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MINUTES OF THE AUGUST 29, 1991, QUALITY ASSURANCE MEETING

A meeting of the staff of the U.S. Nuclear Regulatory Commission (NRC) and representatives of the U.S. Department of Energy (DOE) to discuss items of mutual interest with regard to quality assurance (QA) was held at the NRC Headquarters, Rockville, Maryland on August 29, 1991. An attendance list is included as Attachment 1. The State of Nevada, affected units of local government, and other involved representatives were not in attendance at this meeting.

At the meeting, DOE presented information on the following six topics: (1) Quality Concerns Program; (2) an update on the audit/surveillance schedule; (3) results of the DOE Management Assessment; (4) QA workshops; (5) status of Management and Operations contractor (M&O) QA program; and (6) status of changes to the DOE Quality Assurance Requirements Document (QARD)/Quality Assurance Program Description Document (QAPD). The NRC staff presented observation summaries of the Lawrence Livermore National Laboratory (LLNL) Audit (YMP-91-01), Los Alamos National Laboratory Audit (LANL) (91-03), United States Geological Survey (USGS) Surveillance (YMP 91-S6), and Raytheon Services Nevada (RSN) Surveillance (91-S10). In addition, the NRC staff presented the status of the QA Open Items.

DOE presented the status of the newly initiated Quality Concerns Program (Attachment 2). Six concerns have been received, two of which have been closed, two transferred to the responsible organization for action, and two are still under investigation. Initial training for the Quality Concerns Program is nearly complete. Additional training will be given to individuals unable to attend the initial training program. The NRC staff requested that when the Quality Concerns training is given in the Washington area, it be notified and invited to attend this training in order to better understand and evaluate it. The NRC inquired whether any of the documentation related to quality concerns will be made available to the public to avoid future problems that may surface from interested parties. DOE will check into this matter and respond to the NRC staff inquiry.

The updated revisions to the DOE/Yucca Mountain Site Characterization Project (YMP) FY '91 and FY '92 audit and surveillance schedules were presented and discussed (Attachment 3). The NRC staff noted that with the FY '92 schedule, audits are planned to be conducted by DOE almost every week and that with its limited resources, the NRC staff will not be able to observe all of the DOE audits. Instead, the NRC staff plans to observe at least one audit for each of the program participants which will probably be in the area of design control and scientific investigation and software control (key item C2 for FY '92 Audit Schedule on Attachment 3). DOE plans to cease all surveillances in FY '92 other than its own internal surveillances. The requirements for surveillances will not be deleted from the QARD/QAPD, however, the implementing procedure will probably be revised to reflect the planned FY '92 mode of operations.

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Next, DOE provided the DOE Office of Civilian Radioactive Waste Management (OCRWM) QA Management Assessment final report (Attachment 4). This was an independent QA management assessment to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the OCRWM QA program. The assessment team members consisted of staff from Duke Engineering & Services, Inc., TRW, Roy F. Weston, Inc., and Fluor Constructors International, Inc. Observations and findings from this assessment will be documented and formally resolved through a separate action plan.

The NRC staff gave a presentation on its observations of the DOE audits of LANL (YMP-91-03) and LLNL (YMP-91-01). The NRC staff also presented its observations on the recent DOE surveillances of the USGS (YMP-SR-91-S6) and RSN (YMP-SR-91-S10). Summaries of these observations are presented with this report as Attachments 5-8, respectively. The NRC staff requested DOE to reconsider providing the NRC staff with participant monthly status reports to provide an overview of what work has been accomplished by the auditee prior to the NRC staff observing the DOE audits. The NRC staff rationale for this request is that prior to its observing a DOE audit, the NRC staff may not have an accurate concept of what work has been accomplished by the auditee since the last audit. Consequently, it has been necessary for the NRC staff, on several occasions, to request the auditee to present a status report of the work that has been accomplished since the previous DOE audit as part of the audit entrance meeting. The NRC staff believes that understanding the status of the program to be audited is necessary in order to properly critique the audit, i.e., that the proper work sample was selected and that it is representative for its safety significance. Reviewing the status report would also assist the NRC staff in selecting appropriate NRC QA and technical observers commensurate with the scope of work being audited. DOE stated that they will pursue this matter and get back to the NRC staff.

Next, the NRC staff gave a presentation on the status of open QA items (Attachment 9). The status of Open Item 3-90, "NNWSI Core Handling Procedures", remains unchanged from the past four NRC/DOE QA meetings and the item is still open. DOE again will look into completing these procedures and submitting them to NRC for review. The NRC staff stated that Item 4-90, "Qualified QA Program before start of new site characterization activities" will remain open pending completion of its review of the RSN QA Program Description (Ref. Shelor to Linehan letter dated August 1, 1991). The Science Applications International Corporation QA Program Description portion of this Open Item is closed by virtue of the NRC acceptance letter (Ref. Linehan to Shelor letter dated August 22, 1991). The NRC staff indicated that the M&O contractor QA Program Description review status is indeterminate at this time. Consequently, pending further discussions with NRC management, a new Open Item may be entered under either 4-90 or 8-90. The response to Open Item 8-90, "SCA comments", was submitted to the NRC staff for review (Ref. Shelor to Linehan letter dated August 21, 1991). The matter of closing this item will need to be discussed further with NRC management based on whether it applies solely to QA or all of the SCA comments. For Open Item 10.e, "NRC Observation on the LLNL DOE Audit YMP-91-01 concerning QA Program Plan changes", DOE stated it will provide a list to NRC staff identifying all the DOE approved changes since NRC staff accepted the LLNL QA Program Plan. Open Item 11-90 was closed, and Open Items 12-90 and 1-91 are under review by the NRC staff.

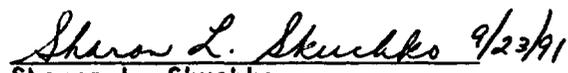
The QA Workshop status for June through August 1991 was then presented by DOE. Attachment 10 provides a summary of the status for the Scientific/QA, Software, QA Grading, and Data QA Workshops.

After the QA Workshop status discussion, DOE gave an overview of the M&O QA Program status (Attachment 11). The only QA-affecting activity the M&O is presently performing is in the area of conceptual design on the Monitored Retrieval Storage system of which DOE will review and accept. All other work performed by the M&O is being performed under the DOE QARD/QAPD. At the request of the NRC staff, DOE will consider providing the NRC staff a list of such activities. DOE plans to submit the M&O QA Program Plan to NRC for review and acceptance in November 1991. In conjunction with this submittal, DOE stated that a presentation may be given at the next NRC/DOE QA meeting to explain the details of the M&O transition phase into the YMP.

The last topic for discussion was a presentation from DOE on the status of the consolidation effort underway for the DOE QARD/QAPD and implementing procedures (Attachment 12). The QARD/QAPD will be consolidated into a single document and program participants will not be required to develop and maintain their own QA program description. The DOE OCRWM Headquarters and Yucca Mountain Site Characterization Project Office implementing procedures will also be consolidated to eliminate redundancy and establish consistency. The QARD/QAPD completion date is planned for October 1991 and the procedure consolidation effort is scheduled for November 1991.

The NRC invited closing remarks from the meeting participants. A tentative date of October 24, 1991, was noted for the next NRC/DOE QA meeting. The meeting was then adjourned.

  
William Belke  
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

  
Sharon L. Skuchko  
Repository Licensing Branch  
Office of Civilian Radioactive  
Waste Management  
U.S. Department of Energy

QA BI-MONTHLY MEETING  
AUGUST 29, 1991

<u>NAME</u>	<u>ORGANIZATION</u>	<u>PHONE NO.</u>
Ken Hooks	NRC	(301) 492-0447
Bill Belke	NRC	(301) 492-0445
Jim Bracket	M&O/Duke Engineering	(703) 934-2403
Donald G. Horton	DOE	(202) 586-7220
Sharon Skuchko	DOE	(202) 586-4590
Mike Finkelstein	NRC	(301) 492-1535
Betsy Shelburne	NRC	(301) 492-4030

## QUALITY CONCERNS PROGRAM

### LOG OF QUALITY CONCERNS:

<u>QCP #</u>	<u>SUBJECT</u>	<u>STATUS</u>
91-001	PUBLIC SAFETY INFORMATION ON HLW PROGRAM	CLOSED
91-002	NUCLEAR WASTE SITES IN U.S.	CLOSED
91-003	DESIGN RELATED STUDY	INVESTIGATION IN PROCESS
91-004	HYDROCHEMISTRY REPORT	INVESTIGATION IN PROCESS
91-005	EMPLOYEE DISCRIMINATION	TRANSFERRED TO ORGANIZATION FOR ACTION
91-006	NUCLEAR WEAPONS TESTING	TRANSFERRED TO ORGANIZATION FOR ACTION

### SUMMARY OF QCP TRAINING COMPLETED AS OF 8/29/91:

<u>DATE</u>	<u>PARTICIPANT</u>
7/17/91	DOE - WASHINGTON, D.C.
7/17/91	R.F. WESTON - WASHINGTON, D.C.
7/18/91	CER CORPORATION - ARLINGTON, VA
7/22/91	DOE - LAS VEGAS, NV
7/31/91	U.S. GEOLOGICAL SURVEY - DENVER, CO
8/5-8/8/91	S.A.I.C. - LAS VEGAS, NV
8/5-8/6/91	REECO - LAS VEGAS, NV
8/13/91	TRW - FAIRFAX, VA
8/19/91	RAYTHEON - LAS VEGAS, NV
8/28/91	LOS ALAMOS NATIONAL LABORATORY - NM
8/29/91	SANDIA NATIONAL LABORATORIES - NM

**OCRWM HQ FY '91 SURVEILLANCE SCHEDULE  
4TH QUARTER UPDATE)  
(REVISION 2)**

<b>SURVEIL- LING ORG</b>	<b>ORGANIZATION TO BE SURVEILLED</b>	<b>ACTIVITY TO BE SURVEILLED</b>	<b>SURVEILLANCE DATE</b>	<b>LOCATION</b>	<b>SURVEILLANCE PERSONNEL</b>
OCRWM-HQ (COMPLETED)	RW-30	Implementation of Functional Analysis Mgmt. PLANS: QAAP 3.1 Review of ESF System Requirements Preparation and Review (Criterion III)	07/09/91 07/11/91	Wash., D.C	*W. Marchand D. Miller
OCRWM-HQ (COMPLETED)	EM-343	Review Implementation of Waste Acceptance Process Technical Docu- ments (SPP 4.11) and Review of Program Execution Guidance Docu- ments (SPP 4.12) (Criterion 3)	07/16/91 07/18/91	Germantown, MD	*F. Bearham M. Meyer
OCRWM-HQ (COMPLETED)	RW-3	Implementation of the QA Audit & Surveillance Program (Criterion XVIII)	07/16/91 07/18/91	Wash., D.C.	*I. Wade CER
OCRWM-HQ (COMPLETED)	ORNL	Peer Review of Characteristics Data- base (Criterion III)	07/18/91 07/19/91	Oak Ridge, TN	*R. Schaffer CER
OCRWM-HQ (COMPLETED)	EM-343	Deviation reporting and Disposition (SPP 5.01), Control of Unsatisfactory Conditions (SWO) (SPP 5.03) and Identification and Analysis of Adverse Quality Trends and Problems. (SPP 10.01) (Criterion 16)	08/06/91 08/08/91	Germantown, MD	*M. Donovan H. Lentz
OCRWM-HQ	EM-343	Certification of QA Audit Personnel (SPP 3.03), and Documentation of Surveillance and Review Personnel Qualification (SPP 3.04) (Criterion 16)	08/20/91 08/22/91	Germantown, MD	*D. Miller D. Hendrix

\*TEAM LEADER

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AND

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE  
 FY-91 AUDIT SCHEDULE\* REVISION 5

<u>ORGANIZATION</u>	<u>AUDIT NUMBER</u>	<u>DATE OF AUDIT</u>	<u>AUDIT TEAM LEADER</u>
REECO	YMP-91-02	Feb. 25 - 28 (1)	Robert H. Klemens
LANL	YMP-91-03	March 25 - 29 (1)	Richard E. Powe
USGS	YMP-91-05	May 20 - 24 (1)	Charlie C. Warren
LLNL	YMP-91-01	June 3 - 7 (1)	Frank J. Kratzinger
SAIC	YMP-91-06	June 17 - 21 (1)	Richard L. Maudlin
RSN	YMP-91-04	July 29 - Aug. 2 (1)	Stephen R. Dana
EM	HQ-91-002	August <sup>26-30</sup> <del>19</del> - 23 (2)	Norman C. Frank
SNL	YMP-91-07	August 19 - 23	Neil D. Cox
OCRWM-HQ	HQ-91-04	Oct. 14 - 18 (3)	Thomas Rodgers
YMPO	YMP-91-I-01	Oct. 28 - Nov. 1 (3)	Richard E. Powe
PNL-MCC	Delayed Until Further Notice (4)		
EG&G	To Be Determined (4)		
RTTD	HQ-91-003	Delayed Until Further Notice	

\* All applicable 20 criteria plus implementing procedures

- (1) Completed as scheduled
- (2) Changed at the request of EM management
- (3) At the request of the NRC and State observers to avoid conflict with ASQC Conference
- (4) Equivalent to Qualification Award Survey

James B. Bayford for  
 Approval: Director, OQA

8/6/91  
 Date:

ENCLOSURE

REPT	ACTIVITY DESCRIPTION	EARLY START	EARLY FINISH	1991							
				AUG 12	AUG 19	AUG 26	SEP 2	SEP 9	SEP 16	SEP 23	SEP 30
LOS ALAMOS NATIONAL LABORATORY											
	CRITERIA 4, 5, 12	23SEP91	27SEP91							LA03 <input type="checkbox"/>	
LAWRENCE LIVERMORE NATIONAL LABORATORY											
	CRITERIA 18	9SEP91	13SEP91	NOTE 3						<input type="checkbox"/> LL03	
RAYTHEON											
	CRITERIA 2, 3, 17 (TITLE II ESF)	9SEP91	20SEP91							<input type="checkbox"/> RM07	
REYNOLDS ELECTRICAL AND ENGINEERING CO.											
	CRITERIA 16, 18	23SEP91	27SEP91							RE05 <input type="checkbox"/>	
SAIC/T&MSS											
SANDIA NATIONAL LABORATORY											
P.O.											
	CRITERIA 2, 3, 17	23SEP91	27SEP91							PO07 <input type="checkbox"/>	
U.S. GEOLOGICAL SURVEY				NOTE 2							
		9AUG91A	9AUG91A								
OCRMM/HG				NOTE 1							
	CRITERIA 16	6AUG91A	8AUG91A	<input type="checkbox"/> H019							
	CRITERIA 18	20AUG91	22AUG91							<input type="checkbox"/> H021	
NOTES: 1. H.G. SCHEDULED SURVEILLANCE 2. SPECIAL 3. RESCHEDULED											

ENCLOSURE

Activity Sur/Or to Date  
 Critical Activity  
 Program Sur  
 Primavera Systems, Inc. 1990-2000

Project Start : 10CT89  
 Project Finish: 30SEP91

DEPARTMENT OF ENERGY  
 SURVEILLANCE SCHEDULE W/ORG  
 FY-91 STATUS, REV 12-

Sheet 1 of 1

Date Rec'd: 5/26/91  
 Date Rec'd: 8/16/91

J. Blaylock 8/16/91  
 APPROVED DATE

## OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AND

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE  
FY-92 AUDIT SCHEDULE REVISION 0

<u>ORGANIZATION</u>	<u>AUDIT NUMBER</u>	<u>DATE OF AUDIT</u>	<u>AUDIT TEAM LEADER</u>	<u>CRITERIA</u>
LANL	YMP-92-01	Sept. 30 - Oct. 4	R. E. Powe	C3
USGS	YMP-92-02	Oct. 14 - 18	C. C. Warren	C1
ORNL	HQ-92-01	Oct. 21 - 27	R. Brown	C1
SNL	YMP-92-03	Nov. 4 - 8	S. R. Dana	C3
OCRW-M-HQ	HQ-92-02	Nov. 4 - 8	T. Rodgers	C3
REECO	YMP-92-04	Nov. 18 - 22	R. H. Klemens	C2
EM	HQ-92-03	Nov. 18 - 22	N. Franks	C2
LLNL	YMP-92-05	Dec. 2 - 6	R. L. Maudlin	C1
PNL	HQ-92-04	Dec. 2 - 6	W. Marchand	C2
RSN	YMP-92-06	Dec. 16 - 20	J. S. Martin	C2
YMPO	YMP-92-07	Jan. 6 - 10	F. J. Kratzinger	C3
M&O (Charlotte)	HQ-92-05	Jan. 13 - 17	L. Wade	C2
M&O (Fairfax)	HQ-92-06	Jan. 21 - 24	R. Schaffer	C2

## KEY

C1 = 1, 2, 11, 15, 16, and 18

C2 = 3, 5, 6, 17, 19, and 20

C3 = 4, 7, 8, 9, 10, 12, 13, and 14

ENCLOSURE

## OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AND

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE  
FY-92 AUDIT SCHEDULE REVISION 0

<u>ORGANIZATION</u>	<u>AUDIT NUMBER</u>	<u>DATE OF AUDIT</u>	<u>AUDIT TEAM LEADER</u>	<u>CRITERIA</u>
SAIC	YMP-92-08	Jan. 27 - 31	C. C. Warren	C3
M&O (Las Vegas)	HQ-92-07	Jan. 27 - 31	T. Rodgers	C2
SNL	YMP-92-09	Feb. 10 - 14	N. D. Cox	C1
REECO	YMP-92-10	Feb. 24 - 28	A. I. Arceo	C3
ORNL	HQ-92-08	Feb. 24 - 28	T. Rodgers	C2
RSN	YMP-92-11	Mar. 9 - 13	F. J. Kratzinger	C1
OCRWM-HQ	HQ-92-09	Mar. 9 - 13	R. Brown	C1
LANL	YMP-92-12	Mar. 23 - 27	S. R. Dana	C2
EM	HQ-92-10	Mar. 23 - 27	L. Wade	C3
USGS	YMP-92-13	Apr. 6 - 10	C. C. Warren	C2
PNL	HQ-92-11	Apr. 6 - 10	W. Marchand	C1
KOH	HQ-92-12	Apr. 14 - 17	J. George	C1, C2, C3
LLNL	YMP-92-14	Apr. 20 - 24	R. L Weeks	C2

## KEY

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## OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AND

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE  
FY-92 AUDIT SCHEDULE REVISION 0

<u>ORGANIZATION</u>	<u>AUDIT NUMBER</u>	<u>DATE OF AIDIT</u>	<u>AUDIT TEAM LEADER</u>	<u>CRITERIA</u>
M&O (Charlotte)	HQ-92-13	Apr. 27 - May 1	N. Frank	C1
YMPO	YMP-92-15	May 4 - 8	R. E. Powe	C1
M&O (Las Vegas)	HQ-92-14	May 4 - 8	L. Wade	C1
M&O (Fairfax)	HQ-92-15	May 11 - 15	R. Brown	C1
SAIC	YMP-92-16	May 18 - 22	R. L. Maudlin	C2
REECO	YMP-92-17	June 8 - 12	A. I. Arceo	C1
RSN	YMP-92-18	June 22 - 26	N. D. Cox	C3
ORNL	HQ-92-16	June 22 - 26	W. Marchand	C3
LANL	YMP-92-19	July 13 - 17	J. S. Martin	C1
EM	HQ-92-17	July 20 - 24	R. Schaffer	C1
USGS	YMP-92-20	July 27 - 31	K. T. McFall	C3
LLNL	YMP-92-21	Aug. 10 - 14	R. L. Maudlin	C3

## KEY

C1 = 1, 2, 11, 15, 16, and 18  
C2 = 3, 5, 6, 17, 19, and 20  
C3 = 4, 7, 8, 9, 10, 12, 13, and 14

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**  
**AND**  
**YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE**  
**FY-92 AUDIT SCHEDULE REVISION 0**

<u>ORGANIZATION</u>	<u>AUDIT NUMBER</u>	<u>DATE OF AUDIT</u>	<u>AUDIT TEAM LEADER</u>	<u>CRITERIA</u>
PNL	HQ-92-18	Aug. 17 - 21	N. Frank	C3
SNL	YMP-92-22	Aug. 24 - 28	F. J. Kratzinger	C2
OCRWM-HQ	HQ-92-19	Aug. 24 - 28	R. Brown	C2
M&O (Fairfax)	HQ-92-20	Aug. 31 - Sept. 4	T. Rodgers	C3
SAIC	YMP-92-23	Sept. 14 - 18	C. C. Warren	C1
M&O (Las Vegas)	HQ-92-21	Sept. 14 - 18	J. George	C3
M&O (Charlotte)	HQ-92-22	Sept. 21 - 25	W. Marchand	C3
YMFO	YMP-92-24	Sept. 28 - Oct. 2	S. R. Dana	C2
PNL - MCC	Delayed Until Further Notice (1)			
EG&G	To Be Determined (1)			

**KEY**

C1 = 1, 2, 11, 15, 16, and 18

C2 = 3, 5, 6, 17, 19, and 20

C3 = 4, 7, 8, 9, 10, 12, 13, and 14

(1) Equivalent to Qualification Survey

Jane Blyford  
 Approval: Director, OQA

8/9/91  
 Date:

QA Management Assessment and OCRWM Office Assignment

<u>OCRWM Office</u>	<u>Recommendation Number</u>
RW-3	1, 2, 3, 6, 13, 17, 19, 23, 24, 26, 27, 31, 32, 34, 36, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62.
RW-4	5, 24, 32, 46, 58, 61.
RW-5	5, 24, 32, 46, 58, 61.
RW-10	4, 5, 7, 8, 16, 23, 24, 32, 39, 44, 46, 52, 58.
RW-20	5, 9, 10, 11, 12, 13, 14, 15, 18, 20, 21, 22, 23, 24, 25, 32, 46, 58.
RW-30	5, 24, 26, 27, 32, 46, 52, 58.
RW-40	5, 24, 28, 29, 30, 31, 32, 33, 34, 35, 46, 58.
RW-50	5, 19, 24, 32, 37, 38, 40, 46, 58.

**U. S. DEPARTMENT OF ENERGY**

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

**QA MANAGEMENT ASSESSMENT**

**FINAL REPORT**

**July 12, 1991**

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## EXECUTIVE SUMMARY

The purpose of the 1991 Quality Assurance (QA) Management Assessment by the Office of Civilian Radioactive Waste Management (OCRWM) was to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the OCRWM QA program. The assessment was based on the requirements of the Quality Assurance Administrative Procedure (QAAP) 2.7, "Management Assessment", and it covered all parts of the OCRWM organization, including both headquarters and field components. The activities evaluated by the assessment were those which took place from February 1990, through May 1991.

The nine-person assessment team had representation from all OCRWM offices except the Office of Quality Assurance (OQA), because QAAP 2.7 specifies that assessment team membership is to be independent of the OQA and of the activities to be assessed. The assessment team was aided by representatives of the TRW M&O contractor, the Weston support service contractor, and an external advisor with nuclear utility QA experience. The team was organized into eight groups with generally three to five members. Seven of the groups were assigned the responsibility of evaluating the QA programs of the line or staff offices of OCRWM. The eighth group carried out an overall evaluation of management involvement in the correction of QA deficiencies.

The methods for performing the assessment included the review of pertinent documents, individual interviews of managers and staff members, the observation of on-going activities, and group meetings with managers and staff.

The assessment did not uncover a significant number of deficiencies that had not already been identified. Furthermore, in most cases, the deficiencies that were identified were in the process of correction. In general, OCRWM staff members were aware of the importance of QA in their work and were conscientiously working to meet QA requirements. To aid in this expanded use, procedures are being simplified and made more "user-friendly".

Because most QA deficiencies had been identified and were in the process of correction, essentially all of the recommendations growing out of the assessment were for ways to strengthen the QA program, rather than to correct newly-found deficiencies.

Favorable trends were identified, indicating a gradual improvement in the OCRWM QA program. During the sixteen months evaluated, the time for definitions of and response to Corrective Action Requests (CAR's) has significantly shortened, showing an increase in management and staff attention to QA issues. One factor which has helped to stimulate this attention has been the bi-weekly review of the status of QA CAR's as part of the Operations Management Tracking System administered by the OCRWM Deputy Director.

The assessment team found that, by and large, CAR's had been prepared in the past by OQA rather than the OCRWM operating organizations. It was recommended that line management become more involved in QA verification activities and help eliminate any concern that a stigma is associated with drawing attention to QA deficiencies in one's own organization. Other efforts may also need to be made to involve the operating parts of OCRWM in the preparation of CAR's.

