May 25, 1995

0393

Mr. Ronald A. Milner, Director
Office of Program Management & Integration
U.S. Department of Energy/OCRWM
1000 Independence Avenue, S.W.
Washington, D.C. 20585

SUBJECT: MINUTES OF THE APRIL 12, 1995, QUALITY ASSURANCE MEETING

Dear Mr. Milner:

I am transmitting the enclosed minutes of the periodic quality assurance (QA) meeting that was held on April 12, 1995. The meeting was held by videoconference between Department of Energy (DOE) offices in Las Vegas, Nevada and DOE contractor offices in Washington, D.C. Attendees represented the Nuclear Regulatory Commission, DOE's Office of Civilian Radioactive Waste Management (OCRWM), the State of Nevada, Nye County, the National Council of American Indians, OCRWM's QA Technical Support Services Contractor (QATSS), OCRWM's Management and Operating Contractor (M&O), Reynolds Electrical & Engineering Company, Los Alamos National Laboratory, and Weston.

This meeting included a discussion of changes in DOE's QA program resulting from DOE's management decision to consolidate its contractor structure under the M&O and to centralize the QA verification function in DOE's Office of Quality Assurance. NRC and the State of Nevada asked for further amplification of this change, and NRC later requested written details of the integration plans by letter (Holonich to Milner, April 12, 1995). During a discussion of NRC's recent in-field verification (IFV) of Yucca Mountain site activities, NRC stated that the report on its IFV would be issued after management review.

If you have any questions regarding this letter or the enclosed meeting minutes, please contact Pauline Brooks of my staff at (301) 415-6604.

Sincerely,

Original/s/ by John O. Thoma for
Joseph J. Holonich, Chief
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: See attached list

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OFC	HLUR	E	HLUR	E	HLUR	E	HLUR	E		
NAME	PPBrooks/jk		JSpraul		JThoma		JHolonich			
DATE	05/25/95		05/25/95		05/25/95		05/25/95			

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CC LIST FOR LETTER TO R. MILNER DATED May 25, 1995

cc: R. Loux, State of Nevada
J. Meder, Nevada Legislative Counsel Bureau
W. Barnes, YMPO
C. Einberg, DOE/Wash, DC
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
W. Cameron, White Pine County, NV
R. Williams, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Hoffman, Esmeralda County, NV
C. Schank, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB
R. Holden, NCAI
A. Melendez, NIEC
S. Brocoum, YMPO
R. Arnold, Pahrump, NV
M. Stellavato, Nye County, NV

MINUTES OF THE APRIL 12, 1995, QUALITY ASSURANCE MEETING

A meeting of the staff of the U.S. Nuclear Regulatory Commission and representatives of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) was held on April 12, 1995, to discuss items of mutual interest with regard to quality assurance (QA). The meeting, held by videoconference between Department of Energy (DOE) offices in Las Vegas, Nevada and DOE contractor offices in Washington, D.C., was convened at 1:00 PM EDT. Attendees represented the Nuclear Regulatory Commission, DOE's OCRWM, the State of Nevada, Nye County, the National Council of American Indians, OCRWM's QA Technical Support Services Contractor (QATSS), OCRWM's Management and Operating Contractor (M&O), Reynolds Electrical & Engineering Company, Los Alamos National Laboratory, and Weston. Attendance lists are Attachment 1.

At this meeting, DOE presented information on the following topics: (1) the DOE/Nye County cooperative drilling program; (2) DOE's fiscal year 1995 audit and surveillance schedule; (3) QA overview of site characterization field activities; (4) changes in the QA program; (5) the status of implementing the revised Quality Assurance Requirements and Description (QARD) document; (6) the status of the M&O design package and related corrective action requests (CARs); (7) the status of consolidating DOE's contractor structure and changing the QA verification function to DOE; and (8) proposed revisions to the corrective action reporting system.

The NRC presented information on the following topics: (1) status of its QA open items; (2) results of NRC observations of recent DOE audits; (3) its review of DOE's QARD; and (4) its planning for in-field verification of the Yucca Mountain site activities. Attachment 2 is the agenda for the meeting and shows the attachment numbers for overheads/handouts presented during the meetings.

The meeting began with opening remarks followed by self-introduction of the attendees. Following the introductions, NRC presented an update on the status of its QA open items. Attachment 3 summarizes the two current open items. DOE stated that a revision of the QARD is in draft that should close out the first open item regarding validation of software programs. NRC agreed to provide comments prior to mid-May. The open item regarding electronic record-keeping resulting from NRC Observation Audit Report 94-12 (dated 01/27/95), which had been added since the January meeting, was discussed. The question of where in-field verification open items might be carried was also discussed.

NRC followed with a summary report of NRC observations of five DOE audits: YMP-94-10 of Lawrence Livermore National Laboratory, HQ-ARP-95-03 of the M&O offices in Vienna, Virginia, YM-AR-95-02 of the M&O offices in Las Vegas, Nevada, HQ-95-01 of quality assurance related to procurement control at M&O offices in Vienna, Virginia, and YM-ARC-95-07 of Lawrence Livermore National Laboratory in Livermore, California. NRC staff agreed with preliminary audit team findings at each of these audits. Additional details are provided in Attachment 4.

The status of the DOE/Nye County cooperative drilling program was then presented by DOE. Attachment 5 provides an update on in-field activities at two boreholes. The Nye County QA plan has been completed and a courtesy copy was sent to NRC. NRC asked to see the test planning package as well.

DOE then discussed the status of its Fiscal Year 1995 (FY 95) schedule for audits and surveillances. Changes to Revision 2 of the FY 95 audit schedule are shown in Attachment 6. The second page of the attachment shows the status of surveillances for FY 95. The NRC is currently following surveillances only through the reports.

An update on QA overview of the Yucca Mountain Site Characterization field activities was provided by DOE. To date, 43 boreholes have been completed, with a total footage of 17,327 feet. QA field coverage was summarized in several different ways. Six surveillances of field activities of affected organizations were completed by YMQAD in FY 95, resulting in three CARs related to the procurement of steel sets. The ensuing discussion provided greater detail on the steel sets which are being installed as the Tunnel Boring Machine bores into Yucca Mountain. It was noted that no significant CARs relative to field activities had been issued since the January NRC-DOE QA meeting. Surveillances, job package reviews, and a test planning package review completed are shown in Attachment 7.

The ongoing revision of the QARD was then discussed by DOE. The revision of DOE's QARD is underway. Revision 3 will be issued in the very near future and comprises a change to Appendix B, "Transportation" to include vendor activities associated with 10 CFR Part 72, for storage. Revision 4 is scheduled for mid-July, 1995 and will respond to approximately 250 comments and will incorporate about 150 of them. Most of the comments are for clarification rather than commitment reduction. EM-343, the Vitrification Projects Division of DOE's Environmental Restoration and Waste Management organization expects to send its Requirements Traceability Network matrix within the month. See Attachment 8.

In the following discussion DOE addressed the status of Design Package 2C corrective action reports (CARs). Attachment 9 summarizes the status of the five open CARs related to Design Package 2C remaining from the original 19 CARs that were issued.

Next DOE addressed the management decision to integrate the National Laboratories into the M&O. DOE explained that this integration would require the M&O to be responsible for providing the technical direction for all work performed at the laboratories, QA being just one part. In response to NRC questions regarding the impact on quality assurance, DOE stated that the QA programs of the National Laboratories will remain intact, with the Laboratory QA managers reporting to the M&O QA manager. Attachment 10 provides a chart showing the projected QA organizational structure. DOE also stated that this reorganization had no impact on the transition of the audit function to the DOE Office of Quality Assurance. NRC and the State of Nevada requested an additional briefing by the appropriate DOE organization on the complete M&O/National Laboratory reorganization.

The revision of OCRWM's corrective action program to use three levels of documents to describe deficiencies was discussed next by DOE. In addition to CARs, there will be performance reports and deficiency reports. The objective is for management to place the focus on the most significant problems. All CARs would be significant. Under the new program, there will be a common trending program and root cause analysis done by OQA for all organizations, but affected organizations will be able to access information centrally and can trend within their area of responsibility. Attachment 11 summarizes changes in OCRWM's corrective action program.

NRC then discussed its recent in-field verification (IFV), which was accomplished April 3-6. The report will include three recommendations. It was noted that the results of ongoing limited scope IFVs by NRC's onsite representatives will be included in their monthly reports.

Finally, DOE presented a proposed change in wording of Section III.2.6 of DOE's QARD. The revision is intended to clarify the wording regarding the model validation process, especially the role of peer review. The original and the proposed wording in the QARD are shown in Attachment 12. NRC staff is to review the proposed change and respond in May, 1995.

In closing remarks, participants agreed that the videoconference had proved to be an effective and efficient means of meeting. It was agreed that the next QA meeting would be in July 1995, and that specific dates for periodic meetings on QA will be established at the next Interactions Scheduling Meeting in May. The meeting was adjourned at 2:40 p.m., EDT.

Pauline P. Brooks

Pauline P. Brooks
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Frederick C. Rodgers

Frederick C. Rodgers
Regulatory Integration
Division
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

NRC-DOE QA MEETING ATTENDANCE LIST
April 12, 1995

Suite 7200, 490 L'Enfant Plaza
Washington, D.C.

PRINTED NAME	ORGANIZATION/COMPANY	PHONE
HORTON, DONALD G.	DOE/DQA	(702)794-7675
CLARK, Robert W.	DOE/OQA	202-586-1238
Buckley, John	NRC /QA	301-415-6607
Karas, Nadina R.	YMQAD/QATSS	702-295-9601
RUTH, Ronald P.	M&O / QA	702-794-7130
Morgan, Robert A	M&O /QA	703-204 8761
Peck, Richard G.	QATSS	202-4885438
KEELE, ROBERT P.	SAIC/QATSS	702-794-7442
THREATT, DENNIS	HQ · QATSS	202-488-5446
WAGNER, LESTER W.	HQ · QATSS	202-488-5420

ATTACHMENT 1

NRC-DOE QA MEETING ATTENDANCE LIST
April 12, 1995

Suite 7200, 490 L'Enfant Plaza
Washington, D.C.

PRINTED NAME	ORGANIZATION/COMPANY	PHONE
JACK SPRAUL	NRC	301-415-6715
Pauline Brooks	NRC	301-415-6604
JOHN O. THOMA	NRC	301-415-7293
Chris Einberg	DOE/HQ	202-586-8869
Ray Johnson	Weston	202-646-6698
L.S. Hopkins	NCAI	202 546 9404
Carl Weber	DOE QA - HQ	202-586-2111

Meeting: NRC/DOE QA mtg.

Location: Las Vegas Rm. 622

Date: 4/12/95 Time: 10:00am

Attendee		Attendee	
1.	Catherine Hampton	26.	
2.	Sandy Batte	27.	
3.	B. C. Spence	28.	
4.	Lowell Glasser	29.	
5.	E. V. Tiesenhausen	30.	
6.	John Schmit	31.	
7.	Jim Schmit	32.	
8.	Robert B Constable	33.	
9.	Dave Fay	34.	
10.	J Blaylock	35.	
11.	Susan Zimmerman	36.	
12.	Tim Hume	37.	
13.	S Dana	38.	
14.	Albert C Williams	39.	
15.	C.C Warren	40.	
16.	J W Willis	41.	
17.	Bill Boyle	42.	
18.	John S. Martin	43.	
19.		44.	
20.		45.	
21.		46.	
22.		47.	
23.		48.	
24.		49.	
25.		50.	

AGENDA
NRC/DOE VIDEOCONFERENCE ON QUALITY ASSURANCE
April 12, 1995

1:00 PM	Introductory Remarks		ALL
1:05 PM	QA Open Items	NRC	3
1:15 PM	Update on Observation of Recent DOE Audits	NRC/NV/LG	4
1:30 PM	Status of DOE/Nye County Cooperative Drilling Program	DOE/LG	5
1:45 PM	Status of DOE FY 95 Audit/Surveillance Schedule and Any Proposed Changes	DOE	6
2:00 PM	Update on QA Overview of Site Characterization Field Activities	DOE	7
2:15 PM	Discussion of QA Program Changes	DOE	8
2:30 PM	Status of Implementing the Revised QARD	DOE	9
2:40 PM	Review of Revised QARD	NRC	
2:50 PM	Status of M&O Design Package and Related CARs	DOE	10
3:00 PM	Status of Consolidating Contractor Structure and Changing the QA Verification Function to DOE	DOE	11
3:10 PM	Update on Proposed Revisions to Corrective Action Reporting Syster.	DOE	12
3:20 PM	Resolution of NRC Comments on Software Requirements in QARD	DOE/NRC	13
3:30 PM	In-Field Verification of Yucca Mountain Site Activities	NRC	
3:40 PM	Items of Concern to the State of Nevada and Affected Local Governments	NV, LG	
3:50 PM	Closing Remarks	All	
4:00 PM	Adjournment		

ATTACHMENT 2

STATUS OF NRC/DOE QA OPEN ITEMS

ITEM	DESCRIPTION	RECOMMENDATION FOR CLOSURE/REMARKS	STATUS
1-95	Test cases used to "validate" software programs were those supplied by the software developer. Thus, "validation" was primarily an installation test that showed that the computer software functioned the same on the user's computer hardware as it did on the developer's hardware. (See OA Report 94-07 dated 12/19/94.)	The NRC staff recommends that acquired computer software (not developed under an Appendix B QA program) be "validated" by more than rerunning the developer's test cases.	Open
2-95	LLNL procedure TIP-YM-12, "Electronic Record Keeping," indicates that electronic records can be used instead of hard copy records generated in scientific notebooks. An NRC "Audit Observer Inquiry" questioned whether the controls in the procedure were specific enough and whether activities in accordance with the procedure could be audited. (See OA Report 94-12 dated 01/27/95.)	There was a commitment by LLNL management to respond, through the DOE, with an expanded response to the inquiry. Expanded response discussed at last LLNL audit. Awaiting formal response from DOE.	Open

ATTACHMENT 3

NRC OBSERVATION AUDITS

YMP-94-10, LAWRENCE LIVERMORE NATIONAL LABORATORY

HQ-ARP-95-03, OCRWM MANAGEMENT AND OPERATING CONTRACTOR

YM-AR-95-02, OCRWM MANAGEMENT AND OPERATING CONTRACTOR

HQ-95-01, OCRWM MANAGEMENT AND OPERATING CONTRACTOR

YM-ARC-95-07, LAWRENCE LIVERMORE NATIONAL LABORATORY

ATTACHMENT 4

YUCCA MOUNTAIN QA DIVISION AUDIT YMP-94-10 OF THE LAWRENCE LIVERMORE NATIONAL LABORATORY

INTRODUCTION

During September 19-23, 1994, members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) audit of the QA program of the Lawrence Livermore National Laboratory (LLNL). The audit, YMP-94-10, was conducted at the LLNL facility in Livermore, CA. The audit evaluated the adequacy and effectiveness of the LLNL QA program in all applicable QA programmatic areas and in selected technical elements. The State of Nevada did not observe this audit.

OBJECTIVES

The objectives of the audit by YMQAD were to determine whether the LLNL QA program and its implementation meet the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and LLNL implementing procedures.

The NRC staff's objective was to gain confidence that YMQAD and LLNL are properly implementing the requirements of their QA program in accordance with the OCRWM QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that LLNL Audit YMP-94-10 was useful and effective. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan. The audit team was augmented with a technical specialist whose qualifications had been previously verified.

The NRC staff agrees with the preliminary audit team finding that the overall implementation of the LLNL QA program is adequate in all applicable QA programmatic areas and in the technical areas audited. One preliminary Corrective Action Request (CAR), regarding incomplete documentation of a management assessment, was discussed by the audit team at the post-audit meeting. Seven other potential CARs were acceptably resolved by LLNL during the audit. Neither the preliminary CAR nor those corrected during the audit were significant in terms of the overall implementation of the LLNL QA program.

One NRC Audit Observer inquiry was not fully responded to during the LLNL audit, and this is being held as an NRC Open Item. The open item involves electronic record keeping at LLNL as described in an LLNL Yucca Mountain Project Procedure.

The LLNL QA program should continue to be monitored to ensure that the deficiencies identified during this audit and previous audits are corrected in a timely manner and that future QA program implementation is adequate. The

NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the LLNL QA program.

NRC Staff Findings

Based on the scope of the NRC observations, the NRC staff agrees with the preliminary YMQAD audit team finding that the applicable QA programmatic elements and the overall implementation of the LLNL QA program are adequate. The NRC staff did not observe any deficiencies in the audit process or in the LLNL QA program, except as found by the audit team and as noted below (under "Weakness").

Good Practice - A good practice was noted during this audit of maintaining a computerized daily status sheet of all segments of the audit which identified the QA program element, the implementing procedures for the element, and the status of each.

Weakness/Open Item - LLNL procedure TIP-YM-12, "Electronic Record Keeping," indicates that electronic records can be used instead of hard copy records generated in scientific notebooks. An "Audit Observer Inquiry" generated by the NRC questioned whether the controls in the procedure were specific enough and whether activities in accordance with the procedure could be audited. The thrust of the inquiry was to ascertain whether controls are in place to prevent changes to the text in the electronic record keeping media just before the hard copy is printed for submittal to the local records center. After some discussion, there was a commitment by LLNL management to respond, through the DOE, with an expanded response to the inquiry. DOE should follow-up to ensure that LLNL adequately addresses the inquiry. The NRC staff will carry this Audit Observer Inquiry as an Open Item until a satisfactory response is received through the DOE.

Audit Team Findings

Within the scope of this audit, the YMQAD audit team concluded that the LLNL procedures and the LLNL implementation of the procedures are adequate. At the post-audit meeting, the ATL-In-Training explained the areas of concern and the one preliminary CAR. The CAR addressed LLNL's Management Assessment 93-01 which was identified as having incomplete documentation. The adverse condition was identified that the associated sources of information (i.e., interviews and documents reviewed), assessment criteria, and the resultant observations and/or recommendations were not documented on Management Assessment Worksheets as required in LLNL 033-YMP-QP 2.3.

Seven other deficiencies requiring only remedial corrective action were acceptably resolved by the LLNL organization prior to the post-audit meeting. In addition, the audit team provided eight recommendations to improve the LLNL YMP QA program.

AUDIT HQ-ARP-95-03 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR

INTRODUCTION

During December 5-8, 1994, members of the U. S. Nuclear Regulatory Commission Division of Waste Management Quality Assurance (QA) staff observed the U. S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of the QA program of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The audit, HQ-95-ARP-03, was conducted at the M&O offices in Vienna, Virginia. The focus of the audit was a performance-based evaluation of the effectiveness of the M&O QA program with regard to the control of the development and the revision of technical requirements documents. The technical requirements documents identify the requirements necessary to develop the design bases for systems of the High Level Waste repository program. No other organizations observed this audit.

OBJECTIVES

The objectives of the audit team were to determine whether the M&O QA program for the development and the revision of the technical requirements documents and its implementation meet the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and associated implementing procedures.

The NRC staff's objective was to gain confidence that OQA and the M&O are properly implementing the requirements of their QA programs in accordance with the OCRWM QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that audit HQ-ARP-95-03 was useful and effective. The audit was very well organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team finding that the overall implementation of the M&O QA program relative to technical documents is effective. The audit team also correctly cautioned that the M&O process controls appear to be complicated, and that "If M&O management does not maintain oversight of user implementation, the process could possibly break down." One preliminary Corrective Action Request (CAR) was discussed by the audit team at the post-audit meeting concerning the distribution of a wrong controlled document. The distribution error was identified during the audit, and the M&O distributed the correct document during the audit as remedial action. In addition, one deficiency was acceptably resolved by the M&O organization during the audit. Six recommendations were also provided to the M&O.

DOE should continue to monitor the M&O QA program to ensure that the deficiencies identified during this audit and previous audits are corrected in a timely manner and that future QA program implementation is effective. The

NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the M&O QA program.

NRC Staff Findings

The NRC staff agrees with the preliminary HQAD audit team findings that the overall implementation of the M&O technical requirements documents development and revision process is being implemented adequately for the areas identified in the audit scope. This determination is based on the audit checklist results and responses provided to the audit team during the course of the audit.

The NRC staff observed that each of the auditors reviewed an appropriate amount of documentation and interviewed sufficient CRWMS M&O personnel to make valid judgments on the adequacy of each critical process step. The audit team was thorough and carefully reviewed a wide spectrum of objective evidence before drawing its conclusions.

The audit findings were minor in nature and the M&O management showed interest and responsiveness to items identified by the audit team regarding the technical requirement documents.

Good Practices - The audit team was thoroughly prepared and understood the programmatic and technical aspects of performance-based auditing. The auditors were thorough, persistent, and professional in their approach. The ATL was effective in the performance of his function. When there was additional work and details to be covered by one of the audit sub-teams, he was prompt to reassign another sub-team to the area that needed to be covered. His use of a comprehensive status board in the audit team meeting room included the process steps, with potential CARs, items corrected during the audit, recommendations, percent complete, and concerns led to excellent caucus discussions and effective tracking of concerns throughout the audit process.

The ATL scoping visit to pre-establish clear measurement criteria for each of the process steps in this performance based audit was instrumental to the success of the audit. This was an important and crucial planning step in the audit process.

Audit Team Findings

The audit team determined that the M&O process controls are being effectively implemented for the areas identified in the scope of the audit. The audit team emphasized during their post-audit summary that the process for developing and controlling the technical requirements documents is complicated and that without continual management oversight, the implementation of the process may not be effective.

The one preliminary CAR issued at the close of the audit regarded the inadequate distribution of technical documents. Specifically, the Document Control organization distributed the wrong controlled document. The distribution error was identified during the audit. The M&O distributed the correct document during the audit as remedial action.

A deficiency, considered isolated by the audit team and which dealt with analyses, was corrected during the audit.

Six recommendations for improvements to the process control system, listed in the OA report, were also presented to CRWMS M&O management for consideration.

AUDIT YM-AR-95-02 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR

INTRODUCTION

During January 9-13, 1995, members of the U.S. Nuclear Regulatory Commission Division of Waste Management Quality Assurance (QA) staff observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance audit of the Civilian Radioactive Waste Management System, Management and Operating (M&O) Contractor QA Program. The audit, YM-AR-95-02, was conducted at the M&O offices in Las Vegas, Nevada, and at the Nevada Test Site. The audit included both a compliance-based audit on QA Program Elements 5.0, "Implementing Documents;" 15.0, "Nonconformances;" 16.0, "Corrective Action;" and 17.0, "QA Records" and a performance-based evaluation of the corrective action process. A State of Nevada representative participated as an observer, and a Clark County representative attended the audit exit meeting.

OBJECTIVES

The objectives of the audit team were to determine whether M&O QA Program Elements 5.0, 15.0, 16.0, and 17.0 were being effectively implemented and met the applicable requirements of the OCRWM "Quality Assurance Requirements and Description" (QARD, DOE/RW-0333P) and associated implementing procedures. Additionally, the performance-based portion of the audit focused on the M&O corrective action process.

The NRC staff's objective was to gain confidence that DOE and the M&O are effectively implementing the requirements of their QA programs in accordance with the QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that audit YM-AR-95-02 was useful and effective. The audit was very well organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team finding that QA Program Elements 5.0, 15.0, and 17.0 were satisfactorily implemented by the M&O. The staff also concurs with the audit team's assessment that QA Program Element 16.0, "Corrective Action," was unsatisfactorily implemented. M&O management should take immediate actions to effectively implement a Corrective Action system which is capable of achieving the desired results. The audit team identified deficiencies with the M&O's Corrective Action process specifically in the areas of timeliness of Corrective Action responses, the adequacy of those responses, and the lack of objective evidence for actions taken. Two preliminary Corrective Action Requests (CARs) were drafted at the conclusion of the audit and discussed in the post-audit meeting, and one potential CAR was corrected during the audit by the M&O organization. One recommendation was also made by the audit team.

The M&O QA program should continue to be monitored by DOE to ensure that the deficiencies identified during this audit and previous audits are corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits or verifications at a later date to assess implementation of the M&O QA program.

NRC Staff Findings

The NRC staff agrees with the preliminary YMQAD audit team finding that M&O QA Program Elements 5.0, 15.0, and 17.0 are being effectively implemented. The NRC staff also agrees with the audit team finding that QA Program Element 16.0, Corrective Action, is being ineffectively implemented.

Each of the auditors reviewed an appropriate amount of documentation and interviewed sufficient M&O personnel to make valid judgments on the adequacy of each QA program element in both the programmatic compliance and the performance-based parts of the audit The audit team was thorough and carefully reviewed a wide spectrum of objective evidence before drawing its conclusions. There were critical discussions during the audit team caucuses which ultimately resulted in the ineffective implementation evaluation of the M&O corrective action process.

The audit findings were important because of the negative results of past M&O audits.

Good Practice- The scoping visit to establish clear measurement criteria for the performance-based portion of the audit was important to the success of the audit.

Weakness - One auditor had to depart the audit for an important conference prior to completing the assigned checklist for the evaluation of Program Element 16.0 because of an airline scheduling problem. The premature departure of the auditor resulted in a substantial duplication of effort and a lack of continuity in the evaluation of this program element. Better audit team personnel planning and utilization is desirable.

Audit Team Findings

The audit team determined that M&O QA Program Elements 5.0, 15.0, and 17.0 were effectively implemented. The team determined that QA Program Element 16.0, "Corrective Action," was not effectively implemented. It was emphasized during the post-audit meeting that M&O management attention and involvement in the corrective action process is important, especially because of past findings in this area.

The two preliminary CARs issued at the close of the audit are: One preliminary CAR identifies the fact that M&O specifications and drawings are not shown as implementing documents in the M&O Requirements Traceability Network (RTN) Matrix as procedures are. The audit team emphasized that procedures, specifications, and drawings are all implementing M&O documents and should be so identified by the RTN Matrix.

The second preliminary CAR, supported by a list of adverse conditions, stated that the corrective action process is not being adequately implemented at the

M&O facilities in Las Vegas, Nevada, with regard to timeliness of corrective action responses, the adequacy of the responses, and the supporting objective evidence for the corrective actions. This CAR was considered significant by the audit team, and the preliminary CAR identified numerous examples of an inadequate corrective action process. The specific adverse conditions are listed in the audit report.

The audit team further identified these general CAR conditions: The present method of not identifying the next sequential page number, the author's name, and the date on CAR responses and amended responses during the development of the CAR record files fails to maintain adequate objective evidence and traceability of actions taken during the corrective action process. There is insufficient objective evidence to support the determination of the root cause or compliance with DOE Guideline DOE-NE-STD-1004-92 for significant CARs as committed to in Paragraph 5.6.3 of M&O QAP-16-1 (Revision 1).

One potential CAR was corrected during the audit. It involved the objective evidence of a Readiness Review which had been constructed by cutting and pasting approval signatures onto a single page. Before the post-audit meeting, a complete record of the Readiness Review approval signatures was assembled and shown to the auditors.

One recommendation was presented by the audit team to M&O management. The audit team recommended that a performance-based surveillance of all Yucca Mountain Project participants be conducted to determine their compliance to YAP-15.1Q, "Control of Nonconformances."

OCRWM HEADQUARTERS AUDIT HQ-95-01 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR

INTRODUCTION

During October 10-14, 1994, members of the U. S. Nuclear Regulatory Commission Division of Waste Management Quality Assurance staff observed a U. S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance audit of Civilian Radioactive Waste Management System Management and Operating Contractor (M&O) quality assurance (QA) program relative to procurement control. The OCRWM audit, HQ-95-01, was conducted at the M&O offices in Vienna, Virginia. The audit was a performance-based evaluation of the processes and products to determine the effectiveness of the M&O QA program with regard to procurement control. In addition, the clarity of task descriptions provided to the M&O by OCRWM were also evaluated. No other organization had observers at this audit.

OBJECTIVES

The objectives of the OCRWM audit were to determine whether the M&O QA program for procurement control and its implementation meet the applicable requirements of and commitments to the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and associated implementing procedures.

The NRC staff's objective was to gain confidence that OCRWM and the M&O are properly implementing the requirements of their QA programs in accordance with Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B) and the QARD.

MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that OCRWM audit HQ-95-01 was useful and effective. The audit was well organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. They were well qualified in the QA discipline, and their assignments and checklist items were adequately described in the OCRWM audit plan.

The NRC staff agrees with the preliminary audit team finding that the overall implementation of the M&O QA program relative to procurement control is marginal. One preliminary Corrective Action Request (CAR) was discussed by the OCRWM audit team at the post-audit meeting. Five other potential CARs were acceptably resolved by the M&O organization during the audit. Nine recommendations were also made by the OCRWM audit team to improve various aspects of the M&O's procurement control program. Though the preliminary CAR and items corrected during the audit were minor in nature, two of the M&O process steps for the procurement control program - No. 2 dealing with work classification, No. 7 dealing with evaluation and acceptance, and No. 8 dealing with the overall process control (See Section 5.3)- were judged marginal. Four other process steps were judged effective and one step - No. 5 dealing with subcontractor (supplier) evaluation and acceptance - could not be evaluated due to the lack of activity. Procurement control should have continued M&O management attention.

OCRWM should continue to closely monitor implementation of the M&O QA program to ensure that the deficiencies identified during the audit are corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess M&O implementation of its QA program.

NRC Staff Findings

The NRC staff agrees with the preliminary OCRWM audit team findings that the overall implementation of the M&O procurement control program is marginal. This determination is based on the preliminary CAR resulting from the audit, on deficiencies corrected during the audit, and on several internal M&O CARs for which corrective action was not being implemented in a timely manner.

The NRC staff observed that each of the auditors reviewed an appropriate amount of documentation and interviewed sufficient M&O personnel to make valued judgments on the adequacy of each step of the procurement control process. In addition, the OCRWM audit team performed a follow-up of corrective actions resulting from previous OCRWM audits covering the same area of procurement control. As a result of this follow-up, planned corrective action completion dates identified with National Underground Storage subcontract deficiencies were moved ahead six months, from June 1995 to December 1994, by M&O management.

The OCRWM auditors followed the prepared checklists, adding questions when necessary to assure complete understanding of the process. Interviews were conducted in a professional manner, with questioning continuing until the auditor felt confident that the personnel were familiar and understood the process. In addition, M&O personnel departmental interfaces were also evaluated. Weaknesses were found in the interfaces, and the OCRWM audit team made four recommendations to improve communication and coordination in this area.

Though the audit findings were minor in nature, the NRC is concerned that the lack of attention to detail on the procurement process for the five subcontracts, if left unchecked, could cause major difficulties with the procurement of multi-purpose canisters.

Good Practices - The OCRWM audit team was well prepared and each team member understood the programmatic and technical aspects of performance-based auditing. The auditors were thorough, persistent, and professional in approach.

The ATL was very effective in the performance of his function. When difficulties arose in contacting M&O personnel, immediate action was taken to resolve the problem. His use of the "numbered" concerns led to good caucus discussions and effective tracking of concerns throughout the week.

The daily management meetings were very effective and conducted in a professional manner, the ATL making sure M&O personnel fully understood each problem. The closing meeting was short, but the ATL provided a detailed summary of the week's activities, making effective use of charts and computer-generated summaries.

Weakness - The assignment of a number of subcontracts to one M&O quality engineer slowed the interview process and caused some audit delay. The functions of M&O Quality Engineering and Quality Engineering Support need to be more clearly defined. The interviews showed that M&O personnel were sometimes confused over which QA organization handles what.

Audit Team Findings

The OCRWM audit team determined that the overall implementation of QA Programmatic Elements 4.0, "Procurement Document Control," and 7.0, "Control of Purchased Items and Services," were marginally effective. The deficiencies identified during this audit and through M&O CARs contributed to this determination.

One preliminary CAR was issued at the close of the audit dealing with the review of Work Authorization Directive/Technical Direction Letter for the impact of quality-affecting work being performed without a documented QA implementing procedure.

In addition, five deficiencies that were considered isolated in nature were corrected by M&O personnel during the audit. These covered timely resolution of CARs, issuance of control changes, and improper correction records.

Nine recommendations for improvements were also presented for M&O consideration.

YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION AUDIT YM-ARC-95-07 OF LAWRENCE LIVERMORE NATIONAL LABORATORY

INTRODUCTION

During March 6-10, 1995, members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) audit of the QA program of Lawrence Livermore National Laboratory (LLNL). The audit, YM-ARC-95-07, was conducted at the LLNL offices and laboratories in Livermore, California.

MANAGEMENT SUMMARY

The NRC staff has determined that YMQAD Audit YM-ARC-95-07 was useful and effective. The audit was organized and conducted in a thorough and professional manner and was generally effective. However, the technical portion of the audit was marginally effective. The Technical Specialist on the audit team was replaced just prior to the audit, and his familiarity with the High-Level Waste program, with LLNL activities, and with the DOE auditing process was less than it should have been. In addition, the scope of technical activities audited was beyond the areas of specialization of most Technical Specialists.

Audit team members were independent of the activities they audited. The auditors were well qualified in the QA discipline, and their assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the YMQAD audit team's preliminary finding that the overall implementation of the LLNL QA program is effective. No Corrective Action Requests (CARs) were identified by the YMQAD audit team. Nine potential CARs were acceptably resolved by the LLNL organization during the audit.

OCRWM should continue to closely monitor implementation of the LLNL QA program to ensure that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess LLNL implementation of its QA program.

NRC Staff Findings

The QA programmatic portion of the audit was conducted in a professional manner, and the auditors adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the LLNL QA program. The technical portion of the audit was marginally effective due to the late substitution of the Technical Specialist, and his lack of training and experience in auditing and with the high-level waste program.

The NRC staff agrees with the preliminary YMQAD audit team finding that implementation of the LLNL QA program is adequate in each of the QA programmatic areas audited. The NRC staff did not observe any deficiencies in either the audit process, the LLNL QA program, or its implementation.

Recognizing the effects of the unavoidable last-minute change of the audit team's Technical Specialist, the NRC presents the following points for DOE's consideration when planning future audits:

· Technical Specialists should be carefully matched to the technical activities being audited. Several Technical Specialists may be necessary to cover the variety of activities as encountered in this audit.

· Technical checklists should be prepared and utilized such that personnel, plans, methods, review documentation, and results are evaluated and so that the objectives of the technical portion of the audit, described in the audit plan, are adequately addressed.

· Technical Specialists should be provided with adequate training and time for preparation. The Audit Team Leader and Lead Technical Specialist should provide appropriate guidance to first-time Technical Specialists to ensure that the objectives of the technical portion of the audit can be met.

Audit Team Findings

No deficiencies were reported regarding whether the applicable LLNL procedures adequately address the QARD requirements as identified in DOE's RTN matrix.

