

JUL 26 1992

Mr. John P. Roberts, Acting Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, D. C. 20585

Dear Mr. Roberts:

**SUBJECT: NRC REVIEW AND ACCEPTANCE OF MANAGEMENT AND OPERATING CONTRACT
QUALITY ASSURANCE PROGRAM**

This letter responds to your letter of June 29, 1992, which documented why the U.S. Department of Energy, Office of Civilian Radioactive Waste Management (OCRWM) does not plan to request NRC staff acceptance of the Management and Operating Contractor (M&O) Quality Assurance Program Description (QAPD) or the M&O quality assurance (QA) program.

The NRC staff agrees with OCRWM that NRC acceptance of the OCRWM QA program establishes that the NRC staff has a certain level of confidence in the OCRWM QA program. However, the staff does not agree that this level of confidence precludes the need for staff review, evaluation, and acceptance of the QAPD and QA program given the present scope and expected future scope and program of the M&O. In addition, at the July 7, 1988, QA meeting, the staff and DOE agreed that NRC acceptance would be requested for all DOE and DOE contractor programs. This request would not be made until DOE first accepted the QAPD, conducted an implementation audit, and accepted the program itself. Although the M&O was not involved in the program at that time, the staff believes that due to the significance of the M&O program the same basic process and steps need to be applied.

While the NRC staff agrees that acceptance is not a prerequisite to the start of quality-affecting work under the M&O program, the need for the NRC staff to evaluate and document the acceptability of the M&O QA program remains. By letter dated April 22, 1992, DOE transmitted to the staff for its information, the M&O QAPD. Based on the reasons cited above, the staff has begun a detailed review of the QAPD. It plans to conduct this evaluation in the same manner as the ones performed for the other QAPDs submitted for review and anticipates providing DOE with comments on the M&O QAPD as part of its normal review practice.

The NRC staff evaluation and acceptance of the effectiveness of M&O implementation of its QA program does not have to be predicated upon a qualification audit of the M&O QA program, but rather on the review and evaluation of a sufficient quantity of M&O quality-affecting activities. The "qualification" audit of other program participants was the result of a series of audits and resultant corrective actions over a period of time, which culminated in an audit demonstrating QA program acceptability. The NRC staff has participated in several M&O readiness reviews and does not believe that these readiness reviews have provided, to date, the same visibility of M&O QA program implementation that was achieved by the periodic audits of the other participants.

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While the overview program described in your letter may eventually provide the necessary visibility, it will result in much more quality-affecting work being at risk than was previously the situation. In addition, the readiness reviews provide little visibility of OCRWM oversight of the M&O QA program which is necessary to maintain the NRC staff's level of confidence in OCRWM's effectiveness in auditing, identifying deficiencies, and pursuing corrective actions. For these reasons, the NRC staff strongly recommends that OCRWM consider auditing significant portions of the M&O quality-affecting activities as early as possible, especially those that may affect site characterization activities. The NRC staff and representatives of the State of Nevada and affected units of local government should be invited to observe such audits.

If you have any questions concerning this letter, please contact me at (301) 504-3391 or Ken Hooks of my staff at (301) 504-2447.

Sincerely,

JJ

Joseph J. Holonich, Director
Repository Licensing and Quality Assurance
Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

- cc: R. Loux, State of Nevada
- T. J. Hickey, Nevada Legislative Committee
- C. Gertz, DOE/NV
- S. Bradhurst, Nye County, NV
- M. Baughman, Lincoln County, NV
- D. Bechtel, Clark County, NV
- D. Weigel, GAO
- P. Niedzielski-Eichner, Nye County, NV
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