Another recommendation was to strengthen the QA training program in OCRWM. It was suggested that, (1) where appropriate, classroom training be used as a replacement for some reading assignments, (2) the training increasingly utilize a workshop format, including the application of QA principles to actual work situations, (3) a computerized Indoctrination and Training (I&T) record system be used to automate the identification of training needs as QA processes or work assignments change, and (4) to the extent possible, "just-in-time" training be stressed to help insure that QA training is available immediately before its planned application. It is recognized that the Program is currently working toward this goal. The OCRWM QA training program is currently undergoing significant enhancement.

As the level of activity expands within OCRWM, the application of QA to future work will increase. More frequent QA internal audits and surveillances will be needed and are planned. Future annual QA management assessments conducted by OCRWM will be part of an expanded self-assessment program throughout the Department of Energy. There should be an effort to apply the lessons learned from this assessment to that broader program.

# **OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

## **QA MANAGEMENT ASSESSMENT FINAL REPORT**

### **1.0 INTRODUCTION**

The Director of the Office of Civilian Radioactive Waste Management (OCRWM) Program is responsible for conducting, or having conducted an independent management assessment of the OCRWM QA Program. The assessment is to be performed at least on an annual basis and is to verify the adequacy and effectiveness of the implementation of the QA Program throughout the OCRWM organization

On March 22, 1991, Dr. John Bartlett authorized the performance of such an assessment, including arrangements for its staffing, and specified that the assessment be completed before the end of June 1991. He specifically asked that major project activities subject to the provisions in the QA Requirements and the QA Program Description documents be covered by the assessment. The Director further requested that the assessment team identify opportunities for simplifying Quality Assurance procedures without compromising their basic intent.

This report describes the results of the QA Management Assessment performed during the period April through June 1991, in response to the Director's requests.

### **1.1 PURPOSE**

The purpose of this management assessment was to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the OCRWM QA program.

## **1.2 SCOPE**

**The scope of this management assessment (1) covered all Federal OCRWM organization components (See Figure 1) involved in QA- affected activities (ie. activities governed by the QA program), including DOE surveillances and audits of direct support contractors (those which use OCRWM QA procedures) and (2) involved an evaluation of the completeness and effectiveness of the QA requirements and procedures comprising the QA Program. In addition, any observed instances where QA procedures and controls were found to be inappropriate or inadequately described were noted and proposed changes were recommended.**

**The assessment covered OCRWM activities during the period of time between February 1990, and June 1991. However, earlier activities were also examined as needed.**

# OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

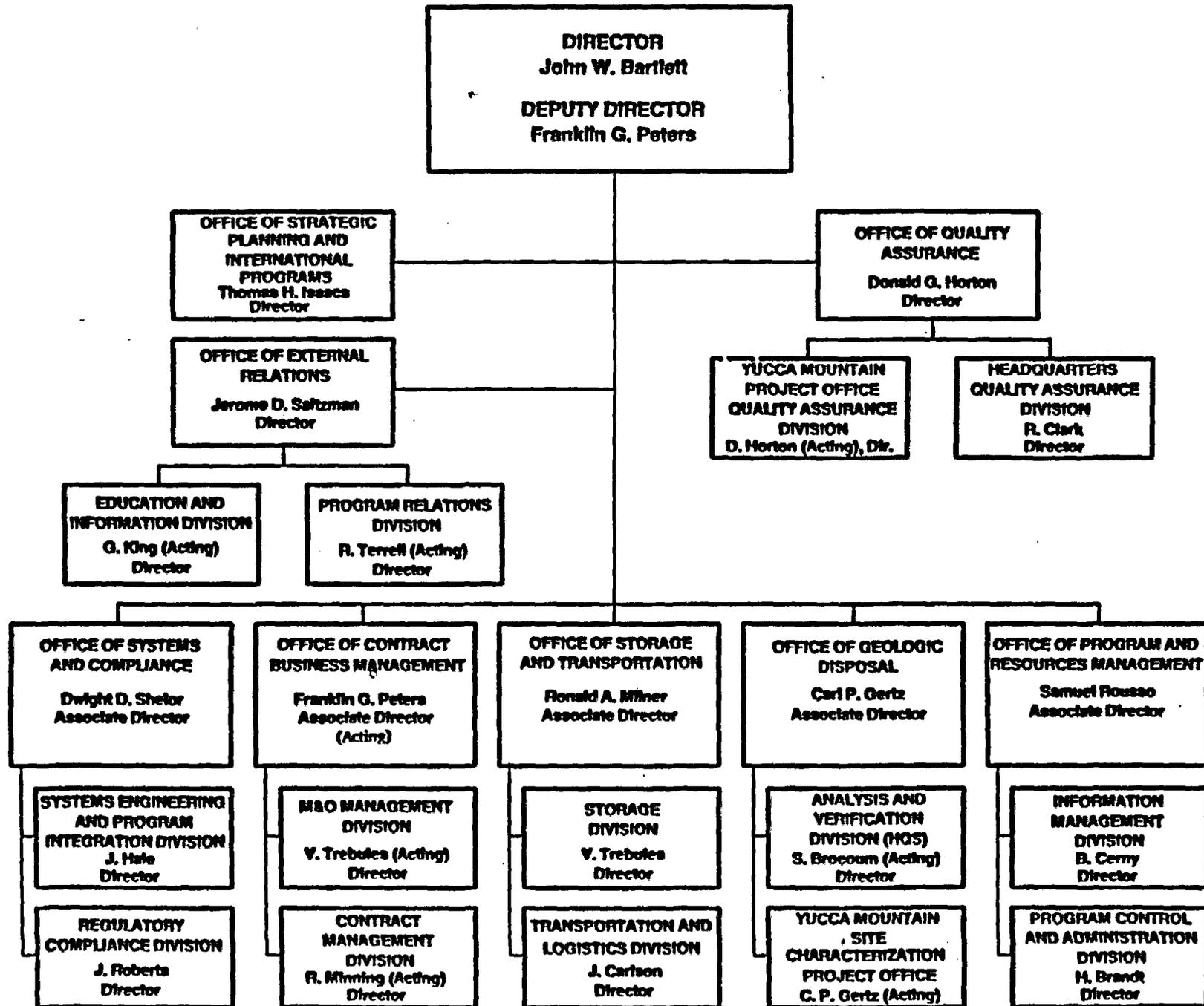


Figure 1

## **2.0 METHODS FOR PERFORMING ASSESSMENT**

The following methods were used, as appropriate, in performing this assessment:

- **Reviews of the Quality Assurance Controls Documents (QACD) for selected OCRWM activities to determine the completeness of their coverage and the specific operations requiring QA controls.**
- **Interviews of selected program managers and staff to assess the effectiveness of implementation of the QA programs.**
- **Observation of ongoing activities to determine: (1) if required QA procedures and controls are being used and (2) the effectiveness with which the desired results are being obtained using the prescribed procedures and controls.**
- **Group meetings with managers and/or staff to attempt to determine the extent to which QA is a part of their normal way of carrying out their program activities and identify ways in which QA procedures can be made more effective and efficient.**
- **Review of audits, surveillances, Deficiency Reports, Corrective Action Reports, and follow-up reports to evaluate the impact of the QA on the quality of OCRWM program results.**

The assessment focussed primarily on determining the following:

- **Effectiveness of procedures and controls for meeting QA requirements.**
- **Extent, adequacy, and effectiveness of QA training.**
- **Effectiveness of audit and surveillance efforts.**
- **Timeliness and effectiveness of corrective actions.**
- **Management and staff understanding of objectives and benefits of the QA program.**
- **Management and staff acceptance of QA procedures and controls as a normal part of their daily activities.**
- **Adequacy of resources available for the development, maintenance, and**

**implementation of QA.**

- **Availability of means for making timely changes, as needed, to QA procedures and controls so as to meet more effectively applicable QA requirements.**

### **3.0 PERFORMANCE INDICATORS**

Performance indicators were used during this assessment to more specifically: (1) gauge the effectiveness of past and present QA activities, (2) determine the extent of management involvement, and (3) establish a baseline by which future trends may be evaluated. Although still rather subjective in nature, these indicators aided in measuring the extent to which QA procedures are being used regularly in those OCRWM activities governed by the QA program. They were also useful in evaluating the overall contribution of QA in achieving the program's goals and intended results.

Examples of indicators that were used in the assessment are:

- Statistical data from audits and surveillances on frequency and source of deficiencies.
- Response time for program offices to carry out corrective actions.
- A measure of the way the end results meet intended program needs.
- An evaluation of communication effectiveness with regard to the expectations of managers and the understanding of the staff.

## 4.0 ASSESSMENT TEAM MEMBERS AND ORGANIZATION

The Director of OCRWM appointed J.C. Bresee the assessment team leader. Team membership and team support staff are listed below.

### TEAM MEMBERSHIP

#### OCRWM STAFF

Jim Bresee, RW-10, Team Leader  
Robert Barton, RW-20  
Charles Brooks, RW-30  
Carl Conner, RW-10  
Glenn Gardner, RW-5  
Jay Jones, RW-40  
Susan Jones, RW-20  
Richard Minning, RW-50  
Nona Shepard, RW-4

#### SUPPORT STAFF

Jim Brackett, Duke  
Fielden Dickerson, TRW  
Vick Dixon, Duke  
Bill Farmer, Duke  
Stan Goldsmith, Weston  
Bill Leonard, Fluor  
Walter Matyskiela, TRW  
E.Y. Wong, TRW

John Miller, TRW  
Dan Rains, Duke  
Brian Sealy, Duke  
Leo Seeber, TRW  
Ed Taylor, TRW  
James Wells, Duke  
Mark Wilkenshoff, Duke

#### External Advisor

Tom Colandrea, Colandrea & Assoc., Inc.

During the initial formation of the assessment team and the preparation of an assessment plan, both Robert Clark and Donald Horton of the OCRWM Office of Quality Assurance (OQA) offered valuable advice on the assessment process and the background reading requirements for the team. Thereafter, OQA, which was itself subject to assessment, played no role in the selection of assessment scope or the evaluation of assessment results.

The team was divided into eight groups. A group assessed each of the major OCRWM organizational components (i.e., components whose managers report directly to the OCRWM Director). In addition, one group made an overall assessment of management involvement in tracking and follow-up activities associated with QA deficiencies. In the case of each team member assignment, care was taken to assure that the team member was independent of any direct responsibility for the performance of the activities which he/she assessed. The group assignments and the members of each group are listed in Appendix A.

As part of the assessment record, each team member documented his/her observations derived from document reviews, interviews, and meetings. Objective evidence that supports observations was also documented.

**Each team member discussed his/her observations with the team to ensure consistency in evaluations and to identify findings that may be widespread throughout OCRWM. Observations and objective evidence were reviewed collectively by the team to arrive at the final results contained in this report.**

## **5.0 DOCUMENTS REVIEWED**

**Reading assignments that were mandatory to prepare and qualify team members are listed in Appendix B.**

**The assessment included critically reviewing documents which describe the OCRWM QA program as well as the results of surveillances and audits of the OCRWM program activities subject to QA requirements and controls. Reviews were made not only of the audits and surveillances of Federal programs participants but also of the direct support contractors who use the OCRWM QA procedures. Appendix C contains a list of these documents. Team members reviewed those documents that were pertinent to their assessment assignments.**

## **6.0 ASSESSMENT RESULTS**

This section begins with a summary of observations and recommendations which were common to several or all organizational units and then continues with those specific to the eight assessment groups: RW-10 through RW-50, RW-3, RW-4/5, and the Director's Office.

### **6.1 GENERIC ASSESSMENT ISSUES.**

#### **6.1.1 GENERAL OBSERVATIONS.**

The 1991 QA Management Assessment was scheduled during a period of flux in the development of quality management programs in the Department of Energy. On February 25, 1991, draft DOE Order 5700.6C, entitled "Quality Assurance", was issued for comments. It explicitly excludes from its terms activities licensed by the U.S. Nuclear Regulatory Commission and subject to the QA requirements of that agency, so OCRWM is not subject to its provisions. Aside from an issue of format, the most significant feature of the draft order is that it includes a number of non-nuclear Total Quality Management (TQM) features.

Thus the term "Quality Assurance" is being proposed in DOE for an expanded definition to cover areas normally within the term "Total Quality Management" or TQM. It was of course necessary for the QA Management Assessment team to use the NQA-1 definition of QA under the terms of QAAP 2.7. However, it is also clear that "quality" has been and will be applied to many management activities outside NQA-1 in DOE and within OCRWM itself. For example, Yucca Mountain Project Office (YMPO) has begun, with the help of the Federal Quality Institute, a pilot TQM program, and the Management System Improvement Strategy (MSIS) calls for the eventual institution of TQM throughout OCRWM.

- [1] Because of these expanded quality activities, existing and proposed, the assessment team recommends that the term "quality-affecting", which appears throughout the QA literature, be replaced for use within OCRWM with one clearly indicating the applicability of NQA-1. We suggest the terms "QA-affecting" or "QA-affected" and have used such throughout this report.

There were expressions of concern throughout the assessment interviews about the status of the QA training program. Some felt that classroom training was preferable to reading assignments. However, some classroom training in the past has suffered from what was perceived as inexperienced instructors and the

lack of understanding of the OCRWM program. Workshops in which a group "role-plays" to gain experience in applying of QA principles were rated highly.

- [2] We recommend that QA training be improved by increased "training-to-train" of the instructors and by the expanded use of the workshop format. We recommend further that consideration be given to some means of evaluating the effectiveness of the training.

The I&T matrices were also the source of concern in several instances, for two reasons. First, information has been collected in several different ways: on a single sheet or consecutive sheets periodically updated or on a mixture of old and new sheets, with new entries for revisions to documents read or training received. Second, with revisions to some QA materials now being effected at the individual paragraph level, it has become increasingly difficult to identify staff members who require updated reading or training. These concerns could be answered by the use of computers.

- [3] We recommend that I&T matrices be entered into a computerized data-base, which would allow automated identification of those requiring update reading or training. Work is underway to establish computerized I&T matrices for QA documents.

Corrective Action Requests are written in accordance with QAAP 16.1 to document discrepancies. The procedure gives all OCRWM and direct support personnel the responsibility to write CAR's. From this, one would expect CAR's to be generated from personnel in all OCRWM offices. However, a common observation is that almost all CAR's are written by QA personnel. Recommendations relating to this are addressed later in the report.

Finally, one of the most common problems identified during the assessment was the potential adverse impact of unfilled openings in many key QA-affected positions. Much of the problem can be traced to the lack of adequate staff resources assigned to OCRWM personnel issues in the recent past by the DOE Office of Personnel. Some progress has been made in this area.

- [4] We recommend that continued emphasis be placed on the problem of unfilled openings by the OCRWM senior management in order to maintain sufficient priority in the DOE personnel system.

## **6.1.2 ANALYSIS OF MANAGEMENT RESPONSE TO DEFICIENCY REPORTS (DR'S) AND CORRECTIVE ACTION REQUESTS (CAR'S).**

### **6.1.2.1 Introduction and Scope.**

The objective of this analysis was to evaluate OCRWM Management's involvement in CAR/DR follow-up actions. Group members performing the study were Nona Shepard (RW-4), Stan Goldsmith (Weston), and Brian Sealy (Duke). The assessment group collected the following data from records of the preparation and disposition of DR's/CAR's:

Issue Date  
Response Date  
Closing Date  
Severity Level  
Responsible Group

These data were then analyzed with respect to three categories of information: (1) severity levels, (2) time required to get an approved response, and (3) time required to close the DR/CAR. Definitions of these categories follow:

Severity Levels: When a CAR is written, it is evaluated for significance and a severity level is assigned (level #1 being the most significant, level #3 the least). DR's were not assigned severity levels.

Approval time: An approved response is considered obtained when the responsible group and OQA reach agreement on the actions required to resolve the discrepancy.

Close-out time: A DR or CAR is considered closed when all corrective actions have been completed and verified.

The group analyzed the data from HQ and YMPO separately and combined: separately because the nature of the work done at each location is different and has its own characteristics; and combined in order to ascertain if management's involvement in QA at the two locations was different and might account for different results.

### **6.1.2.2. Analyses of Headquarters DR's/CAR's.**

HQ wrote 18 DR's and 20 CAR's from February 1990, through April 1991.

DR's were discontinued in October 1990, and CAR's have been written since then. Figures 2 through 4 depict the analyses of these DR's/CAR's.

**Severity Levels.** Figure 2 illustrates the distribution of the severity levels assigned to the CAR's at HQ. There is a fairly equal distribution between level 1 and level 2 deficiencies (40% and 35% respectively). Because the assessment group focussed primarily on response time, no further analysis of Headquarters severity levels was made.

**Approval Time.** Figure 3 illustrates the time required to get an approved response to HQ DR's and CAR's. The average time required to get a response to the HQ DR's has been 79 days. The average time required to get a CAR response was 51 days. While an improvement compared to DR's, 51 days is still considered too long to come to agreement on the resolution to a QA deficiency. However, OQA has pointed out that the 51-day period is an average that does not necessarily represent the typical time period and that further, some initial responses to CAR's were rejected and revised, which could account for this high number.

**Close-out Time.** Figure 4 illustrates the time required to close HQ DR's/CAR's. Bearing in mind that DR's were written prior to October 1990 and CAR's were written after that time, this graph shows that significant improvements have been made in the last 6 months regarding the time required to complete the corrective action on deficiencies. The average time that DR's remained open was 289 days and CAR's have been closed in an average of 68 days.

Distribution of Severity Level  
1991 CAR's - HQ

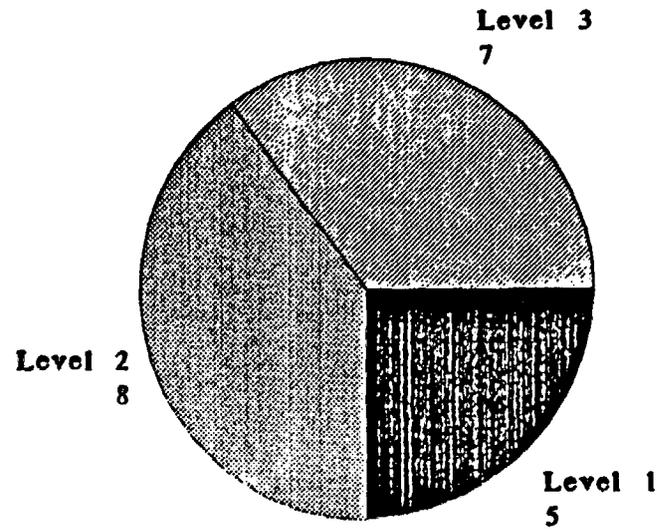


Figure 2

### Time to Approved Response HQ

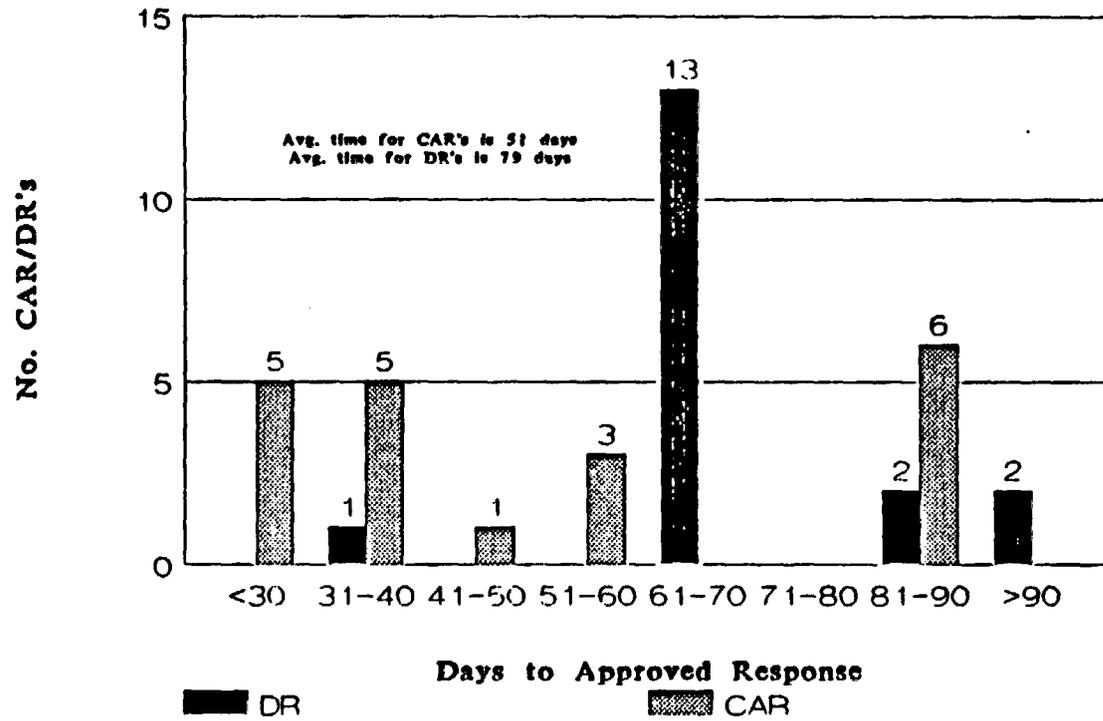


Figure 3

### Time to Close CAR/DR's - HQ

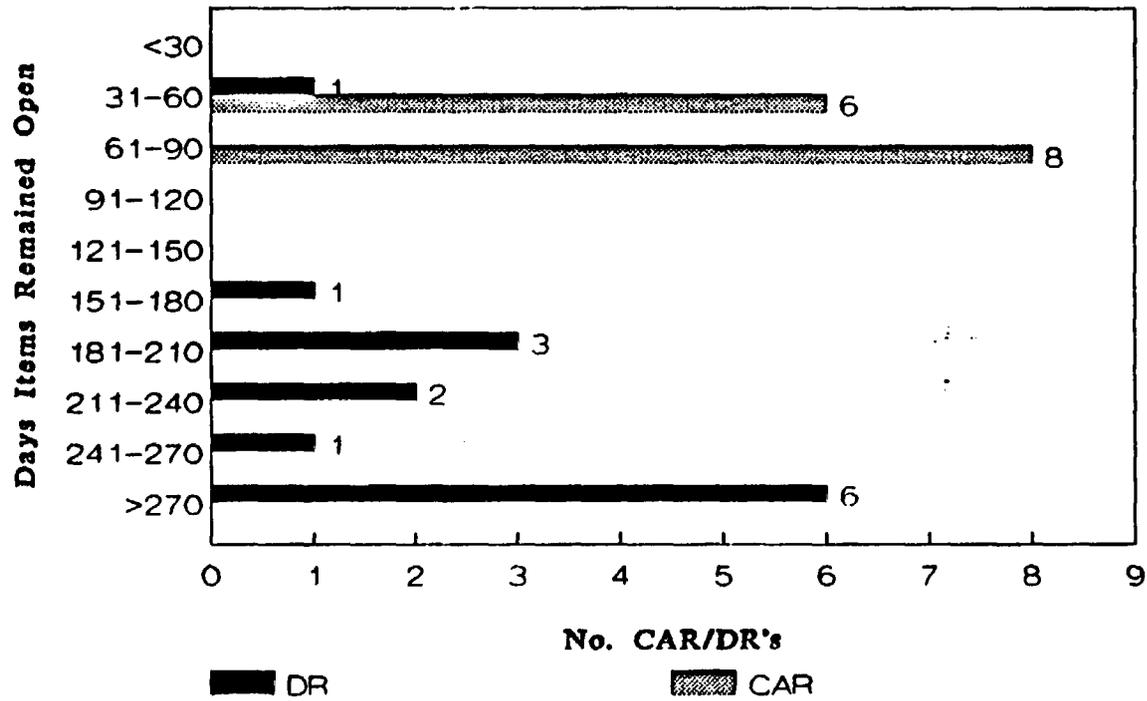


Figure 4

### **6.1.2.3 Analyses of Yucca Mountain Project CAR's/DR's.**

YMPO wrote 105 DR's and 41 CAR's from February 1990 through April 1991. Figures 5 through 8 depict the analyses of these DR's/CARs.

Severity Levels. Figure 5 shows severity level distribution. Two per cent of the CAR's were evaluated to be at severity level #1, 86 percent were evaluated to be at level #2, and 12 percent were at severity level #3. Because the assessment group primarily focussed on response time, no further analysis of the severity level distributions was made.

Approval Time. Figure 6 illustrates the time required to get an approved response to YMPO DR's/CAR's. The average time required to get an approved response for DR's was 90 days and for CAR's, 44 days. Again, because DR's reflected the time frame from February 1990, to October 1990, and CAR's were used after October 1990, this is a significant improvement.

