

## Department of Energy Washington, DC 20585 JUN 2 9 1992

Mr. Joseph J. Holonich, Director Repository Licensing and Quality Assurance Project Directorate Division of High-Level Waste Management Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dear Mr. Holonich:

The purpose of this letter is to clarify and document why the Office of Civilian Radioactive Waste Management (OCRWM) does not plan to provide the TRW Management and Operating (M&O) Contractor Quality Assurance Program Description (QAPD) to the U.S. Nuclear Regulatory Commission (NRC) for acceptance. This was requested by Mr. Ken Hooks of your staff at the DOE/NRC bimonthly Quality Assurance (QA) meeting held on February 18, 1992, at your White Flint office. Mr. Hooks also requested explanation of why a qualification audit of the M&O is not planned prior to authorizing the start of M&O quality-affecting work.

As a brief synopsis of the history of the OCRWM QA Program "qualification", NRC Objection #2 of the Site Characterization Analysis (SCA) documented that DOE (and its participants) did not have acceptable QA Programs in place to begin new site characterization activities. Based on this objection, OCRWM agreed to qualify the QA Programs of OCRWM and its participants and to include NRC acceptance of the programs. NRC "acceptance" was defined as review and acceptance of the QAPDs and observation of successful OCRWM QA qualification audits. This effort culminated in the QA Program acceptance of all participants (including OCRWM) involved in site characterization and a lifting of Objection #2 by the NRC (reference letter dated March 2, 1992, Bernero to Bartlett).

Given the QA Program acceptance by the NRC, our intent with respect to maintaining QA Program acceptance and the role of the NRC should be clarified. It is our position that having received acceptance, the NRC now has confidence in the OCRWM QA Program; therefore, OCRWM now has the basis to evaluate and approve any changes to previously accepted participant QA Programs, where that basis did not exist prior to OCRWM QA Program acceptance. In the past, when such changes were made, OCRWM had requested acceptance of the QAPD change from the NRC. In the future,

9207060182 920629 PDR WASTE WM-11 PDR however, OCRWM will evaluate any changes in accordance with QA program controls and pass on the results to the NRC for information (not acceptance).

This logic also carries into the initial acceptance, by OCRWM, of the M&O documented QA Program. OCRWM has reviewed and conditionally accepted the M&O QAPD in accordance with appropriate QA controls. OCRWM has also directed the M&O (with OCRWM participation) to perform Readiness Reviews in lieu of a qualification audit, as it is more appropriate to authorize initiation of work based on readiness and perform audits after implementation. Upon full acceptance of the QAPD, along with completion and OCRWM acceptance of the M&O readiness reviews, OCRWM will authorize the M&O to initiate specific qualityaffecting activities. It is our position that this approach will give OCRWM the confidence that necessary controls will be in place to initiate work and is consistent with industry audit practice that audits are performed to assess compliance and effectiveness after implementation has occurred. It should be noted that we have scheduled and will continue to perform surveillances to overview M&O implementation of specific activities until an audit is performed.

We feel that our position is appropriate and prudent quality assurance management that will allow us to "get on with the job," without adversely affecting the quality of performance. If you have any questions, please contact me or Mr. Donald G. Horton, Director, Office of Quality Assurance, at (202) 586-8858.

Sincerely,

John P. Roberts

Acting Associate Director for Systems and Compliance Office of Civilian Radioactive

Waste Management

cc:

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K. Hooks, NRC

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M. Baughman, Lincoln County, NV J. Bingham, Clark County, NV

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