirements but whose functions support normal operations of the facility (e.g., occupational exposure, radioactive waste management) and also function to further reduce public, worker radiological, chemical, or environmental risks below performance requirements (e.g., physical interaction protection, radiological and criticality alarms). QL-2 SSCs are not required to meet the regulatory definition of *safety*, and therefore there is no requirement for the application of quality assurance program requirements to them. However, DCS has elected to apply selected

(i.e., graded) QA requirements to emphasize their functions in providing additional measures of protection and/or regulatory compliance beyond 10 CFR 70.61 requirements.

QL-1 grading concentrates on applying all of the applicable requirements and justifying what QA requirements are not needed. As an elective application of requirements to SSCs for which no such control are required by regulation, grading of QL-2 SSCs focuses on selecting what QA requirements should be applied in order to ensure the SSC performs its intended function.

Quality Level 3 (QL-3)

QL-3 is used for SSCs subject to management controls solely for mission and economic related reasons such as throughput, cost, or schedule. These SSCs are unrelated to safety as defined in 10 CFR 70.61 (i.e., QL-1) and do not provide additional measures of protection and/or regulatory compliance (i.e., as described under QL-2). These SSCs are outside the regulatory purview of the NRC, and are controlled by DCS management under the DCS QA Program for efficiency (i.e., to avoid the need for a separate, redundant program for management of these SSCs). Examples of QL-3 SSCs determined to date are the Reagents Processing Building and the Breathing Air, Instrument Air, and Service Air systems. DCS management has the prerogative to apply any or no part of the DCS QA program to these systems. These systems will be installed using drawings and appropriate testing to meet non-QA code requirements, safety requirements and permits. There are no mandatory QA records requirements for these systems as they fall outside of the mandatory controls of the DCS QA Program. QL-3 SSCs are designed, procured, constructed, operated, and maintained in accordance with conventional industry standards and good engineering practice.

Quality Level 4 (QL-4)

QL-4 is used for those SSCs that are not QL-1, -2 or -3. These are classified as conventional quality SSCs and are also outside the purview of the NRC. QL-4 is equivalent to "non-QA" and is used to simply designate that an SSC has been determined not to meet the definition of QL-1, -2 or -3. There are no mandatory QA records requirements for these systems as they fall outside of the mandatory controls of the DCS QA Program. Like QL-3 SSCs, QL-4 SSCs are designed, procured, constructed, operated, and maintained in accordance with conventional industry standards and good engineering practice.

Additional Discussion

The grading process, analyses for which are currently in progress, will define the hierarchical application of QA controls on the basis of SSCs' safety significance. The process uses the framework of controls from 10 CFR Part 50 Appendix B as reflected in the MPQAP. The various MPQAP controls are evaluated for SSCs or categories of SSCs based on their quality levels and functional requirements. The grading process reflects the criteria used for determining what MPQAP requirements are not applicable to IROFS. For example, the grading process for QL-1b SSCs reflects the criteria for reduction of controls where safety significance is reduced, as in the case of the following (generally in order of ascending safety significance):

- an SSC whose safety function is not specifically credited in safety analyses (i.e., an SSC designated as IROFS solely on the basis of defense in depth);

- an SSC whose only function is protection of facility workers, in recognition of the fact that such workers are trained to appropriate procedures for safe operation and self-protection in the event of abnormal occurrences or accidents;

- an SSC whose function is protection against chemical releases and whose suppliers are not likely to have an approved 10 CFR Part 50 Appendix B QA program; and

- use of commercial-grade dedication for hardware used in double-contingency criticality controls, in consideration of the use of validation and verification of software implemented on that hardware.

The grading process also manifests the fact that, for those SSCs of the highest safety significance (i.e., SSCs associated with limiting public radiological exposure, or SSCs whose single failure can result in an accident), grading typically is not performed (i.e., all applicable MPQAP requirements are employed in the control of these SSCs). In addition, the grading process defines the selection of QA controls to be applied to QL-2 SSCs based on their functional requirements (e.g., for fire protection of non-IROFS, occupational exposure control, etc.).

The only specific correlation between QLs-1, -2, and -3 and the performance criteria of 10 CFR 70.61 is that those SSCs credited in the ISA as required to meet those criteria (i.e., items relied on for safety) are, by definition, QL-1. Also by definition, QL-2 and -3 SSCs are not IROFS and not directly credited for meeting the 10 CFR 70.61 performance criteria.

Neither failure probability or reliability rates are related to the definitions of quality levels. The difference between QL-1 and QL-2 is based specifically on whether an SSC is relied on for safety (i.e., required to meet 10 CFR 70.61 requirements). The difference between QL-2 and QL-3 is based on whether an SSC provides additional measures of protection and/or regulatory compliance beyond the 10 CFR 70 definition of safety. Clearly, therefore, failure probabilities and equipment reliability do not play a part in distinguishing between these categories.

The MFFF safety basis is defined using conservative deterministic analyses and qualitative likelihood definitions. Accordingly, specific failure probabilities are not estimated in establishing compliance with 10 CFR 70.61, because the SSCs that are IROFS are designated as such on the basis of the consequences under deterministic SSC failure assumptions.