Close-out Time. Figure 7 shows the time required to close YMPO DR's/CAR's. Because of the number of CAR's that remain open (only 15 of 41 CAR's have been closed as of 6/1/91), it is not possible to draw any definitive conclusions from the data at this time. The CAR's that are still open have been open an average of 62 days at the time of this study.

Responsible Groups. Figure 8 illustrates the distribution on how the deficiencies were discovered. We learned through interviews that essentially all of the CAR's were written by OQA personnel. That is, although QAAP 16.1 does not limit CAR generation to the QA organization, other groups generally have not been writing CAR's.

Distribution of Severity Level  
1991 CAR's - YM

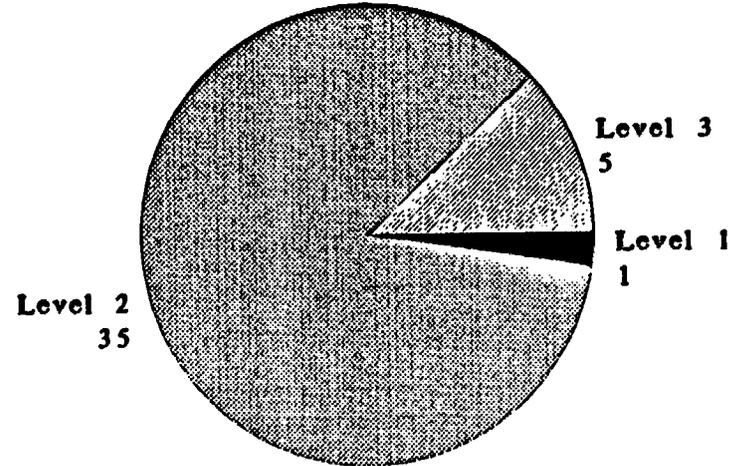


Figure 5

### Time to Approved Response YMP

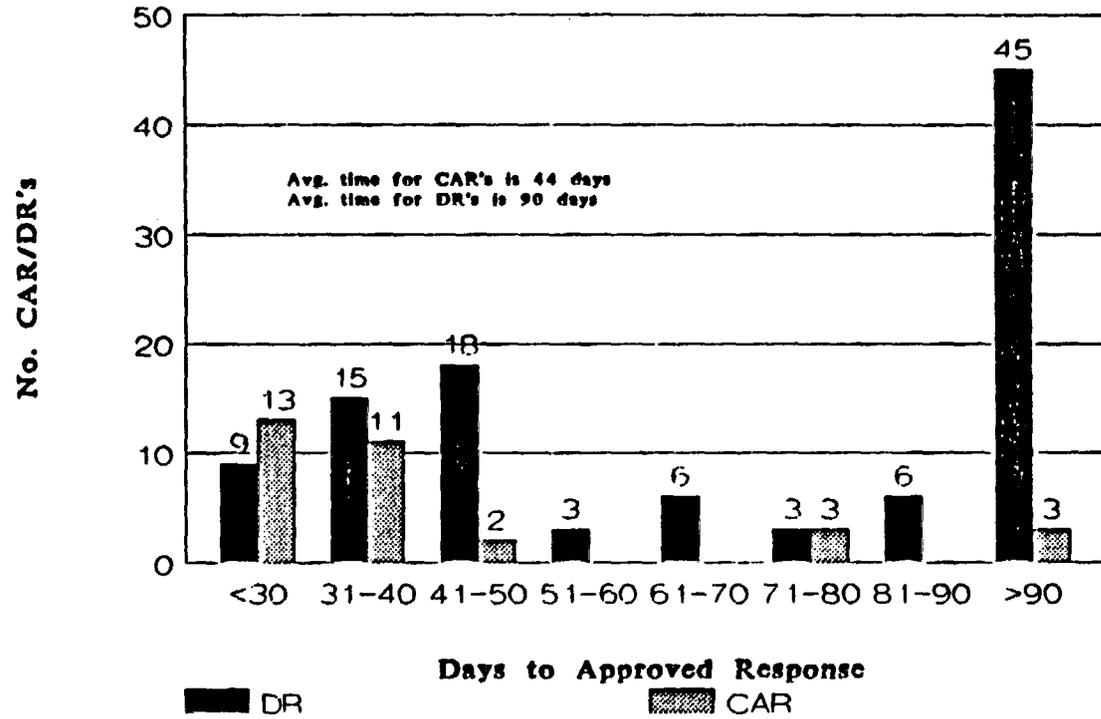


Figure 6

# Time to Close CAR/DR's - YMP

20

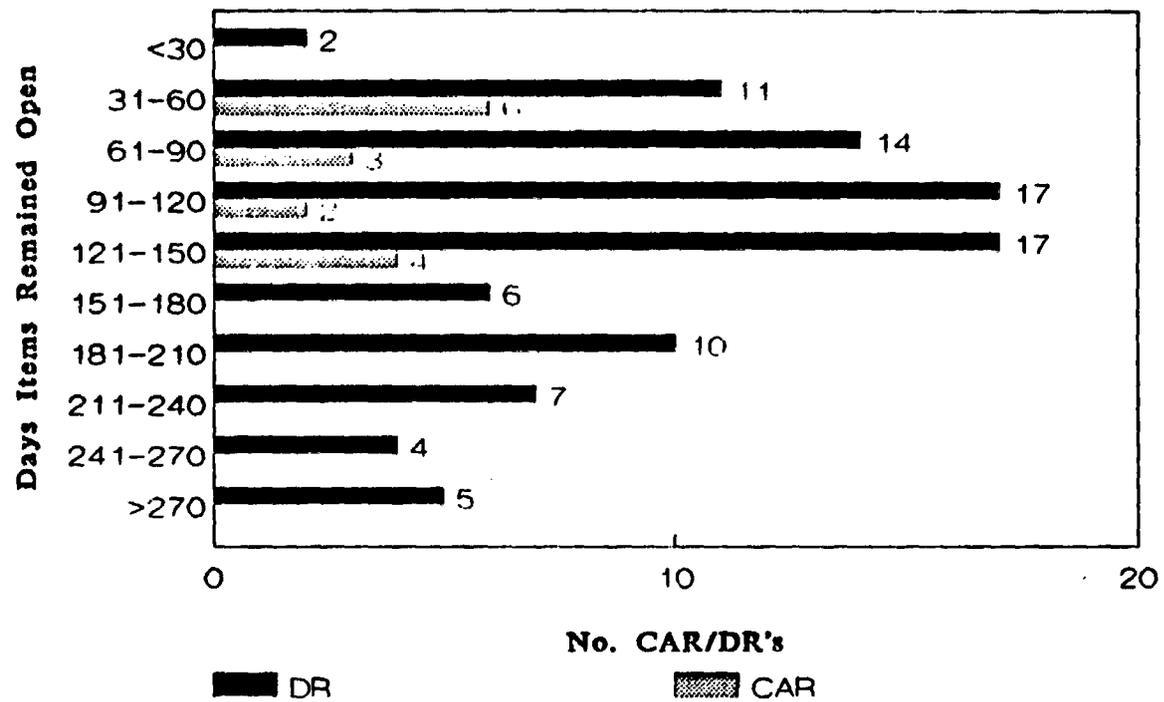
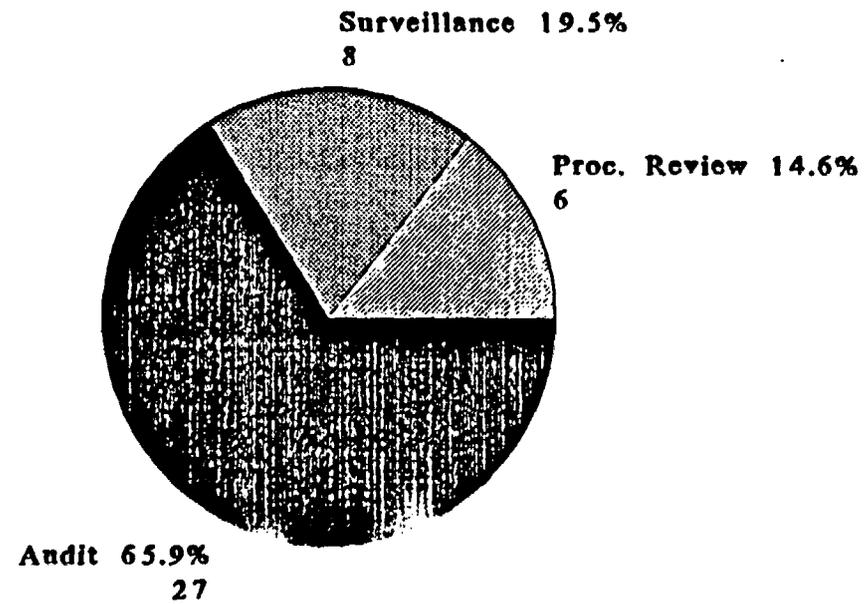


Figure 7

**Problem Discovery  
Distribution of CAR's - YMP**



**Figure 8**

#### **6.1.2.4. Combined Analyses: HQ and Yucca Mountain CAR's/DR's.**

While the two locations (HQ and YMPO) perform different types of work, they work under a common QA program. Figures 9 through 13 compare the results from both locations. The analyses provide some indication of management's involvement in resolving QA discrepancies.

Severity Level and Approval Time. Figure 9 compares the severity level with the average time to get approval of the CAR response. The 145 day average response time at YMPO for level #1 is not indicative of any trends because YMPO had only 1 CAR with a level #1 severity. At both HQ and YMPO, CAR's at level #2 received an adequate response faster than CAR's at level #3. Because level #3 is the least significant, one might guess that such CAR's would require the least amount of approval time. However, it is also probably true that level #3 items, being less significant, received less attention, resulting in longer times before adequate response.

Approval Time. Figure 10 compares the time required to get an approved response for DR's. Even though YMPO had many cases of early approved response, 42 per cent of YMPO's DR's had an approved response time greater than 90 days. At HQ, 89 per cent (all but 2) of the DR's had an approved response by 90 days.

Figure 11 illustrates the time required to get an approved response for CAR's. YMPO shows a significantly better trend. Most of their responses were approved within 40 days. The results at HQ do not show a consistent pattern.

Close-out Time. Figure 12 compares the time required to close DR's. By 150 days, YMPO had closed 58 per cent of their DR's while HQ had closed only 5 per cent. It took 270 days for HQ to close the majority of its DR's.

Figure 13 compares the time required to close CAR's. This graph does not show any significant trends because 33 percent of the CAR's at HQ and 63 percent of the CAR's at YMPO were still open at the time of this study.

### Avg. Time to Approved CAR Response

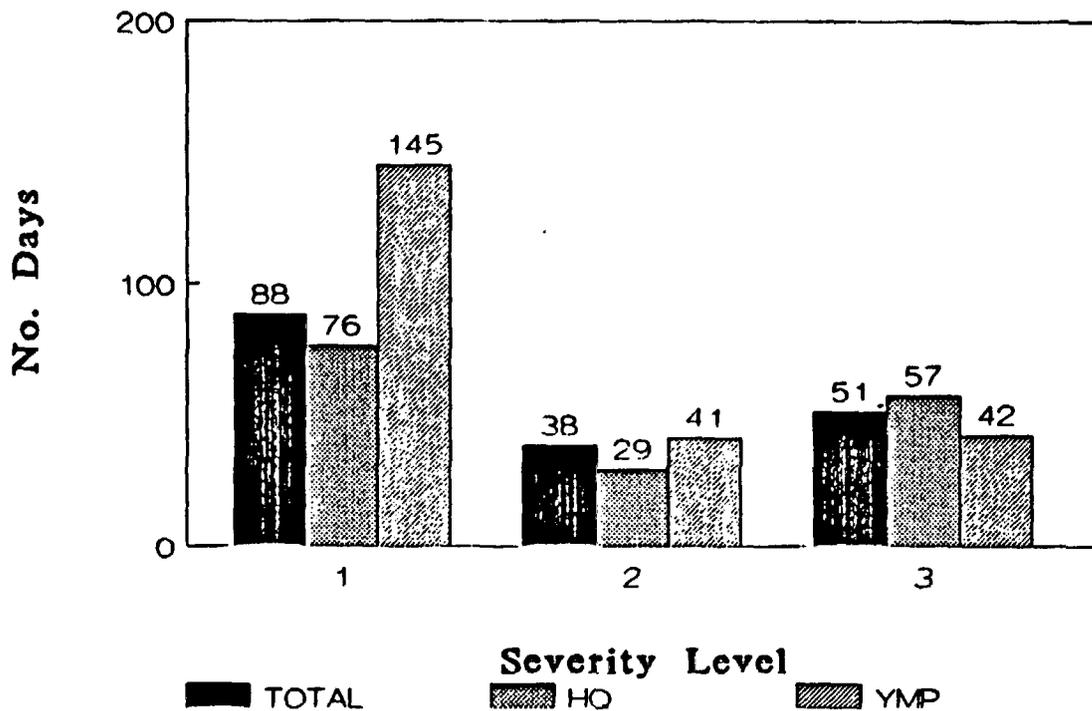


Figure 9

### Time to Approved Response of DR's

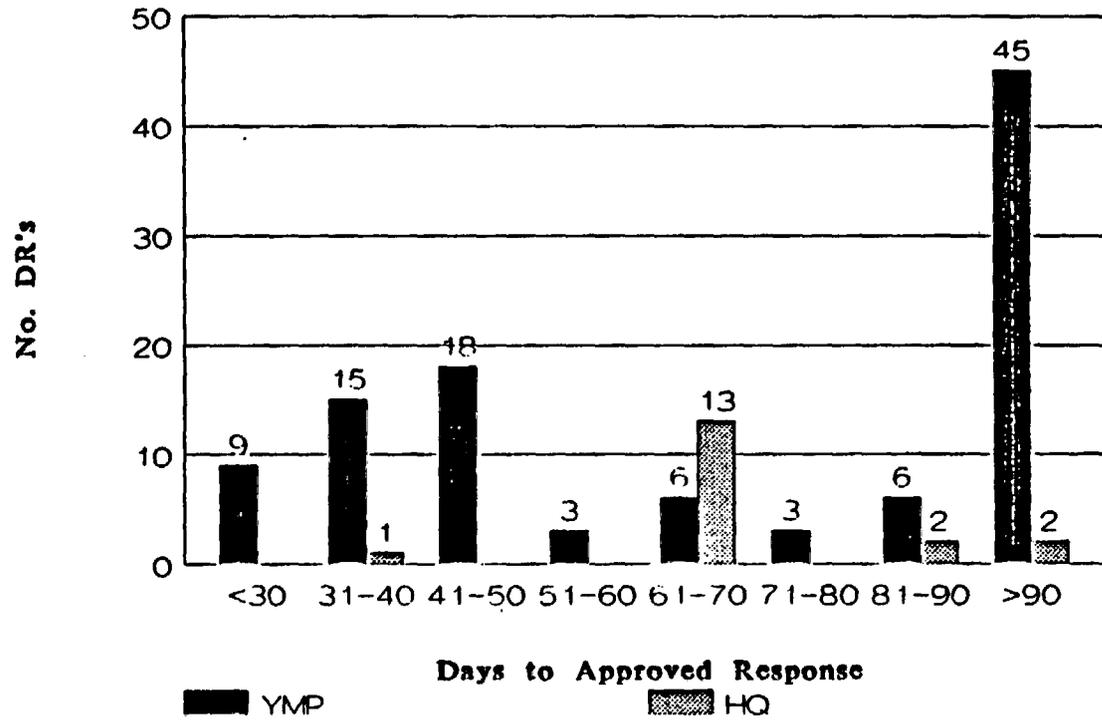


Figure 10

### Time to Approved Response of CAR's

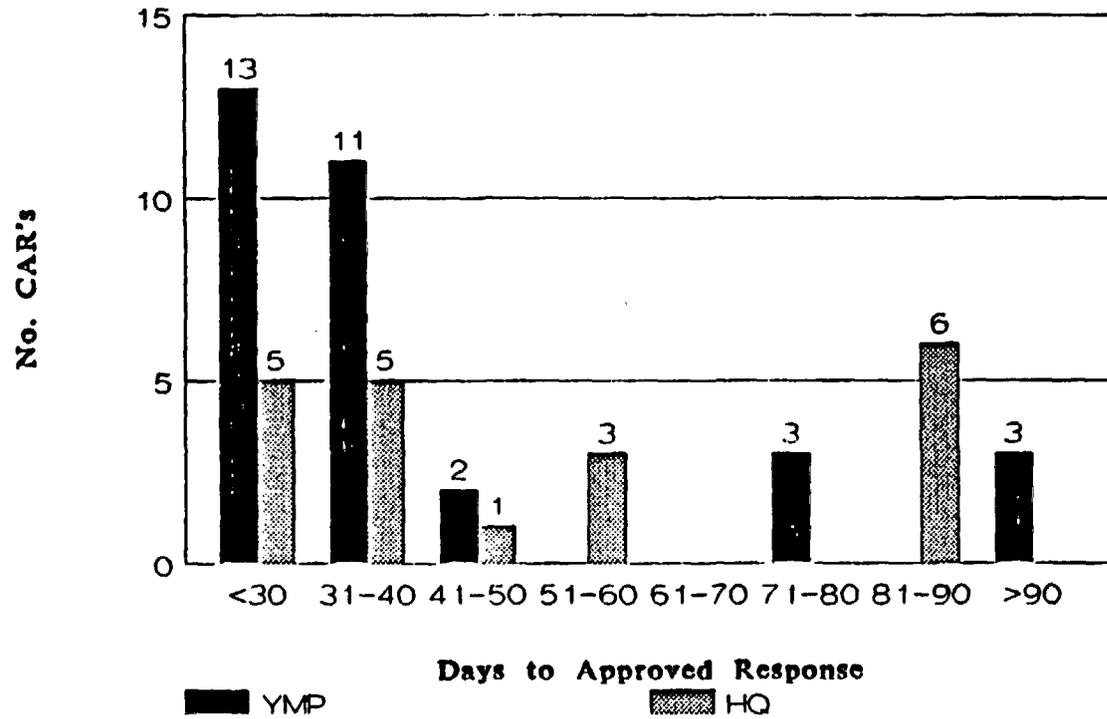


Figure 11

### Time to Close DR's

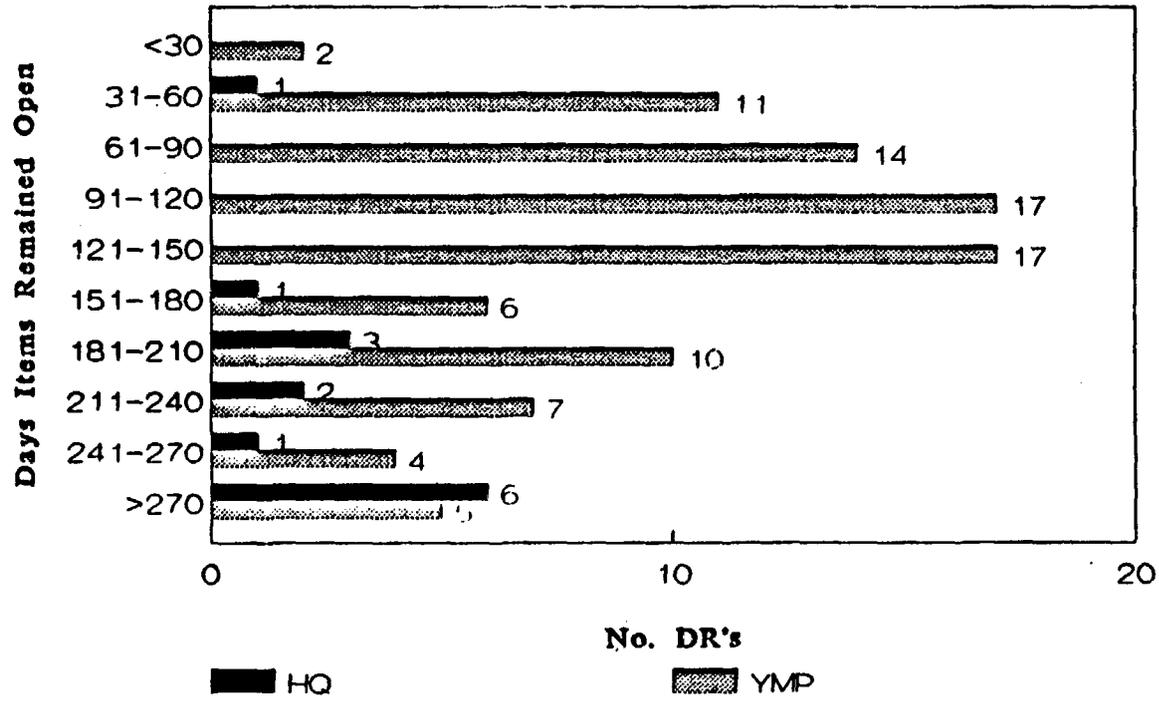


Figure 12

### Time to Close CAR's

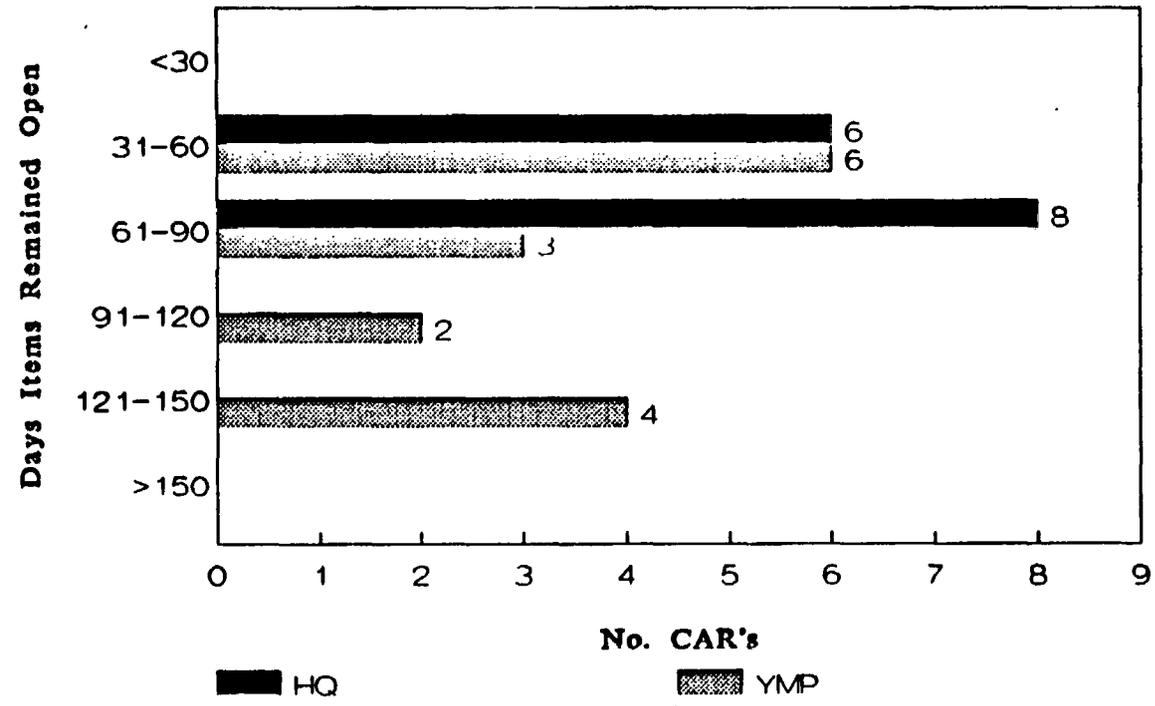


Figure 13

#### **6.1.2.5 Observations and Recommendations**

The databases and tracking systems for DR's and CAR's at both HQ and YMPO were found to be thorough and appropriate for analysis and trending purposes. This result would support the quarterly status and trending reports called for in QAAP 2.9. The HQ Operations Management Tracking System is a valuable management tool for monitoring progress on CAR's and DR's.

There have been significant improvements over the past 6 months in the time taken to respond to and correct QA deficiencies. This is due in part to OCRWM staff responding in a timely manner and also to the bi-weekly status review by RW-2 which has increased awareness of required QA actions.

Virtually all of the CAR's generated to date within OCRWM have been written by QA personnel. This is not unusual since the QA organization has had the most opportunities to identify deficiencies through audits and surveillances it performed. However, in order to provide added confidence that all deficiencies will be identified and properly documented in the future, it is suggested that the provisions of QAAP 16.1 be reiterated to all OCRWM personnel. In particular, it should be emphasized that the QA organization is not the only group charged with writing CAR's. Instead, all OCRWM personnel have the duty and responsibility to report any deficiency they identify.

