DUKE COGEMA
STONE & WEBSTER

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Subject: Docket Number 070-03098
Duke Cogema Stone & Webster
Mixed Oxide (MOX) Fuel Fabrication Facility
Response to Draft NRC Safety Evaluation Report for MOX Project Quality Assurance Plan, Rev.2

Reference: Letter, Persinko to Hastings, 17 August 2001, "Draft Safety Evaluation Report for the Duke Cogema Stone & Webster Mixed Oxide Project Quality Assurance Plan, Revision 2"

Duke Cogema Stone & Webster (DCS) has reviewed your 17 August 2001 letter and draft Safety Evaluation Report (SER) on the MOX Project Quality Assurance Plan (MPQAP), Revision 2. In response to the two issues noted in Section 2, QA Function/Program, of the draft SER, DCS submits the attached clarification and commitments to revise the MPQAP to reflect the discussions provided with this letter. DCS requests that this additional information be considered prior to NRC final issuance of the SER and, if acceptable, that this fact be reflected in the final SER.

If you have any questions regarding this submittal of additional information please contact me at (704) 373-7820 or Jim Brackett at (704) 373-7841.

Sincerely,

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Enclosure: Response to Draft NRC Safety Evaluation Report for Duke Cogema Stone & Webster (DCS) MOX Project Quality Assurance Plan, Rev.2

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RESPONSE TO DRAFT NRC SAFETY EVALUATION REPORT FOR DUKE COGEMA STONE & WEBSTER (DCS) MOX PROJECT QUALITY ASSURANCE PLAN, REV.2

Item 1: "The paragraph on page 1 of 6 of the Introduction Section of the MPQAP that begins with the words "For MFFF design during ....." is not acceptable in that it indicates that the MPQAP requirements for design and construction apply to only principal SSCs prior to completion of the Integrated Safety Analysis (ISA) and items relied on for safety (IROFS) after completion of the ISA. This section must make it clear that all applicable QA requirements apply to Quality Level 2 SSCs, and that all applicable QA requirements, in particular, design and configuration control among others, apply to all SSCs."

Response:

Applicable QA requirements in the MPQAP certainly apply to QL-2 SSCs. In order to correct this editorial error the cited paragraph will be replaced by the following:

> Quality assurance (QA) requirements contained in the MOX Project Quality Assurance Plan (MPQAP) apply to all Quality Level 1 and 2 structures, systems and components (SSCs) during MOX Fuel Fabrication Facility (MFFF) design and construction. Quality Level 1 (QL-1) SSCs as defined in section 2 of this document include principal SSCs and Items Relied on for Safety[1] (IROFS). Completion of the Integrated Safety Analysis (ISA) will validate final classification of principal SSCs as IROFS. Quality Level 2 (QL-2) SSCs are those SSCs that support normal operations of the facility and reduce public, worker, and environmental radiological and chemical risks.
>
> MFFF QL-1 and -2 SSCs and their associated activities are controlled by implementation of applicable QA requirements as applied through the use of graded QA as detailed in section 2 of this document. Design, document, and configuration control and records management QA requirements are implemented from the start of the project. During construction the applicable QA requirements for procurement, materials control (including consumable materials used during construction), installation, use of measuring and test equipment for installation and testing (including computer hardware and software) are implemented to ensure that installed SSCs are available and can be relied on to perform their intended functions.

[1] The word **safety**, when used in this MPQAP, means safety in the context of the 10 CFR 70.4 definition of **Items Relied on for Safety**; i.e., associated with the prevention of, or the mitigation of potential consequences from, potential accidents that could exceed the performance requirements of 10 CFR 70.61.

In general, QA requirements are electively applied to QL-3 and -4 SSCs at the discretion of DCS management as these SSCs do not impact the regulatory basis of the facilty[2]. During licensed operation, 10 CFR 70.72 provides for evaluation, implementation, and tracking of changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. These provisions include evaluation of changes to non-IROFS (i.e., including QL-2, -3, and -4 SSCs) to ensure no inadvertent changes or impacts to IROFS occur as a result.

Applicable requirements for design, document, and configuration control and records management are therefore applied to Quality Level 3 and 4 SSCs as the project procedures controlling these activities cover all Quality Levels."

Item 2: "The current description for graded application of QA controls to QL-1/IROFS, which is contained in Sections 2.2, Graded Quality Assurance (GQA) and 2.2.2, Identification of QA Controls, is not acceptable, as it does not adequately define the process for identifying the SSC functions and characteristics relied on for safety and does not adequately identify the criteria and methods for applying specific graded QA controls to individual and/or types of SSCs. The QA program description should adequately describe the process for determining SSCs safety functions and safety significance of those functions and the adjustments make to the MPQAP requirements associated with the 18 criteria of Appendix B in order to describe how the requirements will be satisfied in a graded manner. The application of graded QA controls should be based on methods, criteria and standards of performance that are clear, definite, supportable and verifiable. The applications of QA controls should be sufficient to reasonably ensure the design integrity and ability of the SSC to successfully perform its safety function. The process, methods, and criteria for applying QA controls to QL-2 SSCs should be clarified."