Within the scope of this audit, the audit team concluded that LLNL procedures are adequate to address the recent revision of the OCRWM QARD (baseline) and that LLNL's QA program implementation is satisfactory. No CARs were identified as a result of the audit. Nine potential CARs requiring only remedial action were acceptably resolved by the LLNL organization prior to the post-audit meeting. In addition, the audit team provided eleven recommendations to LLNL for improving its QA program and two positive comments for good practices.

NYE COUNTY UPDATE

- DOE provided Nye County permission to drill borehole UE-25 ONC#1 and to conduct tests in previously drilled borehole USW-NRG-4
- Test Planning Package (TPP) 95-03, R0 issued in 12/94 provides test to test interference and waste isolation evaluations
- Nye County drilling and DOE geophysical logging of UE-25-ONC#1 is complete; In 4/95 DOE began instrumenting UE-25 ONC#1 for data gathering activities
- In 3/95 Nye County began data gathering in USW NRG-4 for independent field investigations

CHANGES TO OCRWM FY-95 QA AUDIT SCHEDULE, REVISION 2

- **YM-ARP-95-09, USGS, moved up to May 8-12, 1995 due to availability of Audit Team personnel**
- **YM-ARC-95-10, REECo, postponed to June 5-9, 1995 due to an increase in audit scope**
- **HQ-ARP-95-06, OCRWM HQ, postponed to May 8-12, 1995 due to availability of RW Division Managers**
- **HQ-ARC-95-11, SNL, reduced to limited scope audit of burnup credit work due to redundancy with previous audits**

Surveillance Status

Number	Organization	Activity	Status
95-021	M&O	Changes to Class II Drawings	In Progress
95-023	USGS	Verification of Corrective Action of CARs	Planned
95-024	SNL	Verification of Corrective Action of CARs	In Progress
95-025	Kiewit	Water Usage in the ESF	In Progress
95-027	USBR	Sample Handling During Mapping	Planned

FIELD ACTIVITIES UPDATE

APRIL 12, 1995

FIELD ACTIVITIES UPDATE

No Significant CARs Related To Field Activities Were Issued Since January 18, 1995

FIELD ACTIVITIES UPDATE

- **YMQAD Staff Completed Surveillances Of The Following Activities**
  - **Geophysical Logging**
  - **Vendor Submittals For Package 2C**
  - **Steel Set Installation**
  - **Convergence Measurements In ESF**

FIELD ACTIVITIES UPDATE

YMQAD Staff Completed Surveillances Of The Following Affected Organizations:

- REECo, Kiewit/Parsons Brinkerhof
- M&O
- Sandia National Laboratory
- T&MSS

FIELD ACTIVITIES UPDATE

REVIEWS COMPLETED SINCE 1/18/95
NRC PRESENTATION

Job Packages:

JP 95-9, Rev. 0, Foundation Investigations For Surface Muck Handling System

JP 95-16, Rev. 0, Crater Flats Tectonics Trenching

JP 95-17, Rev. 0, Change House Bldg. #5008

FIELD ACTIVITIES UPDATE

REVIEWS COMPLETED SINCE 1/18/95
NRC PRESENTATION

Test Planning Package:

T-93-10, Revision 4, Seismic Reflection Line - - ESF Design Support - (LBL)

FIELD ACTIVITIES UPDATE

SITE COVERAGE FOR TWO WEEK PERIOD

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
Rick Weeks Raul Hinojosa	John Doyle Raul Hinojosa Kristi Hodges	Rick Weeks Fred Lofftus	John Martin John Doyle Pat Cotter	Fred Lofftus Kristi Hodges Pat Cotter
* Bob Holliday →				
Rick Weeks Raul Hinojosa	John Doyle Kristi Hodges	Rick Weeks Raul Hinojosa Fred Lofftus	John Doyle Pat Cotter	Fred Lofftus Kristi Hodges
* Bob Holliday →				

* Permanent QATSS Representative Stationed At Site

QARD REVISION

SCOPE OF REVISION

- 14 SECTIONS
- 4 SUPPLEMENTS
- 2 APPENDICES

QARD COMMENTS

- APPROXIMATELY 250
- INCORPORATING APPROXIMATELY 150

DEPTH OF REVISION

- MOST COMMENTS ARE FOR CLARIFICATION
- POSSIBLY 4 COMMITMENT REDUCTIONS

QARD REVISION

TIMING OF REVISION

- COMMENTS CURRENTLY INCORPORATED IN DRAFT
- DRAFT IN INTERNAL OQA REVIEW
- FORMAL EXTERNAL REVIEW-MID-APRIL
- RESOLVE COMMENTS BY MID-JUNE
- ISSUE REVISION BY MID-JULY

Status of Design Package 2C Corrective Action Reports

OQA has closed 14 of the 19 CARs related to Design Package 2C

STATUS ON THE OPEN CARs IS AS FOLLOWS:

HQ-94-018	Analysis contains multiple deficiencies	Verification Ongoing
YM-94-062	Several errors/inconsistencies in design specs, drawings, and calculations	Verification Ongoing
YM-94-065	Inadequate checking/review process and documentation	Awaiting Amended Response
YM-94-073	No procedures or plans to perform Design Validation	Verification Ongoing
YM-94-100	10CFR 60 Requirements not incorporated in Design	OQA Evaluating Response