- [5] We recommend that a careful evaluation of this problem be carried out with the aim of stimulating line management involvement in verification of QA activities and issuing CAR's. This would insure that those closest to the work would identify and correct QA-related problems.

There are no specific time frames listed for the various phases of the CAR process. An area of particular concern is the time to document a discrepancy after discovery. A CAR should be written as soon as possible after discovery.

- [6] It is recommended that the time between discovery and writing of CAR's be evaluated for possible corrective action.

## **6.2 ASSESSMENT RESULTS FROM LINE ORGANIZATIONS.**

### **6.2.1 OFFICE OF PROGRAM AND RESOURCES MANAGEMENT (RW-10).**

#### **6.2.1.1 Introduction and Scope.**

The Office of Program and Resources Management (OPRM) consists of two divisions: the Information Management Division (RW-12), and the Program Control and Administration Division (RW-13). RW-13 has a substructure of three branches, of which one, the Management Services Branch, is responsible for overseeing verification of qualifications of OCRWM employees for QA purposes, among other responsibilities. RW-12 has overall responsibility for the development and management of OCRWM information systems, and the management of OCRWM headquarters' Quality Records Center (QRC) and Central Records Facility (CRF), which are both contractor-operated facilities.

Interviews were conducted with the Associate Director for Program and Resources Management; the Director, Information Management Division; the Director, Program Control and Administration Division; the Chief, Management Services Branch; and the management and staff of the QRC.

Assessment group members: Rich Minning (RW-50), Stan Goldsmith (Weston), and Jim Brackett (Duke).

#### **6.2.1.2 Observations and Recommendations.**

Written descriptions of the functions of each component organization within OPRM are contained within mission and function statements approved in November 1990, and were clearly understood by the interviewees. Position descriptions reflecting the current organization have been developed, and are being reviewed and processed by the DOE Office of Personnel.

Sections 19 of the QAR and QAPD govern requirements for computer software QA control. Specifically, Section 19 of the QAR establishes detailed criteria for a Computer Software Quality Assurance Plan (SQAP) for "each computer software development or application effort" at the beginning of the effort, and for the establishment of a computer software configuration management system to "assure positive identification of computer software and control of computer software baselines and changes." While RW-12 is responsible for oversight and management of program-wide management information systems, scientific and technical computer software controls are assumed to be the responsibility of project and project contractor organizations (typically DOE National

Laboratories) assigned to the work being supported by the technical/scientific software.

OPRM is involved in the implementation of one QA-affecting function relating to Section 2 of the QAPD: verification of personnel qualifications. The procedure applicable to this function, QAAP 2.2, "Verification of Personnel Qualifications", is being revised. Interviewees expressed doubt as to whether the functions performed by RW-13 in connection with verification of personnel qualifications were truly QA-affecting, despite the classification as such by the QACD. The functions performed consist of liaison activities between the OCRWM manager/supervisor, who performs the verification and DOE's Office of Personnel, which attests that the prospective employee meets minimum education and experience requirements for the position as established by the Federal Government's Office of Personnel Management.

The current revision of QAAP 2.2 permits the supervisor to substitute a statement and justification for an employee where education and experience cannot be verified; Section 2 of the QAPD does not speak to this alternative method. Record-keeping restrictions stemming from Privacy Act provisions have been resolved, with the approval of the DOE System 80 system of records for QA-required personnel records. DOE System 80 now permits these records to be confidentially maintained. While the effective date of this system was October 8, 1990, QAAP 2.2 has not been revised, although a draft revision which does reflect the new record-keeping process has been circulated for comment.

- [7] We recommend that comments and issues regarding the draft revision of QAAP 2.2 be resolved on an expedited basis to permit appropriate confidential protection and management of the records associated with personnel verification.
- [8] In addition, Section 2.8 of the QARD needs to be revised to permit the alternate certification, with justification, of employee education and experience by supervisors when direct verification through school and employer contact cannot be made.

OCRWM headquarters' quality assurance records are governed by QAAP 17.1, QA Records Management, which is in the process of revision. OCRWM has established a Quality Records Center (QRC), under the general management of RW-12, to process and store quality record packages. The QRC operates under Implementing Line Procedure 12.17.01. Dual storage requirements are met through the parallel submission of QA records by the initiator to the QRC, where they are filed by record package and held until the package is complete,

and the CRF, where they are individually microfilmed, with the microfilm sent to off-site underground storage. A two hour fire-rated vault is used by the QRC, and individual QA records are kept in a two hour fire-rated safe in the CRF prior to microfilming.

The interviewees indicated that approximately 10 QA records per week are received by the QRC; any errors or problems with the QA records are handled in person between the QRC staff and the OCRWM initiator. The largest number of QA records packages have been submitted by RW-3. It was noted by the interviewees that QRC staff does not check if the record initiator is forwarding QA records within the required 10 days from authentication. Revisions are currently being made to QAAP 17.1 which will eliminate the 10 day time requirement.

QRC staff appeared fully conversant with their responsibilities, and generally satisfied with their procedures. Any QA problems are discussed in regular staff meetings. No specific comments were received concerning potential improvements in the training they have received.

## **6.2.2 OFFICE OF GEOLOGIC DISPOSAL (RW-20).**

### **6.2.2.1 Introduction.**

This assessment evaluated the scope, status, adequacy, programmatic compliances and implementation of the OCRWM Quality Assurance (QA) program in the Office of Geologic Disposal (OGD). It focused on the sections of the OCRWM Quality Assurance Program Description (QAPD) judged by the assessment team to be most applicable to OGD at this time. Assessment results reflect interviews and document reviews conducted by the Assessment Team in Las Vegas from April 23-30, 1991, and Washington, D.C., May 6-9, 1991.

Assessment group members were Carl Conner (RW-10), Charles Brooks (RW-30), Fielden Dickerson (TRW), John Miller (TRW) and Dan Rains (Duke).

### **6.2.2.2 Organization.**

The functions, responsibilities, and reporting relationships of OGD appear to be, in general, clearly defined and understood. The authorized staffing level is eighty-one, with sixty-three on board at the time of this study. Most of the staff interviewed were aware of their mission and what was expected of them. Some of the staff have been in "acting" positions for a long time. Although they seem

to understand the tasks that they are currently being asked to perform, an extended period of "acting" may hinder their effectiveness in the long term.

- [9] We recommend that the practice of extended periods of "acting" assignments be carefully evaluated for possible adverse impact on Quality Assurance and overall program effectiveness.

The current process of dispute resolution regarding programmatic or technical issues was evaluated. It is somewhat informal, involving successive escalation to higher management levels. However, any QA problems which result from this informality can be addressed under procedures currently being developed under the "Quality Concerns" program, which will provide a formal resolution process for addressing QA concerns.

Stop work order (SWO) authority is now vested in line management when eminent danger to personnel is involved or continued work would produce unacceptable results. The SWO process is documented in procedure QMP-01-02. The procedure does not specifically provide for YMPO staff to directly stop work being performed by the participants; such authority is reserved for Contracting Officers.

- [10] We recommend that the procedures for Stop Work Orders (SWO) be revised to provide that both the YMPO project manager and the YMPO QA division director are authorized, independently if necessary, to request the Contracting Officer to issue a SWO to a participant, when imminent danger or unacceptable work is involved.

#### **6.2.2.3 QA Program.**

Program controls have been established and are effectively being implemented except for the items noted below.

Line managers play a key role in QA by evaluating their subordinates qualifications to perform QA-affecting work. Personnel assigned to perform QA affecting-work have been indoctrinated in the QA aspects of their job. Training of personnel at YMPO in the past year has significantly improved with the development of a structured systematic approach. The development of task qualification requirements will enhance the training of personnel performing quality related work. This will define specific training for a task which should facilitate training "just-in-time" for the work activity.

Surveillances of QA-affecting activities are being performed by personnel knowledgeable of the work and are following written procedures or checklists

with the results being documented. Any deficiencies noted are reported to the organization for resolution and correction. The deficiencies are tracked and corrective action implementation is verified.

It was observed that additional personnel with nuclear licensing experience in a regulated environment would be helpful in implementing the OCRWM program. While the technical experience of Project personnel is high, the program would benefit from more experience in a regulatory (license) environment.

- [11] Although some participants have experience working with the Nuclear Regulatory Commission, we recommend that YMPO consider adding more resources with nuclear regulatory experience to the organization. The staff of the new M&O contractor will provide a significant increase in such resources.

From the interviews, it was noted that some individuals were not fully aware of all aspects of the QA program and did not understand why it kept changing. Additional training on changed QA activities should also focus on communicating the need for the changes and how they will benefit the program.

The nuclear industry over the past twenty-five years has made numerous improvements by learning from mistakes. This knowledge base and application of lessons learned can be utilized by the OCRWM repository project to improve performance. Potential information sources would include the Institute of Nuclear Power Operation (INPO), Nuclear Regulatory Commission (NRC), and Edison Electric Institute (EEI).

- [12] We recommend that YMPO investigate the merits of establishing a group to review nuclear industry publications and extract lessons learned helpful to the Project.

Everyone interviewed was aware of the problems associated with the core samples taken early in the project.

- [13] We recommend that YMPO consider using past problems with the identification and control of core samples as a "case study" to emphasize the importance of quality control requirements. YMPO has begun to develop the case study training material.

#### **6.2.2.4 Design Control.**

The mission of YMPO involves predominately the conduct of scientific investigations. Equipment and facility design are required to conduct or support these studies. YMPO uses similar methods to control scientific investigations

and engineering design.

Engineering design is controlled by the requirements in design plans and requirements documents. These documents are controlled by the Change Control Board under AP-3.3Q. They are distributed as controlled documents under AP-1.5Q.

Facility design and some equipment design is executed by the A/E. The A/E issues an engineering plan, approved by YMPO, and internal procedures, approved by the A/E, to control design. Design verification is performed by the A/E using its procedures; YMPO takes part in the verification. Changes to design documents are subject to change control. Changes are subject to the same review and approval process as the original.

Engineering plans define the types of interfaces to be encountered. Interface control is accomplished under AP-5.19Q through an Interface Control Working Group. Interface control documents/drawings are used to establish and control interfaces.

There appears to be a problem with the definition and use of the term "interface". Normally, interfaces are thought of in terms of physical and functional interfaces, and these are documented formally by Interface Control Documents (ICD's). There is extensive use of the term "interface" by YMPO staff and contractors to indicate many other types of interfaces, such as management and organizational. The broad use of the term "interface" by YMPO and contractors appears to be confusing. Defining a functional interface requires that both sides of the interface be identified and what is passed across the interface described.

An example of such overly broad use of "interface" is found in the YMPO document: "Yucca Mountain Mined Geologic Disposal System Requirements", YMP/CC-0010, Revision 0, dated March 20, 1991. In the report, three sub-elements related by "interfaces" are described: 1.0 Site; 2.0 Repository; and 3.0 System Performance Evaluation. Since the third sub-element is a management function, it has no interface with the physical system listed on pages 12, 13, and 16 of the report.

- [14] We recommend that YMPO investigate the manner in which the various uses of the term "interface" are employed to determine if the extent of confusion warrants establishing specific definitions for each use.

Acceptable design input and technical data are controlled at the project level by three procedures, as well as the aforementioned plans and requirements

documents. AP-5.1Q governs the control and transfer of technical data. AP-5.2Q and 5.3Q govern the flow of information into the technical database and the Reference Information Base.

The scientific investigation program is controlled at the Project level through the Test & Evaluation Plan, the Site Characterization Program Baseline (SCPB), and study plans.

Scientific studies consist of tests and analyses. The Test & Evaluation Plan lays out the process for their control in three phases: planning, implementation, and evaluation. The first two phases are controlled by AP-5.32Q Test Planning and Implementation. The detailed process for the evaluation of test data is described in the Technical Support Documentation Management Plan.

The SCPB is controlled through AP-3.3Q; a change is processed through the Project Change Control Board. Study Plans are controlled by AP-1.10Q. The participants and YMPO perform technical, management, and QA reviews prior to approval.

Each participant also has procedures for change control, the preparation of study plans, and technical procedures for the conduct of the work. Participants are required to perform independent technical reviews of their internal procedures prior to approval for use in design and science. The Project Office relies on audits and surveillances to confirm the effectiveness of this process. Although these audits and surveillances use technical personnel, there is no review of the participant procedures before they are used to perform work.

A readiness review may be conducted by the Project Office prior to the start of a test or other key activity. These reviews are controlled by AP-5.13Q, "Readiness Review."

#### **6.2.2.5 Instructions, Plans, Procedures, and Drawings.**

The Project Management Plan (PMP) governs subject matter plans. The PMP and other management plans, e.g., the Technical Data Management Plan, are judged by YMPO not to be QA-affecting. Interviewees indicated that the QA audit process covers procedures, not plans. Traceability exists between procedures and source plans, e.g., the Configuration Management Plan.

The Change Control Board (CCB) currently controls thirty-four management documents in addition to the technical baseline. The CCB has reduced the average number of days to process a change from 50 to less than 25 days. High priority changes can be made in a day.

Management plans provide the basic guidance for the development of implementing procedures. Management plans are not currently considered QA-affecting. Many of the management plans examined at YMPO had substantial technical content. The concern is that if a plan controls or otherwise has strong input into technical areas that are QA-affecting, the plan may also be QA-affecting.

- [15] We recommend that the issue of whether management plans are QA-affecting should be revisited, in order to assure that the appropriate QA procedures and controls exist.

#### **6.2.2.6 Document Control.**

Improvements in document handling are being made to reduce costs of document control. Current resources for document control are adequate because of cost saving measures instituted. Future needs for document control are anticipated to increase substantially.

The number of controlled documents is increasing substantially and that rate of increase will be even greater in the future. Currently, the document control system is meeting its requirements with existing resources because of efficiencies which have evolved. Future needs are such that an evolution of the existing system may be inadequate.

- [16] We recommend that advanced processes be considered to improve the capability of the document control system to deal with the increasing number of controlled documents. Such an advanced system is currently under design in RW-13 as part of a general enhancement of the OCRWM information management system, tentatively identified as "INFOSTREAM".

Interviews produced no consistent view of how the decision is made to place a document under control nor did a clear view emerge of who or what entity makes the decision.

- [17] We recommend that the process for evaluating whether a document is to be controlled be thoroughly reviewed and documented.

As was said earlier, there are currently thirty-four management plans under CCB control. The usual practice in industry is to include only technical descriptions or technical requirements under a CCB process. Changes to controlled documents such as management plans and data bases can be accomplished with a less formal system, and the reduction in throughput for the CCB might allow it

to function more efficiently.

- [18] We recommend that YMPO investigate the merits of removing management plans now under CCB control from this system for placement under a less complex control system.

#### **6.2.2.7 Control of Purchased Items and Services.**

YMPO is responsible only for the control of purchased services from contractors and for the distribution of grants to government entities and universities. Required items other than Automated Data Processing (ADP) equipment are procured by REECO using procedures subject to OCRWM Quality Assurance Audit. ADP items are obtained by the Nevada Operations Office (NVO). Federal acquisition regulations govern contracting office activities. Generally, contracts for services are awarded conditional upon approval of the contractor's quality assurance program by the YMPO Quality Assurance division.

There was a concern expressed by several YMPO engineers that QA requirements were not being adequately reflected in the competition for contract award. However, the contracting office indicated that any additional conditions associated with QA would be inconsistent with Federal regulations.

- [19] We recommend that the role of QA requirements in the competition for contracts be reviewed.

#### **6.2.2.8 Test Control.**

As stated in the QAPD Section 11, "Test Control", OCRWM performs no test control activities, other than computer software test control requirements. Application of software requirements is addressed under the QAPD Section 19. Under the 1989 NQA-1, test control covers the verification of the conformance of an item or computer program.

YMPO does not currently do conformance tests on items. With the responsibility for scientific investigation control, YMPO treats test control as contained within Section 20 of the QAPD Appendix A. While the performance of scientific investigations is delegated to participant organizations, YMPO is responsible for the direction, guidance, and review of the scientific investigations. The creation and review of documents supporting scientific investigations are treated under QMP-06-04; however, the test control elements derive from AP-5.32Q, "Test Planning and Implementation Requirements". Under AP-5.32Q, test controls are defined as addressing interference between and among tests,

adverse impacts on the waste isolation capability of the site, and adverse environmental impacts.

Operationally, YMPO is using test control as a term to assure that there are no adverse impacts upon the site due to scientific investigation. The establishment of acceptable impacts from proposed tests is done using performance assessment carried out by the National Laboratories.

Test control at the YMPO actually, and appropriately, refers to control in the context of scientific investigations covered by QARD Section 20. Within that context, test control is interpreted as assuring that no adverse impacts occur to the site's isolation capability due to the scientific investigation. The necessary test controls performed by Federal employees are contained in QAPD, Section 20, Appendix A.

#### **6.2.2.9 Corrective Action.**

With a few exceptions, conditions adverse to QA are identified promptly, documented and corrected as soon as practical. Corrective action is implemented by OCRWM using procedure QAAP 16.1, Revision 3. The tracking and statusing of the CAR's is accomplished at YMPO by a CAR coordinator who issues notification of overdue responses. For CAR's being tracked under the YMPO system, fifteen of thirty-eight CAR actions have been received one to five days after the due date. One was received one month late, and one was received four months late.

Approximately forty-five percent of the CAR's were responded to after the due date. One problem has been that all CAR's are sent to the Director, Office of Geologic Disposal, but the person who will respond is not identified. Since the YMPO CAR coordinator does not know who will ultimately respond, it is difficult to follow up when the due date approaches.

- [20] We recommend that YMPO improve communications between the Project Office and the CAR Coordinator in an effort to ensure that responses to CAR's are not late. Efforts are currently underway to solve the problem.

#### **6.2.2.10 Quality Assurance Records.**

YMPO is responsible for collecting quality assurance records from participants. Records from the Local Record Center have received all technical and management reviews prior to transmittal to the CFR at HQ.

We found the storage of records to be consistent with QA standards, including

the protection of records from fire and environmental deterioration. The retrieval system is adequate to ensure that records are readily available when needed. The document control administrator has established performance standards to measure program effectiveness.

A records study has indicated that four million pages of documents, generated prior to August 1988, have not yet been reviewed or processed. It was estimated that perhaps ten per cent may be QA-affecting. With this large backlog of documents to be processed, it is necessary that management develop a methodology to retrieve the useful (QA-affecting) information. While it is probable that ninety percent of the information in the backlog will not be QA-affecting, a plan/strategy has not been developed to identify the relevant information. The development of a schedule is also needed to prevent further delays and possible loss of needed information.

- [21] We recommend that YMPO: (a) determine which of the backlogged records will be needed during the license process; (b) increase efforts to eliminate the backlog for license related records; and (c) establish an action plan which would include a schedule.

Some tracking mechanism (monitoring) of record generation, review, approval and archiving may be necessary to prevent an increase in the present backlog problem.

- [22] We recommend that YMPO identify and take action to ensure that QA records are processed in a timely manner. YMPO is developing such a system.

The microfilming (silver halide) process may not be adequate to ensure that quality assurance records will survive for one hundred years or longer.

- [23] We recommend that YMPO (and other parts of OCRWM) keep abreast of advances in the microfilming process to assure that records will survive over the life of the program. Work is underway in this area.

#### **6.2.2.11 Audits.**

Audits must be scheduled well in advance to allow for adequate preparation of the audit team. Eight audits were conducted in 1990, including a review of all criteria in the Quality Assurance Program Document (QAPD). The QAPD and the Quality Assurance Requirements Document (QARD) serve as the principal documents for the program quality assurance program.

The audit team typically consists of a lead auditor, who is certified, and several

auditors and technical specialists who have the necessary background for the work to be audited. Orientation training is provided for the team, and prior experience is evaluated to ensure that technical processes are effectively audited.

Audit checklists are developed but not retained as part of the audit report. The audit is conducted in accordance with established procedures through interviews of personnel, document reviews, and observation of work activity when possible. The audit reports thus far issued on the YMPO program meet the intent of the QAPD. CAR's are issued if conditions adverse to QA are noted.

Interviews with YMPO personnel indicated that they interpreted the requirements established by the QAPD as the maximum requirements with little need to go beyond those requirements.

- [24] We recommend that the staff be made aware that the requirement established by the QAPD is the minimum requirement. When significant safety issues or a low cost/benefit indicates that a higher standard should be used, management should consider more stringent standards.

The audit team that conducted the OCRWM Audit 90-1-01 in October 1990, consisted primarily of personnel who were responsible for implementing the OCRWM QA program. Although this approach is acceptable from a regulatory standpoint, management should ensure that a sufficient number of totally independent auditors be used on future audits of OCRWM Quality Assurance activities.

#### **6.2.2.12 OGD Headquarters - Analysis and Verification Division.**

The Analysis and Verification Division (AVD) is reviewing Study Plans for YMPO. Earlier reviews were done under HQ procedures; more recent reviews have been done under YMPO procedures.

- [25] We recommend that the AVD consider the merits of operating under a single set of procedures.

#### **6.2.3 OFFICE OF SYSTEMS AND COMPLIANCE (RW-30).**

##### **6.2.3.1 Introduction.**

This assessment involved personal interviews with selected staff in Office of Systems and Compliance and reviews of applicable documents and correspondence. Assessment group members were Jay Jones (RW-40), Ed

Taylor (TRW), Bill Leonard (Fluor)

### **6.2.3.2 Observations and Recommendation.**

**(a) Organization.** The functions, responsibilities, and reporting relationships of the Office of Systems and Compliance appear to be clearly defined, well understood, and effectively implemented. Most individuals interviewed were aware of the mission, functions, organization and tasks within their individual organizations.

The descriptions of organizations and functions in the reorganization memo (November 7, 1990) and the Quality Assurance Program Description Document (QAPD) appear to be essentially compatible, but not entirely consistent. See Section 1.1.5 of QAPD, revision 3.

Most interviewees either had copies of position descriptions in their possession or had access to them and appeared to have a thorough understanding of their individual work scopes, the functions of their organizational units, and how they contributed to the OCRWM mission.

[26] We recommend that a more timely mechanism for organization revisions or updates be developed. A general description in the QAPD, with a reference to a controlled, stand-alone organization chart with accompanying functional statements is a possibility. The QAPD should be reviewed and revised as necessary to reflect the reorganization of November 1990, as soon as practicable.

**(b) Overall QA Program.** Most personnel interviewed said they knew which of their tasks were QA-affecting and which were not, but several stated that the QACD system for specific applications was open to more than one interpretation.

Some interviewees stated that they clearly saw the need and value of a quality assurance program, but others said they considered QA a hindrance to accomplishing work.

There was a clear understanding of the need for good documentation for QA-affecting work, and interviewees knew where the responsibility rested for capturing and maintaining QA records - the QA Records Center.

**(c) Training and Qualification.** The staff members of OSC all appeared to be competent professionals who took their work seriously and performed effectively. Most have been in their present positions since the reorganization in 1990 and were familiar with their functions.

Supervisors said they personally verified qualifications to the extent they were able to for both present employees and new personnel being considered for assignment to OSC. There was a high degree of assurance that personnel came to their positions with the appropriate initial qualifications.

The I&T matrices examined appeared to be current, although not all were maintained in a consistent manner. Some were consolidated into single records, while others were maintained on separate revisions and were more fragmented.

(d) Document Control. The NQA-1 requirements regarding document control appear to be adequately implemented in RW-30. Most interviewees understood that the purpose of document control was to be certain the correct version of key documents, designated "controlled", are in the hands of the users, and that obsolete information is not used.

The Configuration Management Branch has the responsibility for developing and operating the OCRWM document control system. The staff supporting this function has implemented a system which is successful in accomplishing the required control activities.

The controlled documents examined had the prescribed control features including a unique identification, a specific assignee, and a receipt system.

There were no shortcomings regarding the document control system expressed by interviewees, and none were evident to the assessment team.

(e) Management Involvement. Support of the quality assurance program was affirmed by all OSC managers interviewed. Several interviewees mentioned that special emphasis on the importance of the QA program was given at the time of the recent reorganization. Only occasional reinforcement was mentioned subsequent to that time. Interviewees stated that they felt free to communicate with their supervisors if they had any questions or concerns regarding implementation of the quality assurance program.

The extent of QA program assessment by managers of the operations for which they were responsible could not be accurately evaluated because of the lack of specific supporting documentation. Several managers stated that they actually performed an ongoing, day-to-day appraisal of QA program implementation by virtue of their management roles.

(f) QA Audits and Surveillances. The most recent audit of OCRWM,

both at Headquarters and at the Yucca Mountain Site Characterization Project Office, was in October 1990. The QA program was determined to be adequate for initiation of QA-affecting work, but several areas of weakness were identified. It is the assessment team's understanding that these deficiencies are currently being corrected.

