



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 20, 1999

Mr. Bruce Mabrito  
Director of Quality Assurance  
Center for Nuclear Waste Regulatory Analyses  
6220 Culebra Road, Bldg. 189/A121  
San Antonio, TX 78238-5166

SUBJECT: INPUT FOR OBSERVATION AUDIT REPORT QAR-00-01, INTEGRATED SITE  
MODEL - MILESTONE IM20.1402.331.010

Dear Mr. Mabrito:

We have reviewed the Center for Nuclear Waste Regulatory Analyses' (CNWRA's) November 23, 1999, letter to the U.S. Nuclear Regulatory Commission (NRC) which transmitted draft input to the NRC Observation Audit Report No. QAR-00-01 for the U.S. Department of Energy's (DOE's) audit of the Integrated Site Model (ISM) Process Model Reports (PMRs) at its Las Vegas, Nevada, facilities on October 11-15, 1999. Based on our review of this input, we consider that the CNWRA's November 23, 1999, submittal fulfills the Intermediate Milestone Number 20.01402.331.010 for support during the NRC's observation activities for the DOE ISM audit. However, it is noted that the CNWRA's input included preliminary test for the Technical Specialists input.

The objective of the NRC observation of DOE audits of the Yucca Mountain Projects is to gain confidence that DOE is effectively implementing its Quality Assurance (QA) program. This has been accomplished by observing the DOE audit team perform its activities. The following paragraphs identify observation activities that I consider important and need to continue to be addressed in the observation reports.

1. The NRC observation team members need to not only clearly document the areas of the DOE QA program observed during the audit, but also to identify their acceptability. For example, it is important that the observers address their evaluation regarding the acceptability of the qualification of data, software, and models reviewed during the PMR audits. This should be accomplished by the NRC observation team members closely observing the DOE auditor's review activities and, if necessary, selectively requesting and performing further reviews of the documentation for data, software, and models that are part of the audit scope, and part of the sample reviewed by the DOE auditors. It is recognized that in some instances, there may be no data, software, and models presented to the DOE auditors during the audit. The NRC observation audit report shall document the conclusions by the DOE auditors. **The NRC observation report shall document the conclusions by the NRC observers regarding the acceptability of analyses, procedure compliance, and other programmatic aspects of the audit, and the acceptability of the qualification of data, software, and models reviewed during the audit [emphasis added].**

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2. Senior NRC management and the Commission have expressed concerns about the qualification of data, software, and models supporting the Site Recommendation. The progress being made by DOE and its contractors in meeting their qualification goals for Site Recommendation is another area that the NRC observation team needs to review. This should be accomplished by reviewing the same materials that the DOE auditors review and by discussions with DOE and M&O personnel responsible for the qualification activities.
3. As we approach the anticipated DOE submittal of the Site Recommendation and License Application for the high-level waste repository at Yucca Mountain, additional areas that need to be addressed by the NRC observation team may be identified.

Another item that I would like to discuss is the processing of the NRC audit observation reports by the NRC and the CNWRA. Based on our review of the CNWRA's November 23, 1999, submittal, experience during two additional observations of DOE PMR audits (the Waste Package and the Biosphere), and lessons learned, we are providing the following direction for future inputs from the CNWRA to the NRC observation reports of DOE audits.

1. When the CNWRA leads the observation team for the audit, the CNWRA should submit a "Pre-decisional" version of the observation report that the NRC will treat as a draft report. If the CNWRA is aware of any section of the report that requires additional input from the NRC staff, it should be annotated as such in the text of the CNWRA observation report. The NRC staff will insert any additional text and prepare the cover letter forwarding the observation report to DOE. The CNWRA may suggest text for the cover letter.
2. When the CNWRA does not lead the audit observation team and only participates as a team member(s), the CNWRA should provide input to the observation report for the areas it supported. This input should also be identified as "Pre-decisional."
3. The CNWRA letter submitting either the "Pre-decisional" observation report or input should indicate that its deliverable is a pre-decisional document. If possible, attached documents should be identified or stamped as "Pre-decisional" on each page.
4. CNWRA team members will receive a copy of the observation report after it has been processed by the staff and shall be given an opportunity to review the report before it is placed in the NRC management concurrence process. Further, and prior to the concurrence on the report by the NRC Management, the NRC and CNWRA observation team members shall sign the observation report indicating their acceptance of the report.

B. Mabrito

3

If you have any questions regarding the above comments, please contact me at (301) 415-5000. I appreciate your cooperation in this matter.

Sincerely,

[Original signed by:]

Larry Campbell  
Senior Quality Assurance Engineer  
High-Level Waste and Performance  
Assessment Branch  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards

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B. Mabrito

3

If you have any questions regarding the above comments, please contact me at (301) 415-5000. I appreciate your cooperation in this matter.

Sincerely,

A handwritten signature in cursive script that reads "Larry Campbell".

Larry Campbell  
Senior Quality Assurance Engineer  
High-Level Waste and Performance  
Assessment Branch  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards