Department of Energy
Washington, DC 20585

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FEB 13 1991

Susan W. Zimmerman, NWPO QA Manager
Nuclear Waste Project Office
Agency for Nuclear Projects
Capital Complex
Carson City, Nevada 89710

Subject: State Observation of DOE Audit 90-I-01

Dear Ms. Zimmerman:

Thank you for your letter of December 27, 1990, which contained your observations and comments on the DOE QA audit performed at the DOE Headquarters and at the Yucca Mountain Site Characterization Project Office during October 1990. The following comments respond specifically to the observations you made concerning the audit process and program:

The Audit Process

We appreciate your positive observations regarding the professional performance of the audit team and the familiarity of the audit team members with the requirements of the QA program. However, we are concerned about your perception regarding the independence of the auditors. The governing Office of Civilian Radioactive Waste Management (OCRWM) procedures and Federal requirements dictate that the auditors be well versed with the program requirements and also be knowledgeable in the activities being audited. The members of this audit team were chosen specifically because they possessed the requisite knowledge, experience, and professionalism to conduct the in-depth, thorough, and no-holds-barred audit to which you referred. Also, the requirements of NQA-1 Basic Requirement's regarding independence were, in fact, adhered to in that none of the auditors investigated activities "that they were directly responsible for performing". There is a distinct difference between program knowledge and independence. It is unfortunate that an auditor's attempt to minimize time lost by answering his own question for the auditee was perceived negatively. Nonetheless, your point is well taken, and audit teams in the future will be advised to refrain from this practice.

Your suggestion to separate the Headquarters and Project Office audits by at least two weeks has been implemented. The Fiscal Year 1991 audit schedule has the Project Office audit scheduled for July and the Headquarters audit scheduled for September.

With regard to your comments about the timing of the audit in the wake of so many program changes; many of the changes were necessitated by the OCRWM

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reorganization which had just occurred in July. The Department decided that such an important audit should not be delayed and could serve to identify any additional problems which might have arisen as a consequence of the new interfaces under the reorganization. DOE saw no justification for delaying this audit any longer, especially since, as you pointed out, this audit should have been performed two years ago and also the fact that quality-affecting activities were being performed. Also, the milestone referred to in your report is not the milestone of "performing an audit", but rather the milestone of "initiating new site characterization". To not perform an audit to assess the QA program readiness to support initiation of such an important activity would be contrary to our commitment to characterize the Yucca Mountain Site in a manner that protects the health and safety of the public.

The Audit Program

The reason behind qualifying the participants' QA programs prior to the DOE program was simply because it is the participants who have been delegated the detailed work involved with characterizing the site with the Department's program responsible for support activities (e.g., establishment of requirements, review, overview, management, etc.). The process is consistent with DOE/NRC agreement for QA program qualification. Also, there is an abundance of documentation available supporting that impact is minimal on established participant QA programs versus later development of the DOE program.

A QA program is a dynamic entity which must be modified to respond to changing circumstances or requirements. It is unlikely that an audit of a program as complex as this one and with as many interfaces, will ever result in a total absence of findings. It is the significance of the findings that are important, not the fact that there were findings nor the number of them. Neither the Audit team nor DOE management feel that with correction of required deficiencies we cannot proceed with near team new site characterization activities. The deficiencies can also be viewed as opportunities to improve a process which is continually evolving. The auditors specifically looked at key areas where problems were most likely to occur. As you stated, it was an in-depth audit. To condemn an entire program because of deficiencies found during its initial audit would be unsound.

It is unfortunate that your observation with regard to a quote attributed to a member of the Headquarters QA staff was taken out of context. Based on subsequent conversations with the auditor and county representative who were present during this discussion, it is clear that the Headquarters QA staff member was explaining that OCRWM QA and Line organizations were utilizing resources to correct previously identified deficiencies as part of the preparation for this audit; that being the reason why surveillances were not considered necessary nor performed. We would like to note that the deficiency on surveillances only identified a 3 month period that surveillances were not performed. Prior to that period the QA program was extensively reviewed and surveilled. As stated, it was this period that corrective actions were being taken to resolve and close identified deficiencies.

Lastly, we disagree with your assertion that DOE is misleading the public concerning the results of the audit. The audit report is available to the public. In the Executive Summary of the audit report the audit team recommended that certain actions take place prior to the start of site characterization activities. The actions so identified are now being accomplished to satisfy that recommendation. In addition, the NRC has stated that although a number of the areas audited are indeterminate, no findings were identified that would preclude DOE from accomplishing the work required to start site characterization activities in specific, limited areas.

Any other interpretation of the audit is not in agreement with the DOE position regarding the readiness of the QA program for site characterization to begin. Thank you for your input. Comments such as those mentioned in your letter help us to improve as the program progresses.

Donald G. Horton, Acting Director
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