Using the examples discussed above may clarify these definitions. Fire suppression and detection SSCs in the MOX Process Areas are expected to be QL-1b on the basis of in-process analysis. Analysis of these systems has concluded that the MPQAP's audit requirements are not applicable to suppliers of fire suppression and fire detection equipment as long as the supplier is already certified Factory Mutual (FM) or Underwriter's Laboratory (UL) approved. Such certification is a rigorous process, obviating the need for a DCS audit to MPQAP requirements; certification also implies that products meet the appropriate National Fire Protection Association (NFPA) codes. Acceptance of FM and UL approval on such equipment that protects "safety-

related" equipment in nuclear power reactors is consistent with this approach to grading for these SSCs. The DCS QA organization will review and approve the procurement specifications to place the requirement that the equipment must be manufactured and tested under a FM or UL approved program. The equipment will still require receipt inspection, installation by drawings and procedures and installation inspections and witness of acceptance testing.

Other fire protection systems provide an example of QL-2 SSCs. Fire detection and suppression for the balance of the plant outside the process areas containing plutonium are not IROFS. If/when the system could physically interact with QL-1 SSCs, QA procurement requirements would be imposed to ensure seismic integrity of the supports; the system is QL-2. QA requirements determined to be applicable for the QL-2 SSC will be implemented in the appropriate specification, procurement documents and installation and test procedures. This too is consistent with nuclear power reactor practice.

Certain criticality controls are also anticipated to be QL-1b, again on the basis of in-process analyses. Criticality is prevented typically by geometry where practical. Currently DCS does not anticipate grading geometry controls. Other criticality controls are potentially subject to grading, on the basis of the applicability of double contingency (i.e., typically when double contingency is satisfied through independent engineered controls). The determination of which MPQAP requirements are not needed for these SSCs is not complete at this time, An example expected to include the use of commercial, off-the-shelf hardware for computer or PLC controls; QA requirements would include a rigorous verification and validation testing of IROFS process control software on the applicable platform. (Note that, in accordance with procedural requirements, criticality controls will be treated as QL-1a and not subject to grading until the applicable grading analyses are complete.)

Action:

Revise Section 2.2 Graded Quality Assurance of the MPQAP to further describe the grading process consistent with discussion above; the remainder of the descriptions and discussions above are consistent with the MPQAP and no additional change to the MPQAP is required.

RAI Item 5: Clarify what is meant in MPQAP Table 2-1 by "a condition compromising criticality safety," and explain the differences or discrepancies between this statement and the MPQAP Section 2.2.2 statements regarding QL-1a and -b and SSCs whose single failure, or failure with another SSC, can result in a criticality.

SRP 15.1.4.3, Regulatory Acceptance Criteria, states that the applicant should describe, if used, the graded approach for application of QA. MPQAP Section 2.2.2 states that SSCs whose single failure can directly result in a criticality accident are designated QL-1a, and SSCs with an additional, independent, and unlikely failure of an SSC could result in a criticality accident. However, QAP Table 2-1 states that QL-1a controls are those which can cause "a condition compromising criticality safety." This information is necessary to ensure that the quality assurance program provides reasonable assurance of protection against a criticality accident.

Response:

The difference in terminology is semantic and not intended to convey a difference in approach. The Table 2-1 reference to "condition compromising criticality safety" is analogous to a "criticality" or "criticality accident" as a result of the conservative, deterministic assumptions made in the MFFF accident analyses. That is, accident analyses would not require that a postulated criticality actually occur before IROFS SSCs are designated to prevent the event; if safety analysis determined that a failure of a specific SSC resulted in a significant reduction in margin (e.g, $k_{eff} > 0.95$), then the SSC would be designated as an IROFS.

Action:

Clarify MPQAP Section 2.2 Graded Quality Assurance for consistency to reflect discussion above.

RAI Item 6: Provide justification for classification of the criticality monitoring and criticality alarms as QL-2 and not QL-1 (IROFS).

SRP 15.1.4.3, Regulatory Acceptance Criteria, states that the applicant should describe, if used, the graded approach for application of QA. MPQAP Section 2.0 and Table 2-1 classify radiological and criticality monitoring and alarm SSCs as QL-2. In processes dealing with liquids, it is possible to get a pulsating cycle between critical and non-critical conditions, and as such, criticality monitors and alarms could be considered to be mitigating IROFS. Please discuss the functions and/or importance of criticality monitors and alarms for prevention of or mitigation for a pulsating criticality or other events at the MOX facility.

Response:

The requirement for a criticality monitoring and alarm system (10 CFR §70.24(a)) is not associated specifically with meeting the safety criteria prescribed in §70.61. Criticality is prevented by design "under normal and credible abnormal conditions" in the MFFF in accordance with §70.61(d) and the double contingency principle in accordance with §70.64(a)(9). Criticality alarms obviously can play no role in preventing criticality, and mitigation of events beyond the criteria of §70.61 is not required in defining items relied on for safety. Criticality monitoring and alarms are therefore not QL-1.

