



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 10, 1994

Mr. Bruce Mabrito, Director
Quality Assurance
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Road
San Antonio, Texas 78228-0510

Dear Mr. Mabrito:

SUBJECT: REVIEW OF CNWRA QUALITY ASSURANCE REQUIREMENTS

Thank you for your July 29, 1994, letter and its enclosed report, "Evaluation of QA Requirements to CNWRA Activities." The letter and report satisfactorily respond to our request that you re-evaluate the appropriate QA requirements for CNWRA activities.

In general, we are satisfied with the level of QA that is being applied to CNWRA activities. However, we have questions regarding QA controls for software development and use. Your July 29 letter addresses some of our questions; but, based on our review of that letter, we have several comments/questions for which we request your response. The enclosure to this letter lists the statement/commitment in your July 29 letter that led to each specific comment/question. We would appreciate your response on a timely basis so that we can decide what needs to be done, if anything, in the area of QA controls for CNWRA development and use of software.

This request is technical direction only. It overlaps contract Task 5.4, "CNWRA Internal QA Program," in the COPS Element and Task 3 of "External QA," and time should be charged 1/3 to Internal QA and 2/3 to External QA. No change to existing contract scope, schedule, or cost is anticipated. If you disagree, please notify us immediately.

If you have any questions on this letter or its enclosure, please contact Jack Spraul of the NRC staff on (301) 415-6715.

Sincerely,

John G. Spraul
External QA Program Element Manager

Shirley L. Fortuna
COPS Program Element Manager

Enclosure: As noted

cc: J. Linehan, PMDA
B. Meehan, ADM

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 DATED 10/17/94

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NAME	JGSpraul		RLJohnson		SLFortuna				
DATE	10/04/94		10/21/94		08/17/94 10/---/94				

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ENCLOSURE

1. **STATEMENT/COMMITMENT:** Software configuration controls are applied only to (complex) codes that are expected to be utilized in compliance determination. (Background -2)¹

COMMENT/QUESTION: OK, but see comment regarding item 8 below.

- 1.a. **STATEMENT/COMMITMENT:** These codes shall be under configuration control. (Computer Codes)

COMMENT/QUESTION: OK

- 1.b. **STATEMENT/COMMITMENT:** These codes shall be tested to assure proper operation. (Computer Codes)

COMMENT/QUESTION: Are these tests what would be called "Code Validation?"

- 1.c. **STATEMENT/COMMITMENT:** These codes shall have code documentation prepared or obtained. (Computer Codes)

COMMENT/QUESTION: What "code documentation" will be prepared or obtained?

- 1.d. **STATEMENT/COMMITMENT:** When these codes are developed by the CNWRA or NRC, design documents will be prepared. (Computer Codes)

COMMENT/QUESTION: What "design documents" will be prepared?

2. **STATEMENT/COMMITMENT:** NRC and its contractors should not take on the burden of the license applicant. (Re-evaluation ...)

COMMENT/QUESTION: Does this mean that the Center should not have to implement a quality program equivalent to that of the DOE for software development, procurement, and use?

3. **STATEMENT/COMMITMENT:** Software controls should be applied which assure or enhance the quality (of the software) beyond what would be obtained without the controls. (Re-evaluation ...)

COMMENT/QUESTION: Software controls should be applied in order to provide adequate confidence that the software will do what it is designed to do. Describe how, in addition, software controls enhance software quality.

4. **STATEMENT/COMMITMENT:** (Proposed Quality Requirements Application Strategy)

¹ Identification in parentheses indicates the section and its paragraph in the enclosure to the CNWRA letter where the statement/commitment is located. When no number is given, the reference is to the entire section.

COMMENT/QUESTION: Are changes being proposed that will affect current practices? If so, what are they?

5. STATEMENT/COMMITMENT: (Computer Codes)

COMMENT/QUESTION: Are changes being proposed that will affect current SQA practices? If so, what are they?

6. STATEMENT/COMMITMENT: TOP-018 addresses the essential criteria of full software life-cycle requirements documents (e.g., NUREG/CR-4640). (Computer Codes)

COMMENT/QUESTION: What are the non-essential criteria of NUREG/CR-4640 that are not addressed? Why are they considered to be non-essential?²

7. STATEMENT/COMMITMENT: Methods and analyses not involving complex computer codes that are expected to be utilized in compliance determination shall be verified as described in QAP-014. (Methods and Analyses)

COMMENT/QUESTION: Describe how the CNWRA differentiates between "complex computer codes" and "routine calculations."

² Key question. It could be reworded to state: "Justify why any specific guidance of NUREG/CR-4640 is not met by the CNWRA's SQA program."

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