Several CAR's were generated, of which five were written for inadequacies in the Office of Systems and Compliance. These were examined, and all were promptly responded to with QA concurrence in the responses. Surveillances to verify implementation of effective correction actions have been partially completed.

The method of auditing was questioned by some interviewees. They expressed the view that the focus was typically on precise procedural compliance, without sufficient attention to effectiveness. However, audits clearly have evaluated QA effectiveness.

In addition, RW-30 has been issued three DR's based on the program review and a separate surveillance. Corrective actions are in progress for these DR's and are currently on schedule.

Outside of the formal QA audit and surveillance activity, a Corrective Action Request was initiated within OSC, in December 1990, in accordance with the provisions of QAAP 16.1, "Corrective Action Requests". The CAR recommended an evaluation to resolve the concern. The substance of the CAR is not an issue of this assessment report. What is of some concern is that administrative procedures may have been circumvented. QAAP 16.1 specifies a system for QA processing of CAR's. The system includes a means for voiding CAR's considered to be invalid. The system, which requires coordination with the CAR initiator, was not followed; instead, a memo was used to return the package to the CAR initiator, explaining why the concern was considered invalid. The CAR record package, however, was developed and maintained in accordance with QA requirements.

[27] We recommend that the Office of Quality Assurance work with RW-30 to determine if reprocessing the December 1990, CAR is necessary. If reprocessing is necessary, it should be done in accordance with QAAP 16.1. This would allow for a proper resolution of the matter cited. It may also help to promote the use of the CAR system by OCRWM personnel as a viable conduit for perceived or known problems.

### **6.2.3.3 Suggested Improvements to the System.**

The following are suggestions for improvement of the OCRWM QA program which were offered by more than one interviewee. They represent possible revisions to administrative procedures which could strengthen the QA program. However, they have not been evaluated by the QA Management Assessment team and are therefore not part of the team's recommendations.

- The planned procedure for bringing QA concerns to upper management's attention should be finalized. Activities toward this end are under way.
- QAAP 2.3, "Establishing Quality Assurance Program Controls", is confusing in its present form; it should be revised to be more easily understood and useful for the OCRWM staff.
- QAAP 3.6, "Technical Document Input Control" and QAAP 3.7, "Interface Control" are not written clearly enough and need to be revised to be more effective for the users of the procedures.
- Audit emphasis should be shifted to focus on effectiveness, rather than on strict procedural compliance.

### **6.2.4 OFFICE OF STORAGE AND TRANSPORTATION (RW-40).**

#### **6.2.4.1 Introduction.**

The Office of Storage and Transportation (OST) was formed in November 1990. However, work on casks, transportation, requirements, and pre-conceptual design of the MRS occurred prior to formation of OST.

The OST assessment team consisted of Susan Jones (RW-20), Leo Seeber (TRW), Mark Wilkenshoff (Duke), and E.Y. Wong (TRW).

The team had these objectives:

- Confirm that line management in OST was executing its responsibilities for QA, as described in the QAPD (Rev. 3).
- Evaluate the staff's understanding of the purpose of the QA program, its applicability to their work, and its effectiveness.

- Solicit specific recommendations for improvement of the overall QA program.
- Provide recommendations for improvement in QA program implementation in OST.

The results of the assessment of OST are organized according to the six objectives for a management assessment stated in QARD Section 2.10.

#### **6.2.4.2 Observations and Recommendations.**

**(a) Adequacy of Organizational Structure and Staffing to Implement the QA Program.** The QA responsibilities and reporting relationships of the Associate Director, OST; the Division Directors; and Branch Chiefs are defined in the QAPD (Rev. 3; sections 1.1.6, 1.1.11, and 1.1.12). The managers interviewed were aware of the responsibilities assigned to them. But some of the descriptions of responsibilities were not clear, or were subject to various interpretations. These are identified in the recommendations.

OST is seeking to fill its current vacancies. Management was divided in its opinion of whether a fully staffed OST (as defined by the current FTE assignments) will be adequate for the design phase. Adequacy also will depend on the level of OCRWM involvement in the technical aspects of the program. The level of technical involvement has been increasing.

We recommend that:

- [28] • QAPD paragraph 1.1.6 (g) be written to clarify its applicability to the technical management of the Program. Each manager interviewed had a different interpretation of the first part of the paragraph.
- [29] • High priority be given to staffing the Facilities Development Branch to support MRS siting and design. Recruiting is underway to fill these positions.

**(b) Effectiveness of Quality Assurance Program Implementation.** The work being performed that is subject to the QA program includes: (1) cask development; (2) other aspects of transportation; (3) peer reviews of certain work performed prior to acceptance of a QA Program by OCRWM; and (4) qualification, indoctrination, and training. MRS design will begin later in FY 1991. The QA programs at other DOE offices or contractors that directly support OST have not yet been reviewed and

approved by OCRWM. Therefore, the overall effectiveness of the QA program with respect to these other parties cannot be assessed at this time. OST is taking steps to impose the QA program where needed, as described below.

According to OST management, efforts are underway to implement the QAR within OST at HQ, at other DOE field offices supporting OCRWM activities, and by contractors for work performed for OST. Cask development activities are managed by the DOE Idaho Operations Office (DOE/ID). DOE/ID cask development and design activities are being undertaken by contractors that have NRC-approved QA programs.

The contractors are responsible for obtaining NRC certification of cask designs. OCRWM directed DOE/ID to implement the QARD in FY 1990. The DOE/ID Quality Management Plan (QMP) has been in OQA for review since January 1991. Audits and surveillances for DOE/ID will be scheduled after OCRWM acceptance of the DOE/ID QMP. An impact analysis will be conducted on work performed prior to acceptance of the QMP. In addition, a peer review has been initiated for cask design requirements to satisfy QA documentation requirements for cask development activities.

Various other transportation activities are also performed by the DOE Chicago Operations Office (DOE/CH). This work is being transferred to the M&O contractor. Any activities that are QA-affecting will be performed under the M&O QAPD (in preparation). Pending the verification of QA-affecting activities, no audits or surveillances have been performed on the DOE/CH work.

The Energy Information Agency (EIA) of DOE receives spent fuel data from the utilities and other owners and generators. Some portion of these data may be design input for various parts of the waste management system. EIA is under the OCRWM QARD. The EIA QAPD has been reviewed by OQA and comments returned to EIA. No surveillances or audits have been performed on the EIA work to date.

**We recommend that:**

- [30] • The review and acceptance of the QA plans for DOE/ID, the M&O contractor, and EIA be completed in a timely manner. In addition, the OCRWM QAPD sections for Associate Director, Division Directors and Branch chiefs should be rewritten to clearly state that each level of management is responsible for requesting OQA to conduct audits and surveillances of the work under their control beyond those scheduled by

**OQA, as a means of verifying quality.**

- [31] • **OST should continue to work with OQA to schedule surveillances of on going QA-affecting work to ensure compliance with and effectiveness of QA controls. For example, OST could request OQA to conduct a surveillance on the peer review of cask requirements.**

**(c) Effectiveness of Qualification, Indoctrination and Training Programs.** OST demonstrated the most familiarity with the QA program in this area. As a result, training elicited the most criticism, as well as the most suggestions for improvement.

Written position descriptions exist for current staff, and for positions being filled. QA responsibilities are included in a general manner (e.g., a single paragraph or bullet) in some position descriptions. One Branch Chief has written specific QA responsibilities into annual performance plans for his staff. This is an excellent idea.

Qualifications (education and work experience) were personally verified by each manager for his staff. This is done under QAAP 2.2, and also applies to new hires. The process appears adequate.

I&T matrices were prepared for all staff. A few people in each Division receive controlled copies of the QAAP's. OQA notifies those with controlled copies when changes are made to documents. There is no specific process in OST to inform other staff when changes have been made to documents, or to ensure that I&T matrices are updated before the start of a task. Some managers had appointed one person in the branch to coordinate training assignments for the branch. Others left training to individual initiative. QAAP 2.1 requires a quarterly update to the I&T matrix for changes to documents assigned to the person. A quarterly update may not always be of sufficient frequency to ensure that training is current.

- [32] **We recommend that all OCRWM position descriptions and performance plans should contain, where applicable, specific responsibilities for quality assurance. This would clearly document delegation of responsibility for QA as well as promote accountability.**

**(d) Adequacy of Planning and Procedural Controls.** This is the area of greatest concern to the assessment team. MRS design work is scheduled to begin this summer, and transportation cask development has been in progress for many years. An integrated management process, including QA controls, is

not yet in place to ensure the adequacy of QA processes for the MRS or cask development work.

Many of the problems have been recognized by OST and were brought to the team's attention. The MRS chapter in the OCRWM Systems Engineering Management Plan (SEMP) is not complete. While most people indicated that they were getting ready to start MRS design work, there was not a clear understanding of how their work will fit into configuration management or interface controls. There is as yet no OCRWM-wide or MRS configuration management plan. Staff were either unaware that QAAP 3.7, "Interface Control", was in place or had not used it. MRS design will be the responsibility of the M&O contractor, but the M&O QAPD is in preparation. At present, no QA-affecting work is being performed by the M&O. The MRS requirements document has not been prepared.

The "Interim Design Approach for the MRS", prepared by OST, temporarily fulfills the purpose of the (SEMP). The requirements documents and OCRWM configuration management plan will be prepared by the Office of Systems and Compliance as part of the Management Systems Improvement Strategy (MSIS). Conceptual design will begin using the functional analysis Volume IV from the MSIS.

All conceptual design activities will be evaluated after the design requirements document is released. OST has recognized that it is proceeding at risk in its effort to maintain the MRS design schedule. OCRWM is preparing a QAAP for establishing design hold points to ensure that before initiation of Title I design of the MRS, OCRWM system requirements are in place and flowed-down to the M&O as requirements. At the time of this assessment, the QAAP was at OQA for review.

The planning documentation leading to QAAP procedures, or instructions, is not in place to ensure technical adequacy and mission success. While OST may not prepare or generate detailed development plans, procedures, or instructions for the storage or transportation programs, OST should prescribe and document the process and criteria for acceptable plans, procedures, and instructions prepared by others. In addition, OST should plan and actively participate in the review and/or approval of this documentation.

We recommend the following:

- [33] • Delete requirement in "Interim Approach for MRS Design" for OCRWM approval of M&O procedures. OCRWM should accept the M&O's

**QAPD, and then audit the M&O's QA program and procedures. Review and approval of procedures should be done by the M&O.**

- [34] • After the necessary program prerequisites are identified, a OCRWM surveillance schedule should be expanded to ensure that (1) MRS conceptual design prerequisites and activities meet QA requirements; and (2) contractor and OCRWM procedures are reviewed for adequacy early in the design process. This activity is planned.**
- [35] • OST should develop a comprehensive and integrated plan and schedule for project and technical management control and tracking. Existing schedules should be expanded to include a detailed schedule of all prerequisites for the start of MRS conceptual design and for the start of Title I design. The schedule should include all of the missing pieces described above that have to be done by OST, other OCRWM offices, or contractors.**

**(e) Establishing Quality Assurance Program Controls. All OST interviewees recognized the need to identify QA-affecting activities that they personally perform. QAAP 2.3 does not provide a clear process for determining what is or is not "quality-affecting (or the equivalent term). The process is subject to individual judgement. Most OST managers indicated that, when there is not sufficient information, they err on the conservative side and put an activity under that QARD. They do consult with OQA staff for guidance. The guiding factor in applying QA is whether the activity affects public radiologic health and safety. More than one person, however, expressed the opinion that activities of programmatic importance should also be under the QARD, which introduces the TOM issue addressed earlier in this report. This is currently in progress as the result of the QA-grading workshop.**

- [36] We recommend that QAAP 2.3 should be revised to provide an improved process for determining what is "QA-affecting".**

**(f) Technical Document Review. OST staff have participated in reviews of technical documents conducted under QAAP 3.1. The general feeling is that the process improves the reports and provides better quality reports. It was recognized that the formal review process does add time to the preparation cycle. Section 6.3.1.3 of this report addresses OST concerns about use of this procedure and training effectiveness.**

**(g) Effectiveness of Nonconformance and Corrective Action System. OST had little experience with the audit, surveillance, nonconformance, and corrective action systems required by the QARD. OST staff contacted during the**

management assessment had only been interviewed briefly during the surveillance of OST training and qualification records.

No CAR's have been written specifically against OST, either as a result of audits and surveillances, or self-imposed through QAAP 16.1. Staff were not uniformly aware that a process (QAAP 16.1) exists to bring quality assurance deficiencies to the attention of management and the QA organization.

Some managers said that they had benefited from observing other OCRWM offices deal with CAR's. Higher management has attended meetings at which responses to CAR's are prepared and discussed. They feel the CAR process is valuable. It forces much discussion of quality assurance and requires OCRWM to take QA seriously.

(h) Adequacy of the Quality Assurance Information Tracking, Evaluation, and Reporting System. All staff interviewed felt that they could freely discuss QA issues and concerns with their manager. All have worked cooperatively with OQA.

The assessment team feels that the goals of QA have been well communicated to all levels of OST management and staff and have been accepted as a necessary and important part of the program.

## **6.2.5 OFFICE OF CONTRACT BUSINESS MANAGEMENT (RW-50).**

### **6.2.5.1 Introduction.**

This section summarizes the observations of the Office of Contract Business Management (OCBM) during this management assessment. The Office of Contract Business Management (RW-50) has the responsibility for managing the procurement/business activities of the OCRWM Management and Operating (M&O) contract. This activity is conducted by the M&O Management Division (RW-52). OCBM also has the responsibility for managing the procurement/business activities of all other OCRWM contracts program wide. This activity is conducted by the Contract Management Division (RW-53). The observations stem from the following:

- The assessment teams interviews with Victor W. Trebules, Richard W. Minning, Franklin G. Peters, Judy Leahy, Barbara K. Jarrett, and Donna Johnson.
- The review of the following QAAP procedures:

QAAP 4.1, "Procurement Document Review"  
QAAP 4.2, "Establishing Procurement Quality Assurance Controls"  
QAAP 7.1, "Control of Purchased Services"

- Follow-up telephone conversations with Victor W. Trebules, Judy Leahy, and Richard W. Minning.

Assessment team members were Glenn Gardner (RW-5), Stan Goldsmith (Weston), and Vick Dixon (Duke).

### **6.2.5.2 Observations and Recommendations**

OCBM is a relatively new organization, only a little over six months old. Experienced supervision has been placed in the two divisions of OCBM, and they are building up their staffs.

The QA Administrative Procedures which apply to OCBM (QAAP's 4.1, 4.2 and 7.1) have not been corrected/revise in a timely manner. The procedures contain errors in the flowcharts and reflect an obsolete organization structure. The use of outdated/incorrect procedures has led to complications in following the procedure requirements.

- [37] We recommend that QAAP's 4.1, 4.2, and 7.1 be revised to reflect the current organization. Revisions are being made.
- [38] We also recommend that the flowchart in QAAP 7.1 be revised to:
- reference the correct paragraphs and subsections,
  - indicate the point in the procurement cycle where the DOE Office of Placement and Administration (PR-322) has primary responsibility or modify the flowchart to include the independent PR-322 points of involvement, and
  - employ easily understood symbols or provide the definitions for current symbols.

## **6.3 ASSESSMENT RESULTS FROM STAFF ORGANIZATIONS.**

### **6.3.1 OFFICE OF QUALITY ASSURANCE (RW-3).**

The assessment of the Office of Quality Assurance was carried out by a team consisting of Robert V. Barton (RW-20), supported by James Wells (Duke), with

external advisory assistance from Tom Colandrea, Colandrea & Associates, Inc.

The results, conclusions, and recommendations provided below for the activities of the Office of Quality Assurance are largely the result of that team's efforts. However, other comments and recommendations are provided which resulted from the efforts of other teams, who encountered issues of direct concern to OQA while assessing work of other offices.

#### **6.3.1.1 Introduction.**

Management at all levels seem to be very well informed on the QA program. The dedication and competence of the QA staff at both headquarters and YMPO appeared to be very good. All personnel were most cooperative during this assessment and quite dedicated in their efforts to establish a good and effective program for OCRWM. The QA program has made significant progress during the past year.

#### **6.3.1.2 Organization**

The OQA staffing level at the YMPO appears to be adequate at this time. The DOE staff of 6 people is supported by two contractor organizations (T&MSS and MACTEC) whose combined staff of approximately 40 people provide sufficient staff to adequately implement the QA activities of the Yucca Mountain Site Characterization Project (YMP).

It appears that an increase in the OQA staffing level at HQ would be desirable. Five additional positions have been authorized, and the Director of OQA is actively seeking to fill them. At the present time, the HQ idvision has four DOE professionals. The contractors' staffing level of about 18 people supporting the HQ QA Division seems to be adequate to conduct QA activities.

[39] We recommend that every effort be made to expedite the filling of the five open positions within OQA HQ and the YMPO QA Division Director position.

[40] We also recommend that the feasibility of using only one support contractor for OQA instead of the present four be investigated. The Director of OQA is presently exploring the possibility of consolidating this support under one contractor.

Both the DOE staff and the contractor staff appear to have adequate experience in licensing from a QA standpoint. For example, the DOE QA staff of 6 at YMPO has over 60 years combined experience in licensing QA. The contractor QA staff seem to be very experienced in licensing and very knowledgeable in

QA. The quality of the DOE QA staff at HQ also appear to have adequate experience in licensing with over 54 years of combined QA licensing experience on their staff of 4.

### **6.3.1.3 Quality Assurance Program.**

The Director of OQA held a workshop for QA, management, and technical personnel to explore the concerns the scientists had raised that the QA program was too inflexible to use on this type of scientific program. As a result of this workshop, most of their concerns were addressed and are being resolved. Two additional workshops were held to address problems in QA grading and QA software control. These workshops have been very successful in helping set a course of action to resolve these two issues.

The workshops have been very valuable in opening up communications between the QA staff and the scientists. One concern that is being addressed was the need to simplify the QA process. The current apparatus for describing the QA program and its application appears to be somewhat cumbersome and convoluted.

Management has been actively involved in the QA program. The Director of OCRWM receives personal briefings periodically from the Director of OQA. For example, he personally received a briefing by the initial QA workshop participants, and the Director OQA and the Director OGD have received briefings from all the QA workshops.

(a) Training. The responsibility for the training function at HQ is delegated to OQA. At HQ, supervisors are requested to review employee's records quarterly to see if they are delinquent in any training. This appears to be a weakness since employees could be performing work for months before it was discovered that they were working to an outdated procedure.

CAR HQ 91-021 identified a deficiency in training. OQA has developed a plan for a comprehensive training program and is progressing toward that goal. I&T matrices have been prepared for all HQ staff. However, there is no specific process to inform staff when changes have been made to documents, or to ensure that I&T matrices are updated before the start of a task. The matrix contains the training assignments the supervisor had previously assigned. It is up to the supervisor to review this matrix against the changes to procedures and see if the employee is still current in his training. Follow-up is not routinely performed by supervisors to assure that the required training is accomplished. We recommend that:

- [41] • a systematic method be developed for notifying employees and supervisor

that they need to update their training because of changes to procedures, etc.

- [42] • HQ explore the possibility of a computer-generated I&T Matrix, which indicates the requirements for additional reading or training as document revisions are issued. This would eliminate the manual identification method currently used.
- [43] • HQ start a system, similar to that used at Yucca Mountain, for tracking training. It should automatically notify staff when they need to update their I&T Matrices. This "tickler" system must be integrated with the training schedule to ensure availability of classes. It should also be integrated with any decisions based on Recommendations 41 and 42.

These recommendations are being considered under CAR 91-021.

There does not appear to be any systematic way at HQ of defining the QA-related responsibilities in job functions and the appropriate training requirements for OCRWM employees.

- [44] We recommend that a system of job analysis be used as a basis for identifying the QA-related training needs of OCRWM employees. This is part of a general personnel management function.

There was considerable criticism expressed of the training program, perhaps because everyone was more familiar with it than other areas of QA. Listed below are some of the comments:

- Training has tended to emphasize form over substance.
- Training has isolated individual QAAP's from the overall QA program.
- Trainers often can not answer questions on material presented.
- Reading is convenient, but insufficient in some cases. The most effective training in many cases is classroom instruction, with examples and exercises in which the students filled out the forms or did other work required by the procedure.
- Training on specific procedures was not available when needed (e.g., training on QAAP's 4.1, 4.2, and 7.1 was required to clear a CAR but the training was not available).

**We recommend that:**

- [45] • the effectiveness of QA training provided to HQ be reviewed and consideration be given to a training program for OCRWM-contracted instructors, and an OCRWM-prescribed standard for classroom instruction, including an appropriate mix of lecture, discussion, graphics, and workshops.**
- [46] • reviewers of documents under QAAP 3.1 be more sensitive to the definition of "mandatory comment". Trivial or editorial comments should obviously not be "mandatory".**
- [47] • training on specific QAAP's explain the relationship among management plans/processes, the QA program, and the specific responsibilities of OCRWM offices. For example, training on QAAP 3.2, Design Review, would discuss criterion 3, relevant parts of the QARD and QAPD, QA's relation to the Systems Engineering Management Plan and the Configuration Management Plan, and specific responsibilities of the organizations/people in the class.**
- [48] • classroom training include principles and philosophy behind the procedure. Training should be scheduled in advance to allow more effective use of staff. It was suggested that line or senior QA staff (as appropriate) should occasionally serve as instructors.**

**(b) Personnel Qualifications.** The lack of a HQ procedure for personnel qualifications and the Privacy Act concern resulted in a CAR being issued to HQ during the time of the Audit 90-1-01. This procedure has now been issued, and the Privacy Act concern has been resolved.

**(c) Grading.** Several of the people who were interviewed were concerned about the utility of the grading packages as they are now developed. The process is cumbersome and not well understood.

In this regard, the Director of OQA has chartered a QA workshop, consisting of users of this process, to look into the system and recommend changes to it, if needed.

- [49] We recommend that management continue the present course of action for achieving a better understanding of the grading process. Areas needing review may include training, implementation, procedural aspects, or responsibility assignments.**

The QA Control Document (QACD) identifies QA-affecting activities at HQ.

This document and its implementation is not well understood or followed by personnel interviewed. The document needs a thorough review and revision, if necessary; then an extensive training program needs to be held on the resulting process. This approach was one of the goals of the 1991 QA grading workshops.

- [50] We recommend that the QACD be reviewed and either enhanced or the YMPO revised grading system be instituted at HQ.

#### **6.3.1.4 Design Control, Technical Requirements Documents.**

During the Audit 90-I-01, CAR's were issued to both the YMPO and HQ on their processes for developing requirements documents. Corrective actions have been carried out by both HQ and YMPO since that audit.

#### **6.3.1.5 Instructions, Plans, Procedures, and Drawings.**

(a) Requirements Matrix. During Audit 90-I-01, a CAR was issued to OQA, YM-91-005: "Documented evidence of a matrix that cross-references OCRWM procedures and the QAPD to the QARD requirements does not exist." Since the audit, this matrix has been developed, but the CAR has not been closed.

- [51] We recommend that the OQA staff complete their review of the upper tier QA documents before completing the requirements matrix.

(b) Document Control. At HQ, the control of QARD/QAPD/QA procedures is the responsibility of OQA. Because of the problems of obtaining experienced QA personnel, the available QA staff may be better utilized for QA activities if the performance of this activity were transferred to another part of the organization.

- [52] We recommend that the assignment of the document control function to the OQA staff be reviewed. This would be consistent with OGA's oversight rather than operational function.

Some of the staff interviewed expressed concerns because two sets of procedures, one at HQ and the other at YMPO, are being used at the present time. OQA is in the process of consolidating these into one set.

- [53] We recommend that the current effort to consolidate HQ and YMPO QA procedures continue.

- [54] We recommend that sections 5.2 and 6.1.2 of QAAP 3.1 be rewritten to provide

sufficient guidelines for determining what documents require technical review.

Many of the YMPO QA procedures have mixed NRC-QA requirements with management and technical requirements. The OQA division at HQ and the OQA division at YMPO are reviewing their procedures and consolidating them where appropriate. During this task, they are also removing management requirements from the QA procedures and writing separate management procedures for the management requirements.

- [55] We recommend that management and technical management requirements be addressed separately in management procedures and only NRC-QA requirements be included in QA procedures.

Some of the staff interviewed were unaware of the mechanism for changing OCRWM procedures. Also, some of those interviewed were not aware of any mechanism for being informed of what became of comments they submitted during procedure reviews at HQ.

- [56] We recommend that some form of response to all requests for changes to procedures be considered. It is further recommended that additional training on the review procedure be considered so the reviewers are better informed on the process.