INTEGRATING THE NATIONAL LABS INTO THE M&O

April 12, 1995
R. A. Morgan

ATTACHMENT 10

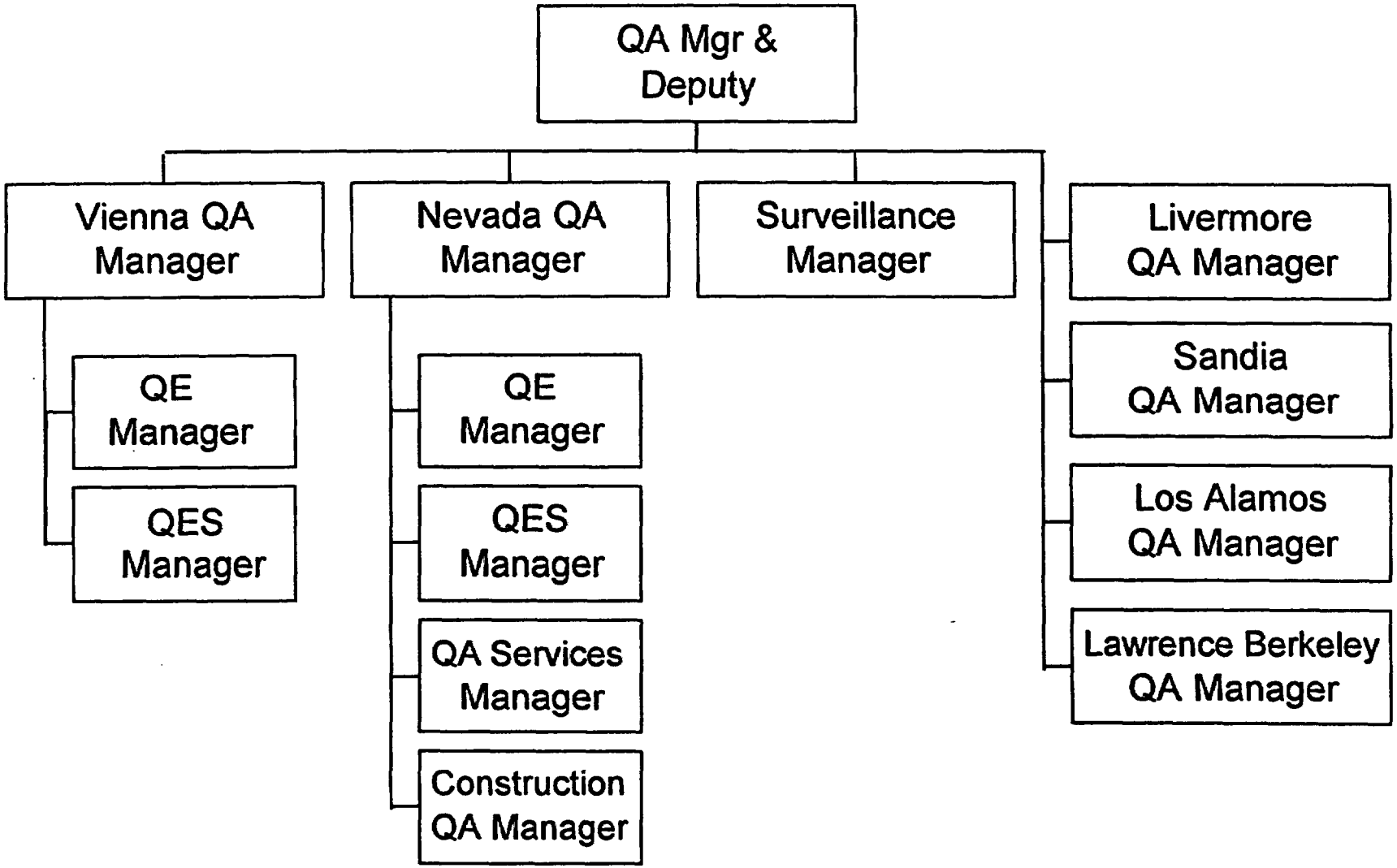
MEMORANDUM OF UNDERSTANDING (MOU)

- **ACCEPTED:**
  - > LLNL - OCTOBER 21, 1994
  - > LBNL - APRIL 3, 1995
  - > SNL - APRIL 3, 1995
  - > LANL - APRIL 3, 1995
  - > USGS - MARCH 31, 1995
  - > REECo - APRIL 3, 1995

M&O QA INTEGRATION PLANS

- TRANSITIONING QA MANAGERS WILL REPORT TO THE M&O QA MANAGER
- TRANSITIONING QA PROGRAMS WILL REMAIN INTACT
  - > NO CHANGES TO OPERATING QAPs
  - > NO SIGNIFICANT CHANGES TO RTN
- AUDIT FUNCTIONS TRANSITIONING TO OQA

Projected Organization Via Integration of Work



OCRWM CORRECTIVE ACTION PROGRAM

- Expanded to apply to all affected organizations under one program
- Utilizes three levels of deficiency documents
- Incorporates extension request escalation policy
- Raises the level of visibility for corrective action requests
- Utilizes a common root cause analysis procedure

OQA FUTURE COMPREHENSIVE TRENDING PROGRAM

- Individual Affected Organizations will have the capability to trend within their respective area of responsibility
  - NCRs
  - PRs
  - DRs
  - CARs
- OQA will trend across all Affected Organizations to assess the OCRWM QA Program
- Corrective Action will be initiated as appropriate for each condition identified during the trend process

OCRWM CORRECTIVE ACTION AND TRENDING PROGRAM STATUS

■ AP 16.1Q, Performance/Deficiency Reporting	QAP 6.2 Review
■ AP 16.2Q, Corrective Action and Stop Work	QAP 6.2 Review
■ AP 16.3Q, Trend Evaluation and Reporting	Preparation for QAP 6.2 Review
■ AP 16. 4Q, Root Cause Analysis Preparation	DRAFT

QARD currently reads as follows:

III.2.6 Model Validation

- A. Use and validation of models of natural phenomena shall be performed and documented to provide adequate justification for the intended use.
- B. Model validation shall be accomplished by comparing analysis results against data acquired from laboratory or field experiments or observations. When data are not available from these sources, alternative approaches (such as peer review or comparisons with data from open literature) shall be documented and used for model validation.

Proposed Change to the QARD:

III.2.6 Model Validation

A. The development of models of natural phenomena shall be documented. Documentation shall identify principle lines of investigation considered.

B. Models of natural phenomena shall be validated. Model validation shall be accomplished by comparing analysis results against data acquired from laboratory or field experiments or observations.

1. When data are not available from these sources, alternative approaches shall be documented and used for model validation.

2. The need to perform a peer review as an alternative approach shall be consistent with consideration criteria specified for peer review in Section 2.0.

C. The selection and use of models of natural phenomena shall be documented.