Center for Nuclear Waste Regulatory Analyses

6220 CULEBRA ROAD • P.O. DRAWER 28510 • SAN ANTONIO, TEXAS, U.S.A. 78228-0510
(210) 522-5160 • FAX (210) 522-5155

December 16, 1994
Contract No. NRC-02-93-005
Account No. 20-5702-331/154

Nuclear Regulatory Commission
ATTN: Mr. Jack Spraul/Ms. Shirley Fortuna
HLUR/PMDA
TWFN, Mail Stop T7J9/T8A-23
Washington, D.C. 20555

Subject: Responses to NRC Comments/Question on Review of CNWRA QA Requirements

Reference: NRC Correspondence from J. Spraul/S. Fortuna to B. Mabrito, Dated 11/10/94

Dear Mr. Spraul:

Enclosed are responses to the NRC staff comments/questions on the CNWRA report "Evaluation of QA Requirements Applicable to CNWRA Activities." This report was submitted to the NRC as Administrative Milestone AD-20-5702-331-416.

These responses provide the additional information required to fully evaluate our proposal for changes in the CNWRA Quality Assurance Program.

Please contact me at (210) 522-5149 if you have any questions.

Sincerely,

Bruce Mabrito
Director
Quality Assurance

BEM/fe
enclosure

cc: J. Linehan
M. Knapp
B. Meehan
S. Fortuna
B. Stiltenpole
J. Holonich
R. Johnson
J. Buckley
W. Belke
W. Patrick
CNWRA Directors
CNWRA Element Managers
S. Rowe, SwRI
R. Brient

4/26.1
WM-11
NH15

Washington Office • Crystal Gateway One, Suite 1102 • 1235 Jefferson Davis Hwy. • Arlington, Virginia, 22202-3293

Response to J. Spraul/S. Fortuna letter of 11/10/94

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

COMMENT/QUESTION: OK, but see comment regarding item 8 (actually 7) below.

No response is necessary.

Item 1.a. STATEMENT/COMMITMENT: These codes shall be under configuration control.

COMMENT/QUESTION: OK

No response is necessary.

Item 1.b. STATEMENT/COMMITMENT: These codes shall be tested to assure proper operation.

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

A revision to TOP-018 currently being developed includes specific requirements for Installation Testing; essentially a verification that the code operates on the CNWRA platform in the same manner as on the developer's platform. This consists of running one of the developer's test cases, and verifying that the results are consistent with those of the developer.

The revision to TOP-018 also includes requirements for Code Validation, in which test cases and, if possible, benchmark test cases, specific to a particular application of the code, will be run. Code validation will be applied to only those codes that have progressed through the earlier stages of development and have been exercised to a degree that they appear to be the most likely candidates for use in licensing.

Item 1.c. STATEMENT/COMMITMENT: These codes shall have code documentation prepared or obtained.

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

Specific code documentation necessary for configuration control includes the software summary form, User's Manual, and as applicable, the Software Requirements Description, development documentation (e.g., Scientific Notebooks), and design verification documentation.

Item 1.d. STATEMENT/COMMITMENT: When these codes are developed by the CNWRA or NRC, design documents will be prepared.

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

For CNWRA developed and modified codes, the new revision to TOP-018 will call for the Software Requirements Description, documentation of the code development in the Scientific Notebooks, and documentation of the design verification tests of the code using software checking tools.

Item 2. STATEMENT/COMMITMENT: NRC and its contractors should not take on the burden of the license applicant.

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?

The NRC and its contractors should not take on the burden of the license applicant because the level of confidence needed in a code to demonstrate compliance (by DOE) is significantly greater than the level of confidence needed in a code that will be used to evaluate DOE's analyses (by NRC). Because of this difference, the CNWRA should not be expected to implement software QA requirements of the same breadth and depth of those of the DOE. The differences in requirements are evident primarily in (i) the number of phases of the software lifecycle being controlled, (ii) the extent of controls applied to each lifecycle phase, and (iii) the validation of the mathematical model supporting codes. Model validation is not addressed by TOP-018, but will likely be addressed at a later date by NRC/CNWRA management.

Item 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.

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 control enhance software quality.

The statement was made to underscore the point that software controls that do not assure or enhance quality should not be considered. Software controls, such as preparing a thorough Software Requirements Description and applying good coding practices during the design and development phase, should provide a code that is more reliable than a (acquired or existing) code that was not developed under those constraints.

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

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

In terms of QA requirements applicability, changes will be implemented in the quality planning process so that each activity will be evaluated for the applicability of specific procedures. This will be much more formal than is current practice, and will involve CNWRA technical, management, and QA staff. In the past, QA staff would identify, in a general way, the portions of the QA program which were applicable based on the type of work being performed (laboratory work, field work, analysis, code development, etc.), which would be concurred in by the Technical Director. This process does not directly evaluate the use of the data or codes in relation to importance-to-licensing or to compliance determination. The surveillance process would also be changed to more specifically verify that the planned QA controls were being properly applied. This proposed approach would significantly reinforce the CNWRA commitment to quality.

Item 5. STATEMENT/COMMITMENT: (Computer Codes)

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

The changes to TOP-018 currently being developed involve (i) including controls for acquired software for which the source code is not available (TOP-018 now excludes scientific and engineering software without the source code), and (ii) organizing the requirements according to software development phases, individual phases applying depending on the category of code (basically existing/acquired and developed/modified codes). A number of other changes are made for clarification, but none of the changes reduce the level of commitment currently in the CNWRA operating procedure.

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

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

This position was taken because NUREG/CR-4640 seems to be extreme in its level of detail and complexity. For example, under the software lifecycle, the functional specification is listed separately from the requirements specification, when one would reasonably expect functions to be included under the requirements specification. The NUREG breaks the design process into several discrete pieces, all with their associated plans, documentation, and review. It also suggests functional configuration audits, physical configuration audits, in-process audits, and SQA audits. These approaches are the most conservative and may be prudent under some circumstances, but that level of detail should be at the option of the developer.

NUREG/CR-4640 also appears to be intended for an organization with no other QA program requirements, having organizational and management criteria that would be redundant with the top level QA program, as would the records controls.

In summary, NUREG/CR-4640 provides many techniques for software control, some that should be considered obligatory, but many that may not provide tangible benefits in an application at the CNWRA.

Item 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."

The difference between routine calculations and those involving complex computer codes is found in QAP-014, Documentation and Verification of Routine Calculations, Section 1. Purpose, "... (routine calculations) include data reduction, statistical, and simple scientific or engineering computations." It continues, "This procedure does not apply to activities involving Scientific and Engineering Software which contain complex mathematical or numerical models of physical processes or configurations." From a practical perspective, routine calculations are those that can be readily verified by hand calculations. Commercially available spread sheets or statistical software perform routine calculations, analysis and modeling software perform complex mathematical functions.