#### **6.3.1.6 Procurement Document Control and Control of Purchased Items and Services.**

In the past, procurement control has been a concern. However, the staff interviewed indicated that, for YMPO, the participants do almost all the procurement for the program and, therefore, the audits and surveillances of the participants would effectively assess the QA program in this area. Examination of the audit and surveillance plan shows that these procurement activities will be adequately covered this year.

#### **6.3.1.7 Corrective Action.**

CAR's receive good visibility with OCRWM management. For example, they are listed on the weekly operations agenda of the Deputy Director of OCRWM. This system was implemented in March 1991. Prior to April 25, 1991, this was limited to HQ CAR's. It now contains all CAR's issued by the OQA. Reports on CAR's are also included in weekly and monthly reports by OQA.

Any extensions in the closure date for CAR's are noted on the weekly Operations Report and discussed with the Deputy Manager of OCR ^Th

responsibilities to document QA deficiencies. Apparently, this training has not been an adequate corrective action.

[57] We recommend additional training to ensure that all staff understand their responsibility for reporting quality problems and initiating CAR's.

[58] We recommend that awareness be improved of the use of QAAP 16.1 as a management tool to improve quality. This should encourage self-policing of the QA program by changing the corporate culture that views a CAR as "bad". A CAR should be encouraged as evidence that we are able to identify problems and correct them ourselves. This is an opportunity to demonstrate that QA is a way of life, and that each person is taking responsibility to see that the QA program works.

#### **6.3.1.8 Trending Analyses.**

Each participant and DOE maintain a corrective action data base for monitoring and tracking. OQA has prepared CAR YM-91-001 because there is no trending procedure in place, and trending is not being performed on these data as required by QAAP 2.9, QARD section 16.1, and QAPD section 16.7. As a result, trending has been temporarily interrupted.

[59] We recommend that OCRWM investigate the merits of integrating all CAR's and DR's into a single data base to ensure that trends adverse to quality not overlooked.

[60] We recommend that CAR YM 91-001 be closed as soon as possible to allow trending to begin.

#### **6.3.1.9 Tracking Systems.**

An overall OCRWM management tracking system has been initiated for CAR's. An Operations Management Tracking System report is issued bi-weekly and discussed at the RW operations meetings. All open CAR's are included in this report.

HQ and NRC jointly maintain a commitment tracking system, and all issues on it are reviewed at the bimonthly QA/NRC meetings.

Some interviewees were critical of the YMPO QA corrective action tracking information, indicating that the status report printout was not clear in what action was required. The printout was typically not accompanied by an explanatory transmittal memorandum. The printout is designed to be an index

for people to use. If they need more information on the CAR's, the printout is supposed to give them the data necessary to get the information.

#### **6.3.1.10 Audits and Surveillances.**

The QA audit and surveillance schedule is well planned and implemented. They cover the entire program in a manner that should result in an excellent QA program for OCRWM.

#### **6.3.1.11 QA Software.**

There has been concern expressed that the QA software requirements are too restrictive. The Director of OQA chartered a QA workshop to investigate this concern. One of the actions resulting from this workshop was the formation of a Software Advisory Group. This group has met a number of times to resolve this issue.

#### **6.3.1.12 Quality Concerns Program.**

It was generally believed by those interviewed that any concerns they had on the QA program could be raised to management and would get a fair evaluation and investigation. Furthermore, a formal system for resolving allegations of QA shortcomings has been developed and is scheduled for implementation in July 1991.

### **6.3.2 OFFICES OF STRATEGIC PLANNING AND INTERNATIONAL PROGRAMS, AND EXTERNAL RELATIONS (RW-4 AND 5).**

#### **6.3.2.1 Introduction.**

The QA management assessment of these two OCRWM offices was conducted together because of similarities in the quality assurance documentation associated with the offices. Within the QAPD, rather extensive quality assurance program activities are listed for both offices (RW-4 has ten listed and RW-5, nine). However, in both cases, the Quality Assurance Controls Document specifies that neither has any quality assurance activities and therefore the QARD is not applicable to either.

Interviews of the two office directors, Thomas H. Isaacs for RW-4 and Jerome D. Saltzman for RW-5, were conducted by Jim Bresee (RW-10). No other staff in either office was interviewed.

### **6.3.2.2 Results of RW-4 Interview.**

The review of activities carried out by the Office of Strategic Planning and International Programs did confirm that at present no work is being done which would affect radiological health and safety or waste isolation. Consistent with that information, the office has not been involved in QA audits or surveillances. The words "at present" are important here, because there may in the future be a role for international input to the OCRWM program in such a way as to require careful QA controls within RW-4. That time has not yet arrived. However, the office director of RW-4 (as well as RW-5) individually has QA responsibilities which are identified below in section 6.3.2.4.

### **6.3.2.3 Results of RW-5 Interview.**

Again, the interview verified that the activities of the Office of External Relations do not involve work which could affect radiological health and safety or waste isolation. As was the case with RW-4, no past audits or surveillances have been carried of the office activities. For both RW-4 and RW-5, the "extensive" QA activities listed in the QAPD are largely generic, taking the form of "carrying out those activities within the office which are QA-affecting in accordance with the QARD". Since none are QA-affecting (with the exception of the individual activities of the office directors), the "controls" identified in the QACD appear to be appropriate.

### **6.3.2.4 Common QA Responsibilities of the Office Directors.**

Both office directors are members of the Program Change Control Board (PCCB), which has extensive responsibilities impacting QA. Changes to all controlled program-level documents, which includes QA as well as non-QA documents, are subject to the review and approval of the members of the PCCB. QA-affecting processes are involved in the work of the PCCB. Therefore, PCCB members individually, rather than as representatives of their particular offices, are subject to QA controls, which in the cases of RW-4 and RW-5, are not described in the QACD.

There has been some confusion in the past about the use of the QACD as the basis for establishing individual I&T matrices. The QACD identifies QA-affecting activities originating in a described office but not necessarily all QA activities which individuals in an office may be involved. The present case illustrates the need for a careful description of all QA activities to be included in the QAPD. The QAPD should then be used as the basis for developing I&T matrices.

A minor additional QA requirement to which the two office directors are subject, again not covered by the QACD's for the two offices, is the result of both office directors having in their possession complete sets of the applicable QA documents such as the QARD, QAPD, QACD, etc. As a consequence, both must carry out the provisions of QAAP 6.1 in order to maintain the QA documentation current. There is no reason to believe that these provisions are not being carried out.

#### **6.3.2.5 RW-4 and RW-5 Assessment Results.**

The assessment results have shown that the two offices are not at present carrying out QA-affecting work and are therefore not subject to the OCRWM QARD. However, both office directors are involved in QA-affecting work through their membership on the PCCB. A separate section in a revised QAPD with the specific QA requirements for all PCCB board members would be helpful. Further, simplification is possible of the current QAPD's for the two offices to reflect the actual activities.

- [61] We recommend that future revisions of the QAPD include both the QA-affecting activities of the PCCB as well as simplified descriptions of the RW-4 and RW-5 activities.

#### **6.4 DIRECTOR'S OFFICE (RW-1 and RW-2).**

##### **6.4.1 Introduction.**

Interviews of both John W. Bartlett, Director of the Office of Civilian Radioactive Waste Management (RW-1) and Franklin G. Peters, Deputy Director (RW-2) were carried out by James C. Bresee (RW-10) and James Brackett (Duke). The QACD for the office identified the QA Management Assessment function as its only QA-affecting work initiated by the Office. The purpose of the interviews was to evaluate the adequacy of the current QA controls applied to the office.

##### **6.4.2 Current QA-affecting Activities of the Director's Office.**

In a broad sense, the Director of OCRWM has every QA responsibility within the high level waste management program. However, all of these QA responsibilities and the authorities that go with them have been delegated to the appropriate associate director or office director. The broad overall QA responsibilities of the Director are clearly recognized in the QAPD, and the impact of delegation is shown in the QACD. The Deputy Director of OCRWM has been named by the Director as the Chief Operating Officer of OCRWM,

and his present PD does not reflect that assignment.

The most important QA function of the Director of OCRWM is not one that is readily identifiable in a QA control matrix. That function is to use his considerable influence to stress the importance of QA to OCRWM and the seriousness with which he approaches the subject. That seriousness has been evident throughout the program, and it is one important reason the OCRWM QA program has been able to achieve the results that it has.

The interviews verified the accuracy of the general delegation of QA authority, but they revealed, in parallel with the individual QA assignments of the directors of RW-4 and 5, that the Deputy Director, as chairman of the PCCB, has QA responsibilities not covered by the QAPD for the Director's Office. In further parallel findings, adequate control of the several sets of QA documentation in the Director's Office also call for use of QAAP 6.1, again not covered by the QAPD. As is the case with RW-4 and RW-5, there is no indication that the provisions of QAAP 6.1 are not being followed.

#### **6.43 Director's Office Assessment Results.**

The QA management assessment of the Director's Office confirmed that the major QA responsibilities of the office are delegated to the OCRWM Associate Directors. The Director's Office has retained and exercised the QA responsibility for the annual QA management assessment, which is obviously a QA activity which cannot be evaluated by this assessment. However, the PCCB QA activities of the Deputy Director are not adequately described in the QAPD.

- [62] We recommend that the next revision of the QAPD cover the Deputy Director's role in the QA activities of the PCCB.

## **APPENDIX A - ASSESSMENT TEAM MEMBERS AND ASSIGNMENTS**

### **Management Involvement Overview**

**Nona Shepard (RW-4)  
Stan Goldsmith (Weston)  
Brian Sealy (Duke)**

### **Director's Office (RW-1 and 2)**

**Jim Bresee (RW-10)  
Jim Brackett (Duke)**

### **Office of Quality Assurance (OQA)(RW-3)**

**Bob Barton (RW-20)  
Jim Wells (Duke)**

### **Office of Strategic Planning and International Programs (OSPIP)(RW-4) and Office of External Affairs (OEA)(RW-5)**

**Jim Bresee (RW-10)**

### **Office of Program and Resources Management (OPRM)(RW-10)**

**Rich Minning (RW-50)  
Stan Goldsmith (Weston)  
Jim Brackett (Duke)**

### **Office of Geologic Disposal (OGD)(RW-20)**

**Carl Conner (RW-10)  
Charlie Brooks (RW-30)  
Fielden Dickerson (RDA)  
John Miller (TRW)  
Dan Rains (Duke)**

**Office of Systems and Compliance (OSC)(RW-30)**  
Jay Jones (RW-40)  
Ed Taylor (TRW)  
Bill Leonard (Fluor)

**Office of Storage and Transportation (OST)(RW-40)**  
Susan Jones (RW-20)  
E.Y. Wong (TRW)  
Mark Wilkeshoff (Duke)  
Leo Seeber (TRW)

**Office of Contract and Business Management (OCBM)(RW-50)**  
Glen Gardner (RW-5)  
Stan Goldsmith (Weston)  
Vick Dixon (Duke)

**External Advisor: Tom Colandrea (Colandrea & Associates, Inc.)**

## **APPENDIX B - QUALIFICATION OF ASSESSMENT TEAM MEMBERS**

An Indoctrination and Training Matrix was completed for each member of the QA Management Assessment Team, documenting the completion of the following reading assignments:

- **Quality Assurance Requirements Document (QAR). DOE/RW-0214, Rev. 4**
- **Quality Assurance Program Description Document (QAPD). DOE/RW-0215, Rev. 3**
- **Quality Assurance Controls Document (QACD). DOE/RW-0289, Rev. 1**
- **QAAP 2.7, "Management Assessment".**
- **QAAP 16.1, "Corrective Action Requests".**
- **NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities.**
- **USNRC Review Plan for High-Level Waste Repository, Quality Assurance Program Descriptions, Revision 2, March 1989.**

## APPENDIX C - LIST OF DOCUMENTS REVIEWED

### AUDITS

90-001 (QA Program Review)	DR's 90-001 thru 90-016 OBS 90-001 thru 90-027 CAR 90-001
91-001 (OCRWM, YMP, & direct support contractors)	HQ-CAR's 91-001 thru 91-020 YMP-CAR's 91-05 thru 91-011
OCRWM QA Management Appraisal of OCR Nov. 13, 1986	

### SURVEILLANCES

OCRWM-HQ-SR-90-001	DR's 90-017 and 90-018
OCRWM-HQ-SR-90-002	No DR's or CAR's issued
OCRWM-HQ-SR-91-001	No CAR's issued
OCRWM-HQ-SR-91-002	CAR HQ-91-021 (indirectly)
OCRWM-HQ-SR-91-003	No CAR's issued
OCRWM-HQ-SR-91-004	CAR HQ-91-021 (indirectly)
OCRWM-HQ-SR-91-005	Report in progress: TBD
YMP-SR-90-021	SDR 497, 498, 508, 509
YMP-SR-90-037	SDR 598 & 599 OBS 37-1 thru 37-4

**SURVEILLANCES**

**YMP-SR-90-040**

**SDR 582 thru 593  
OBS 40-1 thru 40-5**

**YMP-SR-91-001**

**SDR 595**

**YMP-SR-91-003**

**No CAR's Issued**

**YMP-SR-91-006**

**No CAR's Issued**

**OTHER**

**OCRWM Operations Management Comprehensive Tracking System CAR Section**

## **APPENDIX D - LIST OF PEOPLE INTERVIEWED**

### **MANAGEMENT INVOLVEMENT OVERVIEW**

**Janet Arpia, OQA  
Robert Clark, OQA  
Allen Brownstein, OSTP  
Linda Desell, OSC  
Frank Peters, OCRWM**

### **DIRECTOR'S OFFICE (RW-1 & RW-2)**

**John Bartlett (RW-1)  
Frank Peters (RW-2)**

### **OFFICE OF STRATEGIC PLANNING AND INTERNATIONAL PROGRAMS (RW-4) and OFFICE OF EXTERNAL RELATIONS (RW-5)**

**Tom Isaacs (OSPIP)  
Jerry Saltzman (OER)**

### **OFFICE OF PROGRAM AND RESOURCES MANAGEMENT (RW-10)**

**Sam Rousso (OPRM)  
Barbara Cerny (OPRM)  
Harold Brandt (OPRM)  
Christine Lukasik (OPRM)  
Gladys Ruffin (KOH)  
Lou Robinson (KOH)  
Margie Shepard (KOH)**

### **OFFICE OF GEOLOGIC DISPOSAL (RW-20)**

**Max Blanchard, YMPO  
Russ Dyer, YMPO  
Ted Petrie, YMPO  
Mike Cloninger, YMPO  
Wendy Dixon, YMPO  
Winn Wilson, YMPO  
Jim Gardner, YMPO**

Dick Crawley, YMPO  
Roy Long, YMPO  
Lee Carpenter, YMPO  
Claudia Newbury, YMPO  
Cathrine Hampton, YMPO  
Mario Diaz, YMPO  
Carol Rehkop, YMPO  
Nancy Voltura, YMPO  
Jim Blaylock, YMPO  
Don Horton, OQA/YMPO  
Garth Phillips, YMPO  
Bob Barton, YMPO  
Bob Constable, YMPO  
Dean Stucker, OGD  
Alan Berusch, OGD  
Jane Stockey, OGD  
Stephan Brocum, OGD  
Elaine Bean, T&MSS  
Regina McCarthy, T&MSS  
Doug Chandler, T&MSS  
Dave Keller, T&MSS  
Sam Matthews, T&MSS  
Elaine Spangler, T&MSS  
John Waddell, T&MSS  
Albin Brandstetter, T&MSS  
Bob Klemens, T&MSS  
Nita Brogan, T&MSS  
Bob Bostian, T&MSS  
Jim Ryan, T&MSS  
Ken Gilkerson, T&MSS  
John Peck, T&MSS

**OFFICE OF SYSTEMS AND COMPLIANCE (RW-30)**

Dwight Shelor (OSC)  
Jack Hale (OSC)  
Susan Peterson (OSC)  
Choon Kooi Quan (OSC)  
Susan Grodin (Weston)  
Bill Lemeshefsky (OSC)  
Mark Senderling (OSC)  
Deborah Jerez (Weston)

Steve Gomberg (OSC)  
Linda Desell (OSC)  
Sharon Skuchko (OSC)  
Jerry Parker (OSC)  
Sat Goel (OSC)  
Deborah Valentine (OSC)  
Paul Krishna (PNL)

**OFFICE OF STORAGE AND TRANSPORTATION (RW-40)**

Ron Milner, OST  
Jim Carlson, OST  
Nello Del Gobbo, OST  
Jeff Williams, OST  
Chris Kouts, OST  
William Lake, OST  
Tom Pollog, OST  
Jay Jones, OST  
Bob Clark, OQA  
Margaret Fisher, DOE/ID

**OFFICE OF CONTRACT BUSINESS MANAGEMENT (RW-50)**

Vic Trebules (OCBM)  
Frank Peters (OCBM)  
Judy Leahy (OCBM)  
Barbara Jarrett (OCBM)  
Donna Johnson (OCBM)  
Richard Minning (OCBM)

**OFFICE OF QUALITY ASSURANCE (RW-3)**

John Bartlett, OCRWM  
Donald Horton, OQA  
Robert Clark, OQA  
Janet Arpia, OQA  
John Marchand, Weston  
Nancy Voltura, YMPO  
Robert Constable, YMPO  
Cathrine Hampton, YMPO  
Terry Nowland, T&MSS  
James Blaylock, YMPO  
Mario Diaz, YMPO  
Bruce Foster, T&MSS

## **APPENDIX E - PRIOR QA MANAGEMENT ASSESSMENTS**

In September, 1986, a QA management assessment of the Office of Civilian Radioactive Waste Management (OCRWM) was carried out. At the time of the assessment, there were three field site characterization projects for the repository program (in the states of Nevada, Texas, and Washington) as well as a separate Monitored Retrievable Storage program. The scope of the 1986 assessment was focused on the Headquarters Office of Geologic Repositories, which directed the three field projects. The appraisal results were reported in a November 13, 1986, memorandum (and accompanying ten-page report) from Merritt E. Langston, Manager, Quality Assurance, OCRWM to Stephen H. Kale, Associate Director, Office of Geologic Repositories.

Below are listed the twelve recommendations contained in that assessment report, together with comments on progress in achieving those goals:

1. "Develop and provide to the Director, OCRWM, an action plan with rationale for establishing a strong and independent HQ-OGR quality assurance management function with adequate staffing and at an appropriate organizational level for coordination and overview of ongoing and near-term HQ-OGR and project-level activities."

Progress: This recommendation has been implemented. In April, 1988, OCRWM established an independent Office of Quality Assurance headed by an Office Director reporting directly to the Director, OCRWM. Under the most recent reorganization, that office now supervises the work of both a headquarters Quality Assurance Division and also the Yucca Mountain Site Characterization Project Office (YMPO) QA activities.

2A. "Establish a comprehensive and coordinated HQ-OGR plan for indoctrination and training of HQ-OGR and project-level professionals who perform activities affecting quality."

Progress: Indoctrination and training has progressed greatly since 1986, but, as the present assessment suggests, has still some room for improvement.

2B. "Assume a more active leadership in overseeing project-level QA indoctrination and training activities."

Progress: The new QA management structure in which a single organization (the Office of Quality Assurance) oversees QA indoctrination and training at both headquarters and in the field has addressed this

recommendation.

**2C. "Develop measurable standards/elements for quality achievement and quality management improvement in appraisal plans for HQ-OGR technical managers and professionals."**

**Progress:** This recommendation has been implemented. QA elements are currently part of the appraisal plans of every professional in OCRWM.

**3A. "Reestablish dates for timely issuance of identified technical management procedures and for training of personnel in their use."**

**Progress:** The entire technical document hierarchy for OCRWM has undergone intense analysis and improvement during the recent past, and training in the use of the management procedures has kept pace.

**3B. "Complete the documentation and coordination of quality management systems, including review and tracking of HQ-OGR controlled milestone activities."**

**Progress:** The documentation and coordination of the QA management systems presently being used in OCRWM has been greatly improved since the 1986 assessment (e.g., QA milestone tracking appears to be effective under the aegis of the biweekly milestone tracking meetings of RW-2). However, as shown by the results of this current management assessment, additional strengthening in this area is still warranted.

**3C. "Develop a master plan and schedule for determining the readiness status of the HQ-OGR and project-level QA programs, including a listing of tasks to be completed, and issue dates for remaining supplemental requirements and implementing procedures."**

**Progress:** This recommendation has been implemented. This was particularly true in the months before the QA qualification audits in October, 1990.

**3D. "Implement graded QA approach on activities and contracts managed directly by HQ-OGD."**

**Progress:** Through the QA grading being used at YMPO and the QACD approach used at HQ, this recommendation has been implemented.

**3E. "Define the authority of the HQ-OGR QA Manager relative to**

decision making and direction at QACG meetings."

**Progress:** This recommendation has been implemented. Decision making and direction is implemented through a single OCRWM Quality Assurance organization, and coordination is achieved through regular QA meetings with the USNRC, attended by representatives of affected parties.

**4A. "Develop and promulgate HQ-OGR quality management systems for identifying and tracking significant quality problems and NRC issues, and for lifting stop-work orders."**

**Progress:** As was reported under "Progress" for Item 3B. above, QA tracking has improved greatly since 1986 under the Operations Management Tracking System (OMTS) supervised by RW-2. NRC QA issues and commitments are separately tracked by RW-3. The lifting of stop-work orders is covered by QAAP 16.2.

**4B. "Re-evaluate the Ford Amendment Study and take appropriate actions to ensure implementation of applicable lessons to be learned for waste repositories."**

**Progress:** The Ford Amendment Study (NUREG 1055) provided recommendations for improving quality of design and construction of nuclear power plants. Through close liaison with EEI's UWASTE group and close consultation with the new OCRWM M&O contractor (one party of which is Duke Engineering), lessons learned in the nuclear power industry which are applicable to the waste repository program are being incorporated into OCRWM.

**5. "Plan and implement a strong, comprehensive HQ-OGR QA management overview activity which will provide for the performance of management appraisals, technical assessments and audits on a timely basis commensurate with the major program milestone events."**

**Progress:** Until recently, there have been shortcomings with respect to the adequacy of OCRWM's response to this recommendation. Management assessments were not performed during the period 1987-1990. However, during the sixteen month period covered by this assessment, the situation has greatly improved. At the beginning of the period (February 1990), an informal assessment was performed to evaluate the readiness of the OCRWM QA program to carry out a qualification audit. That informal assessment identified many QA inadequacies, and corrective actions were initiated which have greatly strengthened the QA program. The qualification audit in October 1990, was generally successful. The present QA management assessment was ordered by

the Director, OCRWM, after the acceptance by the US Nuclear Regulatory Commission of the readiness of OCRWM to begin certain specific surface-based testing activities at Yucca Mountain under adequate QA controls.

The OCRWM senior management is committed to annual QA management assessments in the future.

## APPENDIX F - LIST OF ACRONYMS

ADP	Automated Data Processing
CAR	Corrective Action Request
CRF	Central Record Facility
DOE/ID	Idaho Operations Office (DOE)
DOE/CH	Chicago Operations Office (DOE)
DR	Deficiency Report
EEl	Edison Electric Institute
FTE	Full Time Equivalent
HQ	Headquarters (DOE)
I&T	Indoctrination and Training
ILP	Implementing Line Procedure
INPO	Institute of Nuclear Power Operations
M&O	Management and Operations
MRS	Monitored Retrievable Storage
MSIS	Management Systems Improvement Strategy
NRC	Nuclear Regulatory Commission
NVO	Nevada Operations Office (DOE)
OCBM	Office of Contract Business Management
OCRWM	Office of Civilian Radioactive Waste Management
OGD	Office of Geologic Disposal
OPRM	Office of Program and Resources Management
OQA	Office of Quality Assurance
OST	Office of Storage and Transportation
PCCB	Program Change Control Board
QA	Quality Assurance
QAAP	Quality Assurance Administrative Procedure
QACD	Quality Assurance Control Document
QAPD	Quality Assurance Program Description
QAR	Quality Assurance Requirement
QRC	Quality Assurance Record Center
RW	DOE Designation of OCRWM
SEMP	System Engineering Management Plan
SQAP	Software Quality Assurance Procedure
SWO	Stop Work Order
TQM	Total Quality Management
YMPO	Yucca Mountain Site Characterization Project Office

## 1.0 INTRODUCTION

From March 25-29, 1991, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. 91-03 of Los Alamos National Laboratory (LANL), which was conducted in Los Alamos, New Mexico. LANL, a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible for radionuclide migration, geochemistry, mineralogy, and petrology studies, and is the lead organization for the coordination and scheduling of the site characterization activities in the Exploratory Studies Facility. This report addresses the effectiveness of the DOE/YMPO audit and the adequacy and effectiveness of implementation of the LANL QA program for YMP work.

