



Department of Energy
Washington, DC 20585

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Mr. Joseph J. Holonich, Director
Repository Licensing & 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

- Reference 1) Letter, J. Roberts to J. Holonich, dated
June 29, 1992
2) Letter, J. Holonich to J. Roberts, dated
July 28, 1992
3) Letter, R. Bernero to J. Bartlett, dated
August 31, 1992

Dear Mr. Holonich:

Please reference OCRWM letter 1) above. This letter documents the Office of Civilian Radioactive Waste Management (OCRWM) position and justification for not requesting Nuclear Regulatory Commission (NRC) acceptance of the OCRWM Management and Operating (M&O) contractor Quality Assurance (QA) Program, and for our not performing a "qualification" audit prior to authorization for the M&O initiation of quality-affecting work. Reference NRC letters 2) and 3) above document NRC disagreement with the OCRWM position. The purpose of this letter is to reaffirm our position and provide you with information supporting it.

To clarify our position I would like to re-state that it is our intent to transmit QA program changes to the NRC for information and to perform audits of the M&O. As you have previously stated, we expect the NRC to review what is transmitted and to continue to observe OCRWM audit activities. The purpose of reference letter 1) was to notify the NRC that, for the M&O, DOE is not required to gain formal NRC "acceptance" of the QA program, nor is a "qualification" audit the appropriate method to determine readiness to initiate quality-affecting activities. Reference NRC letters 2) and 3) state that "during the July 7, 1988 QA meeting, the staff and DOE agreed that DOE would request NRC's acceptance for all DOE and DOE contractor programs." (emphasis added.) Reference NRC letter 3) further states that "... (for the M&O) the same basic processes and steps (for program acceptance) would still need to be applied" and concludes that "... DOE should submit the M&O QAPD for staff review, evaluation and acceptance." (emphasis added.)

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Since the agreement reached at the July 7, 1988, meeting appears to be the only basis for the NRC position (in the absence of any statutory or regulatory requirement), it is imperative to document, for the record, what was actually agreed to at that meeting. Your interpretation that DOE agreed to seek NRC acceptance for all DOE and DOE contractor QA programs is incorrect. The record clearly shows that the purpose of the July 7, 1988, meeting was to agree on a plan for NRC review of the DOE QA program in order to resolve the (at that time) draft SCA Objection 2. Please refer to enclosure 1 of the minutes of the July 7, 1988 meeting, Letter from J. Linehan to R. Stein, dated July 15, 1988, for the QA programs required to be qualified.

NRC Objection 2 concluded that section 8.6 of the OCRWM Site Characterization Plan (SCP) described a QA program to be applied to Site Characterization activities and that OCRWM SCA overview incorrectly stated that "organizations participating in site characterization" (emphasis added) have developed and are implementing this QA program. As a result, OCRWM proposed and agreed to a plan to qualify and request NRC acceptance for those participants, at the time, involved in site characterization. OCRWM also committed that no new site characterization activities would resume until completion of qualification and NRC acceptance of those participants' QA programs.

The fact that the July 7, 1988 agreement did not apply to all participants is supported by the NRC lifting of objection 2 by letter, R. Bernero to J. Bartlett, dated March 2, 1992. This letter stated that the objection could be lifted based on the fact that "...organizations participating in site characterization activities have developed and are implementing a QA program that meets NRC requirements". (emphasis added.) NRC reference letter 3) also supports this by reference to the lifting of the objection being correct because each of the participants which were in place when the SCA objection was initiated have an acceptable QA program.

Furthermore, OCRWM has never requested NRC acceptance of QA programs for the numerous other program participants not involved in Site Characterization (e.g., DOE, Office of Environmental Restoration and Waste Management (EM), Oak Ridge National Laboratory, Energy Information Administration (EIA), etc). The NRC staff has participated as observers on some of the audits of these participants and the subject of NRC acceptance of these programs has never been raised. From our perspective it did not get raised because the agreement clearly did not extend to these participant QA programs. Additionally, since OCRWM QA program was accepted, OCRWM has been sending site characterization program participant changes to the NRC for information, not acceptance. We cannot stress strongly enough that it is an OCRWM responsibility to accept participant QA programs. The record clearly shows that the OCRWM request for NRC acceptance of these programs was limited to those participants, at the time, involved in site characterization.

We also take this opportunity to clarify, for the record, other statements made in NRC reference letter 2). This letter states that the staff "does not believe that (the) readiness reviews (of the M&O) have provided, to date, the same visibility of M&O QA program implementation that was achieved by the periodic audits of the other participants." Although a true statement, the context, as it is used, implies that OCRWM intended for the readiness reviews to assess implementation. If you read OCRWM reference letter 1) more closely, we were making a point quite contrary to that. Please keep in mind that, prior to the readiness reviews, OCRWM had not authorized the M&O to perform quality-affecting work (quite a different situation than that of the site characterization participants at the time of the SCA objection). In our letter we state "it is more appropriate to authorize initiation of work based on readiness reviews and perform audits after implementation." Also, during the qualification audits, DOE was criticized by the NRC staff for performing audits when no implementation had occurred. Furthermore, since the M&O had not been authorized to initiate work, there would not have been any implementation to assess. What the readiness review did accomplish was confirmation that the necessary QA requirements and controls were in place to initiate work.

As stated in our letter, after implementation DOE will continue surveillance activities and schedule audits (FY93 Audit Schedule includes the M&O) to assess adequacy and effectiveness of this implementation. Additionally, we do not agree that this approach, as you state, results in M&O work being at risk. This approach is the most logical for a new participant.

In closing, we will continue to transmit QA program changes to the NRC staff for information and, as in the past, resolve any comments that may result from staff review. We also will continue to extend an invitation to the NRC to observe OCRWM overview activities.

By transmittal of this letter, we consider this issue closed.

If you have any questions, please contact Mr. Donald G. Horton, Director, Office of Quality Assurance, at (202) 586-8858.

Sincerely,



John P. Roberts
Acting Associate Director for
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