



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

July 9, 1997

Mr. Bruce Mabrito, Director  
Quality Assurance  
Center for Nuclear Waste Regulatory Analyses  
6220 Culebra Road, Building 189  
San Antonio, TX 78238-5166

SUBJECT: OBSERVATION AUDIT OF CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Dear Mr. Mabrito:

From June 9-12, 1997, a member of the U.S. Nuclear Regulatory Commission Uranium Recovery Branch staff participated as an observer in the Center for Nuclear Waste Regulatory Analyses (CNWRA) internal quality assurance (QA) Audit No. 97-01 conducted in San Antonio, Texas. The NRC staff evaluated this performance-based audit to determine whether the CNWRA is continuing to effectively implement the requirements of its QA program. This letter transmits NRC Observation Audit Report OA-97-02 for the CNWRA audit.

The audit, which was performed as part of the CNWRA's regular audit program, was used to evaluate the implementation of QA controls associated with CNWRA QA programmatic and technical activities. All fourteen applicable QA programmatic areas and eight technical areas were audited. The technical areas audited included: 1) MULTIFLO Software Code Development, 2) Thermal Effects on Flow, 3) Near Field Corrosion Testing, 4) Igneous Activity Software Development, 5) Total Performance Assessment (TPA) Software Development, 6) Isothermal Flow, 7) Tank Waste Remediation System Tasks, and 8) Uranium Recovery Tasks.

The NRC staff based its evaluation of the audit process and the CNWRA QA program on: 1) discussions with and direct observations of a) the auditors and technical specialists of the audit team [who were on loan from the CNWRA's parent organization, Southwest Research Institute], and b) CNWRA staff being audited; and 2) reviews of pertinent audit documentation such as the audit plan, the audit checklist, and other CNWRA documents. The NRC staff has determined that, overall, CNWRA Audit No. 97-01 achieved its purpose of evaluating the implementation of QA controls of programmatic and technical activities. The audit was conducted in a professional manner. The audit team was well qualified and familiar with the QA requirements of the CNWRA program. The audit schedule and individual assignments were adequately described in the audit plan, and the audit checklist was detailed and complete.

The NRC staff agrees with the audit team's preliminary findings that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated. In addition, the staff believes that the CNWRA audit was thorough and effective. The technical qualifications of CNWRA staff and the technical adequacy of the procedures and work products were found to be generally satisfactory, and are subject to continuing in-depth evaluation by NRC technical staff.

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The recent problems with the TPA Software Development were discussed at considerable length during the audit. It appears that the problems which occurred were primarily due to lack of effective implementation of TOP-018. The release of one or more versions of TPA Version 3.0 to the NRC prior to completion of the checking and test requirements of TOP-018 was a decision made by CNWRA management and does not represent a failure of the CNWRA QA program. The NRC staff recommends that TOP-018 be thoroughly reviewed by CNWRA technical staff and the Quality Assurance Director and revised, as appropriate, based on their recent experience in code development. To ensure effective implementation of the procedure, the technical staff should assume "ownership" of this technical procedure. As part of this review consideration should be given to submission of SRDs as intermediate milestones which will be approved by NRC prior to the beginning of code development. The level of detail to be included in the SRDs, as well as when a modification to the design is significant enough to require a revised SRD should also be evaluated and agreed to by the Center Quality Assurance Director and the NRC CNWRA Operations Program Element Manager.

CNWRA QA personnel should continue to monitor the QA program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to assess the adequacy and effectiveness of the CNWRA QA program.

A written response to this letter or the enclosed report is not required. If you have any questions, please call Ken Hooks on (301) 415-7777.

Sincerely,



Shirley L. Fortuna  
NRC Program Element Manager  
CNWRA Operations

Enclosure: As stated

Bruce Mabrito

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The NRC staff agrees with the audit team's preliminary findings that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated. In addition, the staff believes that the CNWRA audit was thorough and effective. The technical qualifications of CNWRA staff and the technical adequacy of the procedures and work products were found to be generally satisfactory, and are subject to continuing in-depth evaluation by NRC technical staff.

The recent problems with the TPA Software Development were discussed at considerable length during the audit. It appears that the problems which occurred were primarily due to lack of effective implementation of TOP-018. The release of one or more versions of TPA Version 3.0 to the NRC prior to completion of the checking and test requirements of TOP-018 was a decision made by CNWRA management and does not represent a failure of the CNWRA QA program. The NRC staff recommends that TOP-018 be thoroughly reviewed by CNWRA technical staff and the Quality Assurance Director and revised, as appropriate, based on their recent experience in code development. To ensure effective implementation of the procedure, the technical staff should assume "ownership" of this technical procedure. As part of this review consideration should be given to submission of SRDs as intermediate milestones which will be approved by NRC prior to the beginning of code development. The level of detail to be included in the SRDs, as well as when a modification to the design is significant enough to require a revised SRD should also be evaluated and agreed to by the Center Quality Assurance Director and the NRC CNWRA Operations Program Element Manager.

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Sincerely, *LS*

Shirley L. Fortuna  
NRC Program Element Manager  
CNWRA Operations

Enclosure: As stated

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B. Mabrito

The recent problems with the TPA Software Development were discussed at considerable length during the audit. Based on these discussions, the NRC staff recommends that SRDs be absolutely required prior to the beginning of code development, that the SRDs be sufficiently detailed to serve as a contract between the code developer(s) and the potential user(s), and that these requirements be explicitly enumerated in TOP-018. In addition, TOP-018 should be completely reviewed and revised by CNWRA technical staff, based on their recent experience in code development, and the technical staff should assume "ownership" of this technical procedure. The release of one or more versions of TPA Version 3.0 to the NRC prior to completion of the checking and test requirements of TOP-018 was a deliberate decision of CNWRA management and does not represent a failure of the CNWRA QA program.

CNWRA QA personnel should continue to monitor the QA program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to assess the adequacy and effectiveness of the CNWRA QA program.

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Sincerely,

Shirley L. Fortuna  
NRC Program Element Manager  
CNWRA Operations

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