## 2.0 OBJECTIVES

The objectives of the DOE/YMPO audit were to determine the adequacy and effectiveness of implementation of the LANL QA program in meeting the applicable requirements of the DOE Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD) for the YMP work. The NRC staff's objective was to gain confidence that DOE and LANL are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE/YMPO audit and determining whether the LANL QA program is in accordance with the requirements of the OCRWM QARD and Title 10 of the Code of Federal Regulations, Part 50 (10 CFR Part 50), Appendix B.

## 3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMPO audit process and the LANL QA program on direct observations of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., audit plan, checklists, and LANL documents).

The NRC staff found that, overall, DOE/YMPO Audit No. 91-03 of LANL was effective. The programmatic and technical portions of the audit, including their subsequent integration, were effective. The NRC staff concluded that the DOE/YMPO audit team, in general, was well qualified and prepared and conducted the audit in a professional manner. The audit team was familiar with the requirements of the OCRWM QARD and the LANL Quality Assurance Program Plan (QAPP) and their checklists were well prepared and used effectively.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that: 1) the LANL QA program, in general, is adequate to control QA-related activities, and 2) LANL, overall, is satisfactorily implementing an effective quality assurance program in accordance with the LANL QAPP and procedures. The NRC staff also agrees with the audit team's conclusion that one specific element of the LANL QAPP (Section 13, Handling, Storage and Shipping) was considered indeterminate due to lack of activity.

The audit team identified 10 deficiencies during the audit, and all but one were resolved prior to the post-audit conference. The one unresolved deficiency was related to inconsistencies between the LANL QAPP and implementing procedures. This deficiency was documented by the audit team in a Corrective Action Request (CAR) No. YM-91-041.

## **5.10 Summary of NRC Staff Findings**

### **(a) Observations**

The NRC staff did not identify any observations relating to deficiencies in either the DOE/YMPO audit process or the LANL QA program.

### **(b) Weaknesses**

- o The DOE/YMPO technical specialists used SPs and monthly progress reports as bases for developing technical checklists. These monthly progress reports were not included in the audit notebooks sent to the observers. This put the observers at a disadvantage for preparing for this audit. During the audit these reports were made available to the observers but this was too late for the NRC observers to use the material effectively. It is recommended that, in the future, materials such as monthly progress reports used to prepare the technical checklists be included in the audit notebooks.

### **(c) Good Practices**

- o The software QA program is being implemented in an effective manner.
- o There is a strong commitment and support for an effective QA program at the management level. The TPO at LANL has a good knowledge of the QA requirements and demonstrated a positive attitude toward an effective QA program.

## 1.0 INTRODUCTION

From June 3-7, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. 91-01 of Lawrence Livermore National Laboratory (LLNL) conducted in Livermore, California. LLNL, a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible for the development of a waste package which includes the definition of the package environment, waste package material development and testing, and waste package design, performance analysis, and testing. LLNL also provides assistance to other YMP participants in areas of specialized expertise.

This report addresses the effectiveness of the DOE/YMPO audit and, to a lesser extent, the adequacy of the LLNL QA program.

## 2.0 OBJECTIVES

The objectives of the DOE/YMPO audit were to evaluate the implementation and effectiveness of the LLNL QA program. The NRC staff's objective was to gain confidence that DOE and LLNL are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE audit and determining whether the LLNL QA program is in accordance with the requirements of the DOE/Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD).

## 3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMPO audit process and the LLNL QA program on direct observations of the auditors, discussions with the audit team and LLNL personnel, and reviews of pertinent audit information (e.g., the audit plan checklists, and LLNL documents). The NRC staff has determined that, overall, Audit No. 91-01 of LLNL achieved its purpose of determining the effectiveness of the LLNL QA program implementation for the areas that were audited. The audit was conducted in a professional manner. The audit team was well prepared, and their checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that the LLNL QA program was effectively implemented for the areas that were audited, considering the limited amount of work being conducted under the QA program, with the exception that Audits (Criterion 18) was not effectively implemented. However, LLNL should initiate timely corrective actions for the weaknesses identified by the DOE/YMPO audit team and NRC staff.

One Observation (Level 3) was noted by the NRC staff in the QA Program area (Criterion 2). Changes are being made to the NRC accepted LLNL QA Program Plan (QAPP) and are not being transmitted to the NRC staff. This subject has been discussed between DOE and NRC at several of the NRC/DOE QA meetings, and it was agreed that DOE would transmit all changes to the NRC accepted DOE QA programs to the NRC as an "information copy."

The NRC staff is also concerned about what appears to be inadequate communication of QA issues to the respective LLNL individuals and organizations as observed at the audit entrance meeting and in the calibration area.

## 5.10 Summary of NRC Staff Findings

### (a) Observations

Since NRC accepted the LLNL QAPP (ref. October 24, 1988 letter from J. Linehan to R. Stein), several changes have been made to it. These changes have not been furnished to the NRC staff as previously agreed

### (b) Weaknesses

- o A substantive amount of LLNL's activities appear to be conducted under a graded QA approach and designated as "scoping." These activities could produce data that may be used for licensing purposes but at present, are not subject to the QA auditing process. Should this data be used for licensing, it would have to be requalified. It may be beneficial for LLNL to consider subjecting "scoping" activities to the QA process to preclude having to repeat or requalify this data (Refer to Section 5.3(a)).
- o It is the NRC staff's evaluation that there is insufficient QA involvement in the LLNL YMP activities to effectively communicate QA issues to involved personnel. During the audit, it was understood that the ESG was not qualified to do electronic equipment calibrations and therefore, not included as part of this audit. Just prior to the conclusion of the audit, documentation was produced as a result of an NRC Audit Observation Inquiry indicating the ESG was qualified on April 19, 1991. Also, the QA organization did not appear to be as involved and available to the auditors as they normally have been in previous audits. (Refer to sections 5.3(a) and 5.3(g)).
- o At the entrance meeting prior to starting the audit, there was no presentation from LLNL staff to give an overview of the organization, ongoing work, and establish contacts for the auditors. (Refer to Section 5.5)
- o Corrective actions and closeout of all previously issued SDRs/CARs were supposedly verified prior to this audit. The NRC staff looked at only one of the previously closed out SDRs and noted the closeout of the corrective action was not entirely accurate. The NRC staff recommends that DOE/YMPO audit teams increase their attention to the closeout and corrective action aspects of prior SDRs/CARs.

### (c) Good Practices

- o The EMA calibration facility was well developed and implemented in an effective manner. EMA personnel were knowledgeable and the laboratory notebooks were maintained in a neat, orderly manner.
- o Personnel qualification records were well documented and accurate to facilitate reviews and audits.

## SURVEILLANCE OBSERVATION REPORT NO. 91-S6

### 1.0 INTRODUCTION

The United States Geological Survey (USGS), a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible for conducting geologic, geophysical, hydrologic, and seismologic investigations in support of the U.S. Department of Energy's (DOE) waste management and site characterization activities for the YMP. The investigations are ongoing at the Nevada Test Site and the USGS offices in Denver, Colorado; Menlo Park, California; and Las Vegas, Nevada.

On June 12 and 13, 1991, the DOE/Yucca Mountain Site Characterization Project Office (YMPO) conducted a quality assurance (QA) surveillance (YMP-SE-91-020) of the USGS YMP QA program at the Yucca Mountain Site. This surveillance was conducted in accordance with the YMPO Quality Management Procedure (QMP)-18-02, Revision 2, "Surveillance." A member of the U.S. Nuclear Regulatory Commission (NRC) staff participated in the surveillance as an observer. This report documents the staff's assessment of the effectiveness of the DOE/YMPO surveillance, the adequacy of the USGS QA program procedural controls, and procedural implementation under Criterion 12 of the Code of Federal Regulations Title 10, Part 50, Appendix B.

### 2.0 PURPOSE

This DOE/YMPO surveillance evaluated the adequacy of procedural controls and their implementation under selected program elements of the USGS QA program. The staff's purpose in observing this surveillance was to gain confidence that the DOE and its contractors are properly implementing the requirements of their QA programs by assessing the effectiveness of the DOE/YMPO surveillance and determining the adequacy of the USGS QA program in the areas surveilled.

### 3.0 SCOPE

The DOE/YMPO auditors selected Criterion 12, "Control of Measuring and Test Equipment" from the USGS QA Program Plan (QAPP) for review and assessment of adequacy of procedural controls and procedural implementation. The specific area reviewed was the control and use of measurement and test equipment. The scope of this surveillance did not include any review of the technical adequacy and qualification of technical products and activities such as technical procedures, laboratory notebooks and data, or field notebooks and data.

#### 4.0 SURVEILLANCE PARTICIPANTS

##### DOE/YMPO

John Martin, Science Application International Corporation  
Charlie Warren, Management Analysis Corporation Technology

##### NRC

John W. Gilray, Observer

#### 5.0 SURVEILLANCE SUMMARY RESULTS

The DOE/YMPO auditors reviewed a number of USGS procedures used in taking scientific measurements associated with sub-surface moisture content, wind speed, seismic activity, temperature, and relative humidity to identify QA requirements. In addition, the auditors visited four remote measurement locations at the Yucca Mountain site and evaluated the calibration process and records of the measurement instrumentation to determine acceptability of compliance with these procedures.

The surveillance was based on requirements in the following USGS Quality Assurance Technical Procedures: HP-60,R1 - "Method for Monitoring Water-Level Changes Using Pressure Transducers," HP-62,R5 - "Method for Measuring Sub-Surface Moisture Content Using a Neutron Moisture Meter;" HP-96,R0 - "Measurement of Wind Speed Using a Met-1 Model 014AS," HP-97,R0 - "Measurement of Temperature and Relative Humidity Using a Campbell Scientific, Inc. 207 Temperature and Relative Humidity Probe," HP-160,R1 - "Methods of Analysis of Samples for Gas Composition by Gas Chromatography," HP-168,R0 - "Measurement of Energy Flux Density by a Pyranometer," HP-170,R1 - "Method for Measuring Temperature Using a Campbell Scientific, Inc. 107 Temperature Probes;" and SP-11,R2 - "Operation and Calibration of Remote Telemetered Seismic Array."

The auditors concluded that the procedural controls under Criterion 12 are generally adequate and their procedural implementation is satisfactory. No adverse procedural or implementation deficiencies were identified.

#### 6.0 CONTACTED DURING THE SURVEILLANCE

Dee E. Overturf, Technical Manager, USGS  
James R. Brooks, Technician, USGS  
William J. Davies, Technician, USGS  
Michelle Baucher, QA Specialist, USGS  
Tracy Mendez Vigo, QA Specialist, USGS  
Ken W. Causseaux, Sr. QA Specialist, USGS

## 7.0 NRC CONCLUSIONS

The staff observer found the DOE/YMPO surveillance of the USGS QA program useful and effective. The DOE/YMPO auditors were well prepared and were familiar with the USGS QAPP requirements and relevant implementing procedures for the areas surveilled. The surveillance plan for this surveillance was thought-out and used in determining the adequacy of procedural controls under Criterion 12. The auditors were thorough and professional in conducting the surveillance and asked substantial questions to gain information required to demonstrate adequacy of implementation.

In general, the USGS personnel were cooperative, and retrievability of documentation requested by the auditors was generally very good.

The NRC staff agrees with the DOE/YMPO auditor's preliminary conclusions that the USGS QA program provides adequate procedural controls and that the procedural implementation covered by this surveillance is also adequate.

## SURVEILLANCE OBSERVATION REPORT NO. 91-S10

### 1.0 INTRODUCTION

Raytheon Services Nevada (RSN), a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible to the U. S. Department of Energy (DOE) Yucca Mountain Site Characterization Project Office for providing architecture and engineering services to support the investigations at Yucca Mountain in support of testing to determine the suitability of the site for a potential high-level waste repository. RSN is responsible for the design and inspection of the Exploratory Studies Facility, both surface and subsurface. RSN also provides support for the Surface Based Testing Program in the form of drilling engineering, materials testing, and non-destructive examination.

On June 24 and 25, 1991, the U. S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) conducted a quality assurance (QA) surveillance (YMP-SR-91-021) of the RSN YMP QA program at the Yucca Mountain Site. This surveillance was conducted in accordance with the YMPO Quality Management Procedure (QMP)-18-02, Revision 2, "Surveillance." A member of the U. S. Nuclear Regulatory Commission (NRC) staff participated in the surveillance as an observer. This report documents the staff's assessment of the effectiveness of the DOE/YMPO surveillance, the adequacy of the RSN QA program procedural controls, and procedural implementation under Criteria I, V, XVI, and XVIII of the Code of Federal Regulations Title 10, Part 50, Appendix B.

### 2.0 PURPOSE

This DOE/YMPO surveillance evaluated the adequacy of procedural controls and their implementation under selected program elements of the RSN QA program. The staff's purpose in observing this surveillance was to gain confidence that the DOE and its contractor are properly implementing the requirements of their QA programs by assessing the effectiveness of the DOE/YMPO surveillance and determining the adequacy of the RSN QA program in the areas surveilled.

### 3.0 SCOPE

The DOE/YMPO auditors selected Criteria I, "Organization;" V, "Instructions Procedures and Drawings;" XVI, "Corrective Action;" and XVIII, "Audits" from the RSN QA Program Plan (QAPP) for review and assessment of adequacy of procedural controls and procedural implementation. The scope of this surveillance did not include any review of the technical adequacy and qualification of technical products and activities such as technical procedures, laboratory notebooks and data, or field notebooks and data.

#### 4.0 SURVEILLANCE PARTICIPANTS

DOE/YMPO - John Martin and Bob Klemens, Science Application International Corporation.

NRC - John W. Gilray, Observer

#### 5.0 SURVEILLANCE SUMMARY RESULTS

The DOE/YMPO auditors reviewed the RSN QA Program Description for the YMP and the following RSN quality procedures: QAP 1.1, "Organization;" QAP 5.1, "Development of QA Procedures;" QAP 6.1, "QA Controlled Document Distribution;" QAP 6.2, "Review of Documents;" QAP 16.1, "Deficiency Reporting;" QAP 16.2, "Corrective Action;" QAP 16.3, "Trend Analysis;" QAP 18.1, "Audits;" and QAP 18.2, "Surveillances", to identify applicable QA requirements. The RSN QA Program Description for the YMP was approved by the YMPO February 22, 1991, and is in full implementation.

The auditors concluded that the procedural controls under Criteria I, V, XVI, and XVIII are generally adequate, and their procedural implementation is satisfactory. No adverse procedural or implementation deficiencies were identified.

#### 6.0 CONTACTED DURING THE SURVEILLANCE

Mike Regenda, Manager, Quality Assurance  
Richard Bullock, Technical Project Officer  
Arshad Ali, Manager, Audit and Surveillance  
Dan Tunney, Manager, QA Engineering  
Ron Sabol, QA Sr. Specialist  
Bob Dahlberg, QA Specialist  
Harry Tutthill, Manager, Quality Control

#### 7.0 NRC CONCLUSIONS

The staff observer found the DOE/YMPO surveillance of the RSN QA program useful and effective. The DOE/YMPO auditors were well prepared and were familiar with the RSN requirements and relevant implementing procedures for the areas surveilled. The surveillance plan for this surveillance was well thought-out and used in determining the adequacy of procedural controls under Criteria I, V, XVI, and XVIII. The auditors were thorough and professional in conducting the surveillance, and asked substantive questions to gain information required to demonstrate adequacy of implementation.

In general, the RSN personnel were cooperative, and retrievability of documentation requested by the auditors was generally very good.

The NRC staff agrees with the DOE/YMPO auditors' preliminary conclusions that the RSN QA program provides adequate procedural controls and that the procedural implementation covered by this surveillance is also adequate.

STATUS OF NRC/DOE OPEN ITEMS - AUGUST 29, 1991

\*\*\* BRACKETED PORTIONS INDICATE CHANGES RESULTING FROM 6/25/91 QA MEETING OR ADDED AS A RESULT OF NRC REVIEW ACTIONS.

ITEM	DESCRIPTION	STATUS	RECOMMENDATION FOR CLOSURE/REMARKS
3-90	NNWSI Core Handling Procedures	Open	DOE submitted the Core Handling procedures to the NRC staff in a 8/11/89 transmittal (Gertz to Stein). The issues raised in the YMP Surveillance Report (YMP-SR-89-134) will need to be resolved before this item can be closed. NRC will determine acceptability of implementation and adequacy of procedures when they are issued in final form and subsequently implemented. At the 11/8/90 QA meeting, DOE indicated that based on the prototype drilling at Apache Leap, the procedures have been revised and should be submitted for NRC review and comment before the end of 1990. No change in status <u>resulting</u> from 1/18/91, 4/25/91, or <u>6/25/91</u> QA meetings.
4-90	Qualified QA Program before start of new site characterization activities.	Open	DOE has made a commitment to having a qualified QA program before the start of new site characterization activities. However, this item remains open up until the the NRC staff accepts the DOE QA program as qualified for the start of new site characterization activities. At the 11/8/90 QA meeting, NRC provided a letter (Linehan to Shelor dated 10/24/90) which addresses the acceptance of (6) participant QA programs. The NRC accepted the QARD/QAPD 12/3/90 (see open item 12-90). Subsequent NRC letters of 1/18/91 & 3/11/91 state that the OCRWM QA program is acceptable only for new site characterization activities associated with Midway Valley Trenching and Calcite-Silica Activities. The 8/1/91 DOE transmittal of the Raytheon QA Program for NRC review and acceptance is in process. NRC finds the DOE 7/16/91 transmittal of Rev. 4 to the T&MSS (SAIC) QA program acceptable and is preparing the NRC Safety Evaluation.

8-90	SCA comments	Open	Responses provided to NRC 12/14/80, NRC comments issued to DOE 7/31/91, wtg. DOE response.
10-90	Responses to NRC Observation Audits		DOE should respond within 30 days after NRC Observation Audit Report transmittal. The DOE responses are to be reviewed and considered by NRC staff in accepting DOE QA programs. DOE should respond to the following NRC staff Observation Audit Report:
10.e	LLNL	Open	(1) Observation noted in the 7/31/91 NRC Obs. report: Changes made to the LLNL QA Program Plan w/o being furnished to NRC as previously agreed to by DOE.
11-90	DOE QA Participants Acceptance Letter Dated 10/24/90	Closed (see 4-90 above)	DOE should provide a response to the open items for the following DOE participant QA programs: FSN-Procurement Software } H&N-Procurement Software } Combined as RSN-see Open Item 4-90 REEC-Privacy Act-Closed-NRC 8/15/91 Acceptance ltr. USGS -Privacy Act-Closed-NRC 8/16/91 Acceptance ltr.
12-90	DOE QARD/QAPD Acceptance Letter Dated 12/3/90	Open	DOE should provide a response to the (6) open items listed for the NRC review of the QARD/QAPD. NRC staff presently evaluating the 8/21/91 DOE response.
1-91	NRC 4/15/91 letter accepting QARD/QAPD for MRS & Transport of Spent Fuel	Open	DOE should provide a response to the (5) comments listed for the NRC review of the QARD/QAPD pertaining to MRS & transport of spent fuel. NRC presently evaluating the 8/21/91 DOE response.

## QUALITY ASSURANCE WORKSHOP STATUS

June through August 1991

1. Scientific/Quality Assurance Workshop

The Quality Integration Group (QIG) met July 27-29 at MACTEC/San Diego office to review applicability of NQA-3 for the scientific community. A letter noting results, comments and recommendations was sent to Don Horton on August 3.

QIG did not recommend endorsement of NQA-3. The standard does not represent scientific methods and attempts to regulate scientific investigation from an engineering perspective.

The QIG met again August 7 & 8 at Las Vegas to review the latest draft of the Quality Assurance Requirements and Policy (QARP) for application to scientific investigation/research. A letter delineating results is being sent to Don Horton on August 23.

2. Software Workshop

The Software Advisory Group (SAG) met June 19-21 at USGS/Denver to rewrite the old Section 19 and to address the 39 issues identified in the previous review. At the completion of this meeting, SAG agreed that all issues were addressed in the consensus rewrite document.

The old Section 19 will become Supplement I, Computer Software, of the new QARP document. The draft document computer software was submitted to DOE QA for incorporation into the QARP on June 28.

3. Quality Assurance "Grading" Workshop

• PROCEDURE WILL BE DONE 9/30/91  
• Q LIST UPDATED TO NEW BASELINE OF CONCEPTUAL DESIGN

~~Implementation of new grading process is pending a vision statement and guidance for implementation from Project Management.~~

4. Data (identified as a condition in the Lakewood, Colorado Issue meeting)

A letter is being prepared to Project Management, Carl Gertz, from Don Horton reporting results of data interviews at the different laboratories and recommendations for improvements.



Department of Energy  
Yucca Mountain Site Characterization  
Project Office  
P. O. Box 98608  
Las Vegas, NV 89193-8608

WBS 1.2.9.1  
QA: N/A

JUN 18 1991

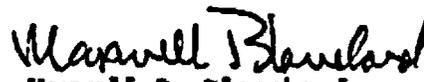
Robert V. Barton, Chairman, Quality Assurance Workshop Review Team, YMP, NV  
QUALITY ASSURANCE (QA) GRADING WORKSHOP

As a result of the QA Grading Workshop, a number of recommendations were presented to management by a review team consisting of participants in the workshop. Management endorsement or revision of this set of recommendations was considered necessary by the review team as a prerequisite for completion of other action items resulting from the Grading Workshop.

Accordingly, management action (enclosure 1) and review team recommended actions (enclosure 2) are included herewith. You are encouraged to implement these actions as soon as possible. To this end, please provide a plan of your intended resulting actions including a schedule of major events by July 1, 1991.



Donald G. Horton, Director  
Office of Quality Assurance



Maxwell B. Blanchard  
Deputy Project Manager

YMP:MBB-4248

Enclosures:

1. Management Action
2. Review Team Recommended Actions

Robert V. Barton

- cc W/encl:
- Robert Clark, HQ (RW 3.1) FORS
- James Blink, LLNL, Livermore, CA
- S. L. Bolivar, LANL, Los Alamos, NM
- Tom Colandrea, Colandrea & Associates, Inc., San Diego, CA
- R. C. DeKlever, RSN, Las Vegas, NV
- A. H. Handy, USGS, Lakewood, CO
- D. I. Hulbert, SAIC, Las Vegas, NV
- R. R. Richards, SNL, 6319, Albuquerque, NM
- N. A. Voltura, YMP, NV

# **GRADING PROCESS REVISION PLAN**

- **RECAP**
- **Planned Work with Target Dates**
- **Management, Administrative, and other Management Control Systems (MCS) List Draft Letter**

# **GRADING ENHANCEMENTS**

## **Salient Features**

- o REVIEW TEAM (consisting of representatives of each participant) will develop grading enhancements plan and shepard it through to implementation.**
  - Procedure revisions necessary**
  - MCS list criteria**
  - Examples of classification and grading**
  - Methods to communicate process to users**
  - Schedule**

# GRADING PROCESS REVISION PLAN

	<b>TARGET DATE</b>
<b><u>PROCEDURE REVISIONS - DETERMINATION OF IMPORTANCE &amp; GRADING</u></b>	
• Markup Existing Procedures	<b>8/30/91</b>
• Meld in separately prepared "Q" & MCS List Procedure Drafts	<b>9/30/91</b>
• Complete QMP 06-04 Procedure Approval	<b>10/18/91</b>
<b><u>INDOCTRINATION &amp; TRAINING</u></b>	
• Develop Indoctrination & Training Program	<b>9/30/91</b>
• Complete Initial Cadre Training	<b>10/31/91</b>

# GRADING PROCESS REVISION PLAN

<u>PERFORMANCE BASED Q-LIST</u>	<u>TARGET DATE</u>	<u>PURPOSE</u>
<ul style="list-style-type: none"> <li>• <b>Shifting "Q" List from Direct Inclusion to Performance Based Process</b> <ul style="list-style-type: none"> <li>- <b>Baseline the SCP CDR and App. F</b> <span style="float: right;">8/15/91</span></li> <li>- <b>Update the Items Important to Safety (ITS) List</b> <span style="float: right;">8/30/91</span></li> <li>- <b>Baseline the Performance Assessment and other Evaluation Documents used to identify ITS and IITWI</b> <span style="float: right;">8/30/91</span></li> <li>- <b>Draft Modifications to AP 6.17Q</b> <span style="float: right;">8/30/91</span></li> </ul> </li> </ul>		<p><b>Establish the SCP physical configuration baseline and use as basis for draft ITS.</b></p>
<ul style="list-style-type: none"> <li>• <b>Performance Based "Q" Lists</b> <ul style="list-style-type: none"> <li>- <b>IITS</b> <ul style="list-style-type: none"> <li>Update CDR to ESF Title I Configuration <span style="float: right;">8/30/91</span></li> <li>Update IITS <span style="float: right;">9/30/91</span></li> </ul> </li> <li>- <b>IITWI</b> <ul style="list-style-type: none"> <li>Develop IITWI Reflecting new QARD and Baseline Documents - Existing Quality Activities List to be superseded <span style="float: right;">9/30/91</span></li> </ul> </li> </ul> </li> </ul>		<p><b>Baseline current knowledge and use as basis for updating the ITS and defining IITWI.</b></p>

# GRADING PROCESS REVISION PLAN

<u>MANAGEMENT CONTROL SYSTEM LIST</u>	<u>TARGET DATE</u>	<u>PURPOSE</u>
<ul style="list-style-type: none"> <li>• <b>Controls for Management Plans and conduct of similar management activities</b></li> </ul>	<b>7/31/91</b>	<b>Uniform Project approach.</b>
<ul style="list-style-type: none"> <li>• <b>Other Regulatory (non-NRC App. B) Coverage (NEPA, MSHA, DOE Orders, NRC Non-Q)</b> <ul style="list-style-type: none"> <li>- <b>Identify Requirements Documents</b></li> <li>- <b>Identify Requirements</b></li> <li>- <b>Ensure Requirements are Baseline (MSIS)</b></li> <li>- <b>Develop Procedure Draft for MCS Controls</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><b>8/15/91</b></li> <li><b>8/30/91</b></li> <li><b>9/15/91</b></li> <li><b>9/15/91</b></li> </ul>	<b>Trace requirements and apply appropriate controls.</b>

ATTACHMENT A

VISION STATEMENT

OCFWM will implement a classification process that will result in two categories of items:

1. Q-List - Items important to radiological safety and waste isolation, including the natural items important to waste isolation.
2. MCS Management Control System (MCS) List - Other items, whose importance to the successful accomplishment of the OCFWM mission, warrants application of selected controls.