Response:

Question 4 of the NRC's "Request for Additional Information on the Duke Cogema Stone & Webster (DCS) Mixed Oxide Project Quality Assurance Plan, Revision 2" (NRC letter dated 6/19/01) requested similar information. See the DCS response to that question in DCS letter dated 7/18/01, DCS-NRC-000054, "Response to NRC Request for Additional Information on MOX Project Quality Assurance Plan (MPQAP) Revision 2."

In addition, the following information is to further clarify the process and criteria for grading IROFS and QL-2 SSCs under the QA program.

[2] The phrase "outside of the regulatory purview of the NRC" used in Section 2.2.1 of the MPQAP is not intended to imply a limitation as to the NRC's access to QL-3 and -4 SSCs or associated information. In the next revision, this phrase will be revised to indicate that QL-3 and -4 SSCs do not impact the regulatory basis of the facility.

General Discussion

Grading refers to the selection of QA controls. Graded QA provides a safety benefit by allowing DCS and the NRC to preferentially allocate resources based on the safety significance of SSCs. Grading an SSC will not degrade its performance or prevent it from meeting its intended safety function. The QA grading process is implemented to match the necessary QA controls with SSC safety significance so that technical, engineering, design and safety requirements are met.

The requirements delineated in Appendix B to 10 CFR Part 50 recognize that QA program controls should be applied in a manner consistent with the importance to safety of the associated structures, systems, and components (SSCs). Because the quality level of an SSC is determined by the role of the SSC in meeting the performance requirements of 10 CFR 70.61 (which provides the Part 70 definition of items relied on for safety [IROFS]), the quality level also serves as an indicator of the safety significance of the SSC in the context of grading. Additional SSCs that are not IROFS, but which help minimize risk below the criteria of 10 CFR 70.61, are also controlled under selected elements of the DCS QA program (i.e., under QL-2). These SSCs are not required to demonstrate safety in the context of Part 70, but are controlled voluntarily as "augmented quality provisions."

QL-1a SSCs are not typically graded; QL-1b and -2 SSCs are graded as discussed below.

Initial Assignment of SSC Quality Levels

MFFF SSCs are assigned a quality level (QL) commensurate with each SSC's function and safety significance. The initial QL designations (or QA classifications) of SSCs were established at a functional level based on engineering review of the following:

- design criteria and design requirements;
- safety significance relative to 10CFR70.61 performance requirements;
- consideration of failure consequences (i.e., single failure vs. defense in depth);
- consideration of the MELOX and La Hague design and operating experience; and
- MPQAP Section 2.2.1 definitions for quality levels.

This review resulted in a deterministic QL designation for each SSC. This QL was documented and controlled in a "functional classification list" as part of the design hierarchy, and on the applicable design documents, to indicate where QA controls were needed during initial design development. Upon completion of the safety assessment of the design bases of principal SSCs and the Integrated Safety Analysis (ISA), these initial SSC quality level assignments will be either confirmed or changed. Changes to quality level designations necessitates re-evaluation of any QA grading applied up to that time (see "Feedback Mechanisms and Reassessing Safety Significance" below).

Grading Process

DCS consulted the applicable provisions of Regulatory Guide 1.176, *An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance*, and NRC Inspection Procedure 35703, *Graded Quality Assurance*, to develop the process and criteria for grading SSCs. These documents are focused on *changes* to existing *reactor* quality programs on the basis of formal *probabilistic risk assessments* performed for those facilities, and are therefore not directly applicable to the MFFF process. However, they provide some guidance in the development of a framework for the grading process and for the establishment of criteria for determining which 10 CFR 50 Appendix B controls apply to SSCs with limited safety significance.

The classification process consists of assigning a quality level (QL) to an SSC on the basis of its role in meeting 10 CFR 70.61 performance requirements (i.e., QL-1 for IROFS). Certain non-IROFS are also included in the QA program (i.e., as QL-2) if they serve to minimize certain risks below the 10 CFR 70.61 performance requirements. (QL-3 is used to identify SSCs with non-regulatory programmatic importance, such as investment protection or production capacity, and are not discussed here, as they have no bearing on the safety or licensing bases for the MFFF. Similarly, QL-4 SSCs are not discussed here, as QL-4 is simply a designation indicating the QA program is not applicable.)

Quality levels are defined in the MPQAP.

While a direct correlation between QLs and safety-significance thresholds in RG 1.176 does not exist, it is informative to compare them as follows:

- QL-1a is used to designate MFFF SSCs whose single failure could cause an accident with consequence exceeding the 10 CFR 70.61 performance criteria. This designation is comparable to "high safety significance" described in RG 1.176.

- QL-1b is used to designate MFFF SSCs whose failure could indirectly lead to exceeding 10 CFR 70.61 performance criteria (i.e., failure in conjunction with an independent, unlikely failure of another item or administrative control). This designation is comparable to "medium safety significance" described in RG 1.176.[3]

[3] RG 1.176 includes discussion that indicates that the diversity of systems that are able to fulfill critical high level functions (e.g., reactivity control, decay heat removal) can have the result that each individual system could meet all quantitative guidelines to be categorized in the low safety-significance group. The guidance indicates that the licensee is expected to designate at least one system associated with critical high-level functions as high safety significant. DCS complies with this guidance by (a) providing that "critical high-level" safety functions of confinement and single-failure-prone criticality (if any) are QL-1a; (b) designating all "sole IROFS" as QL-1a; and (c) *not* taking credit for single-failure-based redundancy in determining QL-1b designations (i.e., if an SSC is one of two active components providing the same function, it is still designated as QL-1a).