In particular for liquids in the MFFF, criticality is prevented typically by the geometry designed into the facility (See Table 6-1 in CAR Chapter 6). As described in the MPQAP, QL-1 SSCs are reserved for those SSCs whose failure can potentially result in an accident or which are needed to mitigate potential accident consequences, or prevent criticality. SSCs whose failure can result in a criticality accident are designated QL-1; the failure of the criticality monitors can not result in a criticality accident.

Because the criticality monitoring and alarm system is not QL-1 does not mean it is unimportant. Such a system is a specific requirement of the regulation, and as an SSC that functions to further

reduce worker risks beyond §70.61 performance requirements, it is subject to QA controls under QL-2.

Action:

None

RAI Item 7: Explain why the requirements of Section 7.2.12, Commercial Grade Items, are applied only to IROFS and not to QL-[2] SSCs.

SRP 15.1.4.3, Regulatory Acceptance Criteria, states that the applicant should describe, if used, the graded approach for application of QA. The methods for grading should be described, including how the QA program controls are applied or not.

Response:

The definition and requirements for "Commercial Grade" are found in 10 CFR Part 21. The Commercial Grade Dedication process allows for the dedication of standard off the shelf items for use as basic components where the items are (1) not subject to design or specification requirements unique to a nuclear facility; (2) used in an application other than in nuclear facilities; and (3) can be ordered from the manufacturer's/supplier's standard catalog. As discussed in the response to RAI Item 2 above, DCS has defined "basic component" consistent with "items relied on for safety" (i.e., QL-1 SSCs) as defined in 10 CFR 70.61. QL-2 items are not required to meet the performance requirements of 10 CFR 70.61, are therefore not IROFS and not subject to 10 CFR 21.

Please note that the attributes important to QL-2 SSCs' performance will be determined as part of the DCS grading process discussed in the response to RAI Item 4, and will be included in procurement specifications for those SSCs as appropriate.

Action:

None

RAI Item 8: Clarify the QA requirements for subcontractors' control of special processes for, or during, fabrication, assembly, and construction. Confirm that subcontractors are required to implement the requirements of NQA-1 for special processes or justify the DCS requirements for subcontractors.

The MPQAP commits to compliance with NQA-1, but MPQAP Section 9.0, Control of Special Processes, is not clear on the commitments and requirements for subcontractors.

Response:

The DCS procurement process is described in sections 4 and 7 of the MPQAP for items and services controlled under the DCS QA Program. These sections require procurement documents to contain the applicable QA requirements for the scope of work being provided. If subcontractors who are suppliers of items and services to DCS are to perform special processes then procurement documents will require the suppliers to have a QA Program that implements the requirements of Basic Requirement 9 and Supplement 9S-1 of NQA-1-1994. DCS QA will evaluate and audit the subcontractor's QA program as described in section 7.2.2 of the MPQAP. If acceptable (i.e., their QA program meets the requirements of Basic Requirement 9 and Supplement 9S-1 of NQA-1-1994 and other applicable requirements) the supplier is then placed on the DCS Approved Suppliers List (ASL) and then the purchase order and contract can be placed with the supplier for the item or service. Since this process is driven by MPQAP sections 4 and 7 revision to section 9 of the MPQAP to address this is not necessary.

Action:

None

RAI Item 9: Clarify the intent of the wording in MPQAP Section 10.2.4, Statistical Sampling, or commit to the NQA-1, supplement 10S-1, Section 5.2 wording that the sampling procedure be based on recognized standard practices.

The SRP Chapter 15.1 states that the applicant's QA program may commit to conformance with NQA-1-1994, etc. The MPQAP commits to compliance with NQA-1, but Section 10.2.4 only states that statistical sampling shall be based on practices specified by DCS approved procedures.

Response:

Section 10.2.4 of the MPQAP was intended to stress that DCS works to developed, reviewed, approved and issued procedures that are based on the appropriate recognized standards. This section, as presently written, does not convey this.

Action:

Section 10.2.4 is to be revised to state:

> "When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method used shall be based on recognized standard practices and these practices shall be implemented through applicable approved procedures."

RAI Item 10: Clarify the QA requirements for subcontractors' QA records during construction, both for records in general and for temporary storage. Confirm that subcontractors are required

to implement the requirements of NQA-1 for QA records or justify the DCS records requirements for subcontractors.

The MPQAP commits to compliance with NQA-1, but MPQAP Section 17.0, QA Records, and in particular Section 17.2.2.2.E, is not clear on the commitments and requirements for subcontractors.

Response:

Subcontractors who are contracted to perform quality affecting activities (i.e., provide items or services that are controlled under the DCS QA Program) are required to have a QA program that meets the records requirements of Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 as revised by RG 1.28 (Rev.3). The purchase order and contract for the quality affecting items or services shall identify these requirements along with records turnover requirements upon job completion. The identification of these requirements is controlled under the procurement documents generated in accordance with the requirements of section 4 of the MPQAP. This is a similar concern to what was addressed in RAI Item 8. Since this process is also controlled under sections 4 and 7 of the MPQAP revision to section 17 is not necessary.

Action:

None