DEFINITIONS AS APPLIED TO CLASSIFICATION AND GRADING

**Classification -** The process of determining the functions, and end uses of an item. The results of this process will provide the information necessary to determine whether an item is placed on the "Q" list or "MCS" list.

**Grading -** The process of identifying administrative and technical controls that will be applied to an item. The purpose of this process is to establish a level of confidence that the item meets its functional performance and end use design requirements.

QUESTIONS AND ANSWERS

I. Quality Program and QA Organization Coverage

- a. Is it intended that a quality program (as distinct from the QA Organization) be developed for application to the total OCFWM program?

Answer - Appropriate controls shall be employed in all OCFWM endeavors. For the NRC license based portion of OCFWM activities the controls required by the QARD are applicable. Other OCFWM activities will be subject to controls determined by management.

- b. Should the QA Organization responsibilities be limited to the "Q" (10CFR60 Subpart G) program only?

Answer - The responsibilities of the QA Organization are as defined in the QARD and QAPD. As such, the QA Organization is the responsible in-house overview organization for OCFWM's QARD responsibilities. The QA Organization will, in addition, provide comparable oversight for other program activities to the extent that they are separately requested and funded by management.

## II. Grading Coverage

- a. Should grading be applied to "Q" items only?

Answer - No

- b. Should grading be applied to "Q" and Management Control System (MCS) items?

Answer - The application of controls required to assure the quality for both "Q" List items and Management Control System (MCS) items is required for the OCFWM Program. Implicitly this is done for "Q" items by appropriate application of the participant's QA Program. For MCS items this is done explicitly by the specific controls to be placed on the item based upon criteria established by DOE management.

- III. Should the Project Office request the NRC for a deviation from the NUREG-1318 requirement for a Quality Activity List in favor of a "Q" Items List only which would include natural items? (Activities associated with items would take on the importance of the items with which they are associated.)

Answer - No. The QA Organization is in the process of revising the QARD and QAPD. This document combination will be changed to reflect the use of a "Q" List only. Since this is not considered to be a reduction in commitment, a specific request for elimination of the Quality Activities List is not considered necessary.

## IV. Centralized vs Decentralized Grading/Classification

- a. Should grading be centralized and be performed by a group of technical experts who identify applicable criteria?

Answer - No for Grading; Yes for Classification.

- b. Should identification of criteria as well as controls be developed under the aegis of a central grading group?

Answer - Yes for criteria to be used for classification; No for controls to be used in implementation.

- c. Should grading be decentralized such that each participant would identify its own criteria and controls?

Answer - Yes for controls.

For amplification of these answers please see following discussion.

Classification: (Centralized for both the "Q" List and MCS List)

1. The DOE will establish the criteria to be used to classify items. These criteria will be based on licensing requirements for "Q" items and the definition of Mission Importance for MCS items.

2. Based on the DOE developed criteria, the Assessment Team process will identify the functional performance and end use design requirements for items, establish the initial versions of the "Q" and MCS Lists, and distribute both to all participating organizations. Further (lower tier) classification will be performed by the responsible participating organizations according to the criteria established in 1. above and the functional performance and end use design requirements to be promulgated with the initial versions of the "Q" and MCS Lists.
3. The DOE will review and approve the classifications performed by the responsible participating organization.
4. The DOE is responsible for determining those non-Q list items that are important to the success of the OCFWM mission. Therefore, the DOE will identify the items, and establish criteria to be used with those items placed on the MCS list.
5. The DOE will maintain a master "Q" list and a master MCS list.

Grading: (Decentralized as noted below)

1. Decentralized for "Q" list items - Participating organizations will grade "Q" items and activities within their scope of work by the application of controls appropriate to the items as prescribed by their QA Program.
  2. Decentralized for MCS items - The participant will identify the specific controls for each item on the MCS List according to the criteria established by the DOE.
- V. Should the above identified "review team" be designated as a standing committee to review and make recommendations on future issues which arise in the grading process? It being the understanding that they meet by telecon or in person only when needed.

Answer - Although the answer to question IV above may eliminate the need for the "review team" in the long term, the "review team" will remain functional during the implementation of the revised grading process to assure a smooth transition.

#### DESCRIPTION OF CLASSIFICATION AND GRADING

**CLASSIFICATION** - The classification process will require the development of criteria for determining the classification of items on the basis of (1) the definition of waste isolation and importance to radiological safety; and (2) importance to the OCFWM mission. These criteria will then be used to identify the functional performance and end use design requirements which will, in turn, result in the identification of "Q" List and MCS items. It should be noted that an item is not to be placed on the "Q" List just because it is built to "Q" standards.

The classification process will systematically break down the repository into component parts. These parts will then be classified according to criteria established for waste isolation and radiological safety. This systematic process continues until all elements of a structure, system or component is broken down to its lowest level. Each participant's QA program should include controlling procedures which describe the process for breaking an "item" down to its lowest level.

**GRADING** - The application of administrative and technical controls is to be consistent with the item's classification.

The controls of the QA Program are to be appropriately applied to "Q" List items. This process, which is to be proceduralized should also enable accommodation of the unique and the common nature of individual "items" and subparts.

Management will identify the specific criteria applicable to MCS items. Participants will select the specific procedural controls to be applied to MCS items based on established criteria. These controls may include use of "Q" procedures for MCS items as determined by appropriate management.

#### EXAMPLES OF CLASSIFICATION AND GRADING

##### **CLASSIFICATION**

In each of the "engineered item" cases (commercial, off-the-shelf items or design and build from scratch) the key to determining its "Q" nature is to determine the end use characteristics of the item (system, structure or component). If one or more of these characteristics is important to the radiologic health and safety of the public, then the item is a "Q" List item. Further breakdown of the item into its component parts is frequently required to: 1) separate those parts to which application of "Q" controls are necessary from those which are not important to public radiologic health and safety, and 2) enable examination of the intrinsic characteristics of a part which might in their own right and under some operating mode(s) have an adverse effect on public radiologic health and safety (sometimes referred to as the "2 over 1 concept").

As an "engineered item" example, let us examine the "engineered barrier system". The overall Waste Isolation system has been examined in some detail and, within this larger system, the "engineered barrier system" (EBS) contributes to the 10000 year total required isolation period for radioactive material to reach the accessible envirosphere. This time period for radionuclides to be substantially contained within the waste package boundary is a minimum of 300 years and a maximum of 1000 years. Since the 300 to 1000 year radionuclide hold up time period has been specified as a performance requirement for the waste package the waste package is therefore identified as a "Q" List item.

The waste package however is a system made up of subsystems, components and parts. As this system is broken down into its "parts", (which it must be to effectively manufacture the "parts" which will make up a system which meets overall system requirements) the performance requirement of 300 to 1000 years must also be allocated appropriately to each of the "parts". Some of the

"parts" may have nothing to do with 1) direct attainment of the 300 to 1000 year specification OR 2) inhibition of another "part" from attaining its specified requirements. In this case, the parts would be non "Q" and the approved QA program procedures under which this determination is made should provide a means to document such a finding. However, those parts which contribute to meeting the 300 to 1000 year requirement would be "Q", would be identified in a subtler fashion on the "Q" List, and, to complete the classification process, must have documented therewith its allocation from requirements (e.g., 300 to 1000 years) together with its characteristics (sometimes called "critical characteristics") which meet the allocated requirements.

Turning now to the natural barriers, the overall analysis of Yucca Mountain has identified the geologic units which make up the mountain and some of these units have been determined to have either a direct effect on the isolation of radionuclides from the envirosphere or on our ability to characterize the quantitative effects of each unit on waste isolation. As a result, certain geologic units are on the "Q" List.

As an example of the manner in which we might classify the geologic units, let us examine the Calico Hills rock unit. This rock unit, as presently perceived, lies partially in the unsaturated zone between the Topopah Springs rock units (the proposed repository horizon) and the saturated zone. The rock unit is envisioned as a barrier because the zeolite minerals in the rock are expected to significantly retard migration of radionuclides passing through rock unit on their way to the saturated zone. Accordingly, the characteristics of this barrier which are important to us are: 1) establishing the degree to which the barrier will function to retard radionuclides so that these characteristics may be used in performance assessment calculations of the repository and 2) maintaining its potential to retard radionuclides during site characterization to assure that we do not unacceptably degrade its natural contribution to performance.

For the natural item, Calico Hills rock unit, the classification process is complete when we have quantitatively identified and documented each of the characteristics which make it important to waste isolation. This documentation will be promulgated to all participants who must interact with or impact the performance of, either physically or analytically, the Calico Hills rock unit so that they may properly identify controls which they must apply under their QA program. See Grading below.

The foregoing is a hypothetical example of classification and may not have identified all of the characteristics pertinent to the Calico Hills rock unit. The "official" classification must be done by appropriate personnel identified in the OCRM QA program who are investigating the functional performance of the rock unit.

#### GRADING

Given the characteristics of each of the items constituting a system, personnel responsible for, lets say designing the item, can select the procedures that are appropriate to the items intended use.

A "Q" list item that is commercially available off-the-shelf may not need the same degree of control as a "Q" list item that was specifically designed and manufactured for the OCRM Program. The off-the-shelf item may only require a receipt inspection or test whereas the complex item that is specifically designed for the Program may require the application of additional controls to provide an appropriate level of confidence that the item meets its design or performance requirements. The additional controls for the complex item could include requiring the vendor to perform design activities according to an approved QA Program and the purchaser to perform source inspections or surveillance, inspection or test of the item upon receipt, and operational tests after installation.

For items on the "Q" list, the objective of the grading concept is to identify and document specific controls applicable to the item, and its associated activities, through the appropriate implementation of the plans and/or procedures of an approved QA Program. Accordingly, controls as identified in program procedures are a prerequisite to the performance of actions by personnel on a "Q" List item. In like manner, in an operating mode, controls/procedures are a prerequisite to operation and maintenance of "Q" List items.

For MCS items, where the application of QA Program controls is not a regulatory requirement for licensing, the grading process is for DOE management to identify and document criteria and, thereafter, for participants to identify specific controls so that they may be handed down, implemented, and assessed for sufficiency.

"Grading Reports", per se, will not be submitted to the Project Office for approval but may, if they are used by a participant, be subject to management assessments.

## STATUS OF M&O QA PROGRAM DEVELOPMENT

- M&O QAPD Conditionally accepted by DOE on 7-25-91  
Conditional acceptance pending submittal and acceptance of QA Software Plan

M&O QA Software Plan has been drafted and is in the M&O review process.

- The following M&O Quality Administrative Procedures (QAPs) have been approved: *(BY M & O) per J. BRACKETT 8/25/91 QA MTS. Jelle 8/25/91*

QAP-5-1, Preparation of Procedures  
QAP-2-1, Indoctrination and Training  
QAP-2-1, Verification of Personnel Qualifications

- The following M&O Quality Administrative Procedures (QAPs) have been drafted and are in the review process:

QAP-2-3, Establishing QA Program Controls (Grading)  
QAP-2-4, QA Program Status Reporting  
QAP-2-5, QA Surveillance  
QAP-2-6, Readiness Review  
QAP-3-1, Document Reviews  
QAP-3-2, Design Reviews  
QAP-3-3, Peer Reviews  
QAP-3-4, Configuration Control  
QAP-3-5, Preparation of Technical Documents  
QAP-3-6, Technical Document Input Control  
QAP-6-1, Document Control  
QAP-16-1, Corrective Action  
QAP-16-2, Stop Work  
QAP-17-1, QA Records Management  
QAP-18-1, Certification of Audit Personnel  
QAP-18-2, Audits  
QAP-19-1, QA Computer Software Control

## STATUS (CONTINUED)

- o The following MRS Design Implementing Procedures have been approved in accordance with the M&O QA Program:
  - Implementing Procedure 01-10, MRS Design Group Organization
  - Implementing Procedure 02-10, Quality Assurance Plan
  - Implementing Procedure 02-20, Quality Assurance Training and Qualification
  - Implementing Procedure 02-30, Personnel Selection and Qualification
  - Implementing Procedure 03-10, Design Specifications
  - Implementing Procedure 03-20, Engineering Calculations
  - Implementing Procedure 04-30, Procurement of Services
  - Implementing Procedure 05-10, Engineering Drawings
  - Implementing Procedure 06-10, Control of the Quality Assurance Procedures and Manuals
  - Implementing Procedure 06-20, Document Control
  - Implementing Procedure 16-10, Design Nonconformance
  
- o The following procedures that MRS Design wishes to adopt from Duke Power Company are being reviewed for compliance with the OCRWM QARD:
  - PR-101, Engineering Calculations/Analyses (QA Software Control)
  - PR-931, QA Records Collection, Maintenance, and Storage
  
- o The Program Management Plan, System Engineering Management Plan, and the Configuration Management Plan are all under development.
  
- o Training
  - 12 M&O employees have completed 4.5 day instructor certification training.
  - QA Orientation Training in progress.
  - QAP-2-1 Training in progress
  - Other training will start as procedures are approved.

# **GOAL**

**TO EFFECTIVELY TRANSITION THE M&O  
CONTRACTOR INTO THE DOE-YUCCA MOUNTAIN  
SITE CHARACTERIZATION PROJECT**

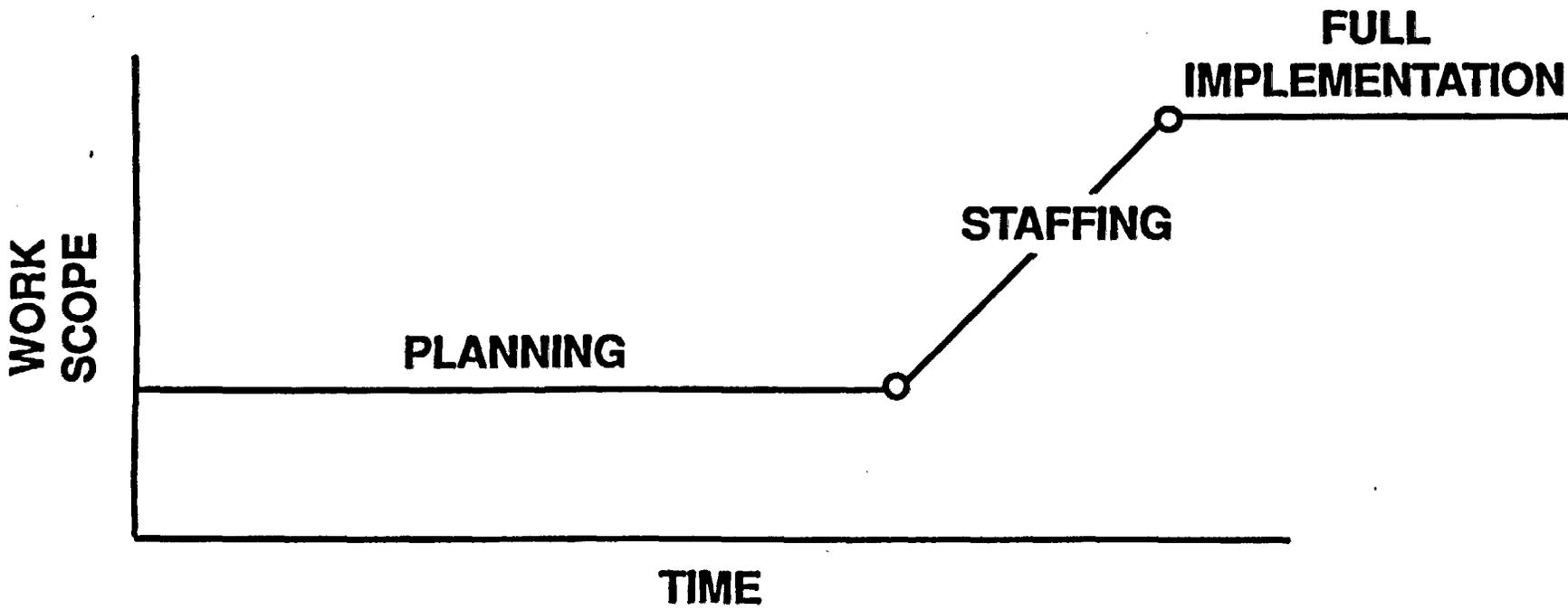
- **PARTIAL TRANSITION DURING FY 1992**

- **COMPLETE INFRASTRUCTURE TO MANAGE AND INTEGRATE; i.e., TPO/STAFFING INTERNAL COST/ SCHEDULE SYSTEM AND QA**
- **DEVELOP PLANS, PROCEDURES AND RECORDS**
- **DEVELOP TRAINING**
- **LIMITED IMPLEMENTATION OF WORK IN TECHNICAL AREAS**
- **INITIATE INTEGRATION OF ALL FUNCTIONS ACROSS WBS ELEMENTS**

● **COMPLETE TRANSITION BY END OF FY 1993**

- **FULLY FUNCTIONING ORGANIZATION**
- **PASS APPROPRIATE QA AUDIT**
- **IMPLEMENTING QUALITY AFFECTING WORK USING PLANS AND PROCEDURES**
- **FULLY FUNCTIONING TRAINING**
- **FULLY FUNCTIONING PROJECT CONTROL SYSTEM**
- **INTEGRATION OF ALL TECHNICAL AND ADMINISTRATIVE FUNCTIONS ACROSS WBS ELEMENTS**

# GENERAL APPROACH TO TRANSITION



# **STATUS**

## **of QA Program Changes**

- **QARD/QAPD consolidation effort**
- **Procedure consolidation effort**

# **QARD/QAPD**

## **Consolidation Effort Status**

- **Preliminary Draft Issued - 7/15/91**
- **Scheduled Issue Date For Review  
- 9/9/91**
- **Scheduled Concurrence Time Frame  
- Late October**

# **QARD/QAPD**

## **Consolidated Coverage**

- **All Four CRWM Program Elements**
  - **Waste Form Production and Acceptance Process**
  - **Transportation**
  - **MRS**
  - **MGDS**
- **Scope designated for each element, MGDS - Thru license application**

# **QARD/QAPD**

## **Consolidation Highlights**

- **There will be only one document**
- **Eliminates the need for Participants to have their own QAPD**
- **Basically a stand-alone document (NQA-1 and other requirements brought into document and clarified to make them CRWM specific)**

# **OCRWM**

## **Procedure Consolidation Effort Overview**

- **Requested By: John Bartlett**
- **Purpose:**
  - **To combine HQ and PO procedures to the max possible**
  - **Establish consistent formats**
  - **Establish consistent hierarchies**
- **Basically OCRWM HQ & PO effort**

# OCRWM

## Procedure Consolidation Effort Overview (continued)

- **Revised Procedure for Procedures**
  - **Scheduled Effective Date: 11/4/91**
- **Schedule for combining procedures that have been determined feasible to combine: Complete in November**
- **Administrative Procedures (AP-"Q"s) will be revised as a minimum to conform to new format requirements**

**SCHEDULE  
HQ/YMP PROCEDURE CONSOLIDATION EFFORT**

*Mr. R. Hood - 9/29/91  
Issued weekly to Dir.  
Eck 9/29/91*

Attachment

**PHASE I**

QAAP	Input	Complete Preliminary Draft QAAP	Initial Review of Preliminary Draft by HQ/YMP	Resolve Initial Comments and Prepare Formal Review Draft	Complete OCRWA Review of Draft QAAP	Resolve and Incorporate Review Comments	Complete QAAP Approval	Issue QAAP
2.6	Complete	Complete	Complete	Complete	08/30/91 (F)	09/08/91 (F)	09/11/91 (F)	09/13/91 (F)
2.7	Complete	Complete	Complete	Complete	08/30/91 (F)	09/06/91 (F)	09/11/91 (F)	09/13/91 (F)
2.9	Complete (F)	Complete (F)	Complete (F)	Complete (F)	Complete (F)	08/29/91	08/30/91	09/02/91
3.3	Complete	Complete	Complete	Complete	08/30/91 (F)	09/13/91 (F)	09/18/91 (F)	09/20/91 (F)
16.1	Complete	Complete	Complete	08/30/91 (F)	09/13/91 (F)	09/20/91 (F)	09/27/91 (F)	09/30/91 (F)
16.2	Complete	Complete	Complete	Complete (F)	09/13/91 (F)	09/20/91 (F)	09/27/91 (F)	09/30/91 (F)
18.1	Complete	Complete	Complete	Complete	Complete	09/06/91 (F)	09/13/91 (F)	09/20/91 (F)
18.2	Complete	Complete	Complete	Complete	Complete	09/06/91 (F)	09/13/91 (F)	09/20/91 (F)
18.3	Complete	Complete	Complete	Complete	Complete	09/06/91 (F)	09/13/91 (F)	09/20/91 (F)

**PHASE II**

2.1 <sup>1</sup>	10/07/91(F)	10/14/91 (F)	10/21/91 (F)	10/28/91 (F)	11/18/91 (F)	12/02/91 (F)	12/09/91 (F)	12/16/91 (F)
3.5	09/06/91 (F)	09/30/91 (F)	10/14/91 (F)	10/28/91 (F)	11/18/91 (F)	12/02/91 (F)	12/09/91 (F)	12/16/91 (F)
5.1	Complete (F)	09/30/91 (F)	10/14/91 (F)	10/28/91 (F)	11/18/91 (F)	12/02/91 (F)	12/09/91 (F)	12/16/91 (F)
6.2	Complete (F)	09/30/91 (F)	10/14/91 (F)	10/28/91 (F)	11/18/91 (F)	12/02/91 (F)	12/09/91 (F)	12/16/91 (F)

(F) Revisions from the previous week

(1) QAAP 2.1 will combine all HQ/YMP Training and Qualification procedures into one consolidated procedure.

## SCHEDULE

HO PROCEDURE REVISIONS

QAAP	Input	Complete Preliminary Draft QAAP	Initial Review of Preliminary Draft by HO/YMP	Receive Initial Comments and Prepare Formal Review Draft	Complete OCHRR Review of Draft QAAP	Receive and Incorporate Review Comments	Complete QAAP Approval	Issue QAAP
2.1	Complete	Complete	Complete (R)	Complete (R)	Complete (R)	Complete (R)	09/08/91 (R)	09/10/91 (R)
3.2	Complete	09/30/91 (R)	10/14/91 (R)	10/28/91 (R)	11/18/91 (R)	12/02/91 (R)	12/09/91 (R)	12/18/91 (R)
7.1	Complete	Complete	Complete	Complete (R)	09/08/91 (R)	09/20/91 (R)	09/27/91 (R)	09/30/91 (R)
17.1	Complete	Complete	Complete	Complete (R)	09/13/91 (R)	09/27/91 (R)	10/04/91 (R)	10/25/91 (R)