- QL-2 is used to designate SSCs that do not contribute to safety as defined in 10 CFR 70, but which minimize risk below the performance thresholds of 10 CFR 70.61. This designation is comparable to "low safety significance" in that the SSCs, by definition, are not relied on for safety.

The grading process defines the selection of QA controls on the basis of SSCs' safety significance. The 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 which MPQAP requirements are not applicable to IROFS and QL-2 SSCs as described below.

The grading process is conducted by design, safety, and quality assurance personnel, and is documented in an engineering analysis subject to review and approval by both engineering and QA management in accordance with QA procedures. Grading analyses will apply to QL-1b and -2 SSCs.

Grading Criteria

The evaluation of SSCs for selection of QA controls takes into account the following considerations:

- the function or end use of the SSC;
- the consequence of failure of the SSC;
- the importance of the data being collected or analyzed by the SSC;
- the complexity of design or fabrication of the item or design or implementation of the activity;
- the reliability of the associated processes;
- the reproducibility of results;
- the uniqueness of the item or service quality;
- the necessity for special controls or processes; and
- the degree to which functional compliance can be demonstrated through inspection or test;

along with any other relevant factors, including program risk, as applicable. As examples of the above considerations:

- 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) is considered QL-1b and subject to graded controls. This conclusion reflects consideration of the function/end use of the SSC and the consequences of its failure as indicated in MFFF safety analyses.

- An IROFS that is specifically engineered for the MFFF, such as a glovebox, will not likely be graded (i.e., QL-1a), but rather subject to all applicable 10 CFR 50 Appendix B criteria, in contrast to a thermocouple that is IROFS but is readily available "off the shelf" (assuming its safety significance does not otherwise preclude grading). This conclusion reflects consideration of the comparative complexity and uniqueness of the SSCs.

RG 1.176 identifies the following 10 CFR 50 Appendix B criteria as candidates for grading:

- Procurement;
- Inspection;
- Records and Documentation;
- Audits;
- Staff Training and Qualification;
- Corrective Action; and
- Design.

These criteria, and the basis for grading them as indicated in RG 1.176, will be appropriately considered in the detailed grading analyses currently in progress.

QL-1 SSCs (QL-1a and QL-1b)

QL-1a SSCs and their associated activities (to prevent or mitigate a postulated confinement or criticality accident) are subject to all the requirements in sections 1-18 of the MPQAP. No grading of QA controls applies to QL-1a SSCs (unless justified on a case-by-case basis in discrete SSC-specific analyses; this is expected to be very rare, and no instances have been identified to date).

QL-1b SSCs and their associated activities (criticality controls subject to double contingency, except for geometry control, and SSCs that provide defense-in-depth) are evaluated against the requirements in sections 1-18 of the MPQAP. Based on the SSC's function, this evaluation determines which (if any) MPQAP requirements are not applicable or are only partially applicable (i.e., are not required to provide assurance the SSC will perform its intended function). Since the single failure of a QL-1b SSC cannot, by definition, result in exceeding 10 CFR 70.61 performance requirements, they have more potential to be graded. Justification for grading these SSCs may include unnecessary credit attributed to the SSC in the ISA; application of additional control from other SSCs or management measures; and industry precedent in justifying exclusion or partial application.

QL-2 SSCs

QL-2 SSCs and their associated activities – i.e., those SSCs that provide support of normal operations of the facility (e.g., occupational exposure, radioactive waste management) and SSCs

that minimize public, worker, and environmental risks below 10 CFR 70.61 performance criteria (e.g., physical interaction protection, radiological and criticality alarms) – are also evaluated against the requirements in sections 1-18 of the MPQAP. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions. (This evaluation may also include nuclear industry precedent in the application of augmented QA requirements.)

Application of Graded QA Controls

QA grading analyses for QL-1a, QL-1b and QL-2 SSCs are used to identify QA requirements to the design, construction, and (later) operation of these SSCs. These requirements are reflected in applicable project procedures, analyses, specifications, and other QA program documents. Revision and approval of these documents is in accordance with applicable procedures.

Feedback Mechanisms and Reassessing Safety Significance

Changes in quality level classification of an SSC will necessitate re-evaluation of assigned QA controls. Changes to quality levels may result from ISA completion, design changes (including changes to safety significance), or elevation to a higher quality level by management decision.

Quality level classification changes require updating of the applicable design documents for the particular SSC that was changed. These changes necessitate review of applicable QA requirements for confirming or changing the previously established graded QA controls. Affected documents are revised in accordance with the requirements of the controlling procedures for the specific documents.

Action

DCS commits to revise the MPQAP to reflect the discussion above and clarify the application of the graded QA program to QL-1 and -2 SSCs.