

March 27, 1998

Mr. Samuel Rousso, Director
for Program Management and Administration
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585

SUBJECT: MINUTES OF THE JANUARY 21, 1998, QUALITY ASSURANCE MEETING

Dear Mr. Rousso:

Enclosed are the minutes of the January 21, 1998, Quality Assurance (QA) meeting between the staff of the U.S. Nuclear Regulatory Commission and representatives of the U.S. Department of Energy (DOE).

The purpose of the January 21, 1998, meeting was to discuss items of mutual interest regarding QA and those areas contributing to resolution of Key Technical Issues of DOE's site characterization program for Yucca Mountain. The meeting was a video conference between the DOE office in Las Vegas, Nevada, NRC headquarters in Rockville, Maryland, and DOE headquarters in Washington, D.C..

If you have any questions regarding this letter, please contact Ted Carter of my staff. Mr. Carter can be reached at (301) 415-6684.

Sincerely,

[Original signed by:]

Michael J. Bell, Chief
Performance Assessment and HLW
Integration Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

NHXT 11
102.7

Enclosure: As stated

cc: See attached list

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NAME	TCarter <i>THC</i>		SWastler <i>SW</i>		MBel <i>MB</i>			
DATE	3/24/98		3/25/98		3/27/98			

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Letter to S. Rouso from M. Bell dated: March 27, 1998

cc: R. Loux, State of Nevada
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
W. Barnes, YMPO
C. Einberg, DOE/Wash, DC
N. Slater, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
W. Cameron, White Pine County, NV
T. Manzeni, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Regan, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB
R. Holden, NCAI
A. Collins, NIEC
S. Brocoum, YMPO
R. Arnold, Pahrump County, NV
N. Stellavato, Nye County, NV
J. Lyznicky, AMA
R. Clark, EPA
F. Marcinowski
A. Gil, YMPO
R. Anderson, NEI
C. Henkel, NEI
S. Frishman, Agency for Nuclear Projects

**MINUTES OF THE JANUARY 21, 1998,
U. S. NUCLEAR REGULATORY COMMISSION/U. S. DEPARTMENT OF ENERGY
QUALITY ASSURANCE MEETING**

On January 21, 1998, staff of the U. S. Nuclear Regulatory Commission and U. S. Department of Energy (DOE) held a Quality Assurance (QA) video conference meeting in Washington D. C. and Las Vegas, Nevada. The purpose of the meeting was to discuss items of mutual interest regarding Quality Assurance and those areas leading toward or contributing to resolution of NRC Key Technical Issues of DOE's site characterization program for Yucca Mountain. The meeting was a video conference between the DOE office in Las Vegas, Nevada and NRC headquarters in Rockville, Maryland. DOE headquarters in Washington, D.C. also attended the meeting.

Attendees

Attachment 1 provides the name, affiliation and telephone number of the attendees.

Agenda

Attachment 2 provides the agenda.

Opening Remarks

The meeting opened with the introduction of attendees. There was a short discussion to determine the frequency of the QA meetings. Among the attendees, it was suggested that scheduling a QA meeting annually or twice a year should be adequate. DOE wanted input from the State of Nevada before determining our next QA meeting, therefore the frequency of the QA meeting will be determined at a later date.

Status of Open Items

Attachment 3 provides the list and current status of open items. Since our last meeting, 11 of 16 open items have been closed. Items 12, 14, 15 and 16 remain open. The actions taken to resolve the Open Items are described in the comments column of the NRC QA Open Items Status Report.

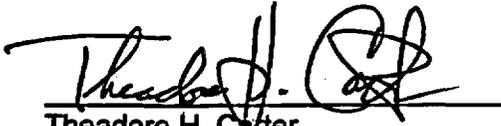
Other QA Topics

Attachment 4 provides the presentation handouts in accordance with the agenda.

Enclosure

Closing Remarks

There were no additional issues noted by the representatives in attendance. The meeting was adjourned at 1:45 p.m. EST.



Theodore H. Carter
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission



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

ATTACHMENT 1

**NRC-DOE QUALITY ASSURANCE MEETING
NRC-DOE QUALITY ASSURANCE MEETING ATTENDANCE LIST**

January 21, 1998

Videoconference between
DOE Las Vegas/YMSCO
NRC/Rockville

Bob Clark	DOE/OQA	702-794-5583
Bill Belke	NRC	702-794-5047
Catherine Hampton	DOE/OQA	702-794-1387
Woody Hudson	QATSS	702-794-1490
Richard Peck	QATSS	702-794-245_
Hank Greene	QATSS	702-794-1498
Robert Habbe	QATSS	702-295-2675
John Therien	QATSS	702-794-5408
Richard Kettche	QATSS	702-794-1412
Ali Haghi	M&O/DUKE	702-295-487_
Mary McDaniels	QATSS	702-794-1468
Charlie Warren	QATSS	702-794-1487
Dan Tunney	QATSS	702-794-1489
Albert C. Williams	DOE/OQA	702-794-5580
Donald G. Horton	DOE/OQA	702-794-5568
Emily Reiter	QATSS	702-794-5013
Ted Carter	NRC	301-415-6684
Sandra Wastler	NRC	301-415-6724
Sidney Crawford	Self	301-515-6398
John L. Russell	CNWRA	301-881-0289
Bakr Ibrahim	NRC.	301-415-6651
Anne Ramirez	NRC	301-415-6631

ATTACHMENT 2

AGENDA
NRC/DOE QUALITY ASSURANCE MEETING
January 21, 1998
Video conference: DOE/LV, Atrium Room; NRC Headquarters

10:00 AM PST (1:00 EST)

- **OPENING REMARKS**
- **QA TOPICS**
 - **Status of Open Items** **NRC/DOE**
 - **10 CFR, Part 21 (DOE Response)** **DOE**
 - **QARD, Revision 8 Overview** **DOE**
 - **DOE Audit Schedule (Potential Audits Observed by NRC)** **DOE**
 - **Results/Report of 1997 Independent QA Management Assessment** **DOE**
 - **Brief Overview by DOE of the M&O Engineering Assurance Organization Responsibilities and Activities performed** **DOE**
 - **Discussion of Combining or Absorbing Compliance Audits with Performance Based Audits** **DOE**
 - **Supplier Baselineing Effort** **DOE**
 - **Transition of TSPA from Non-Q to Q** **DOE**
 - **QA Involvement in Application to Viability Assessment** **DOE**
- **CLOSING REMARKS**
- **ADJOURN**

12:00 PM PST (3:00 PM EST)

ATTACHMENT 3

NRC QA OPEN ITEMS STATUS REPORT

JANUARY 20, 1998

Item #	NRC QA Issue #	Issue Item	Reference	Responsible (Affected Organization) Individual	Responsible (QATSS) Individual	Comments	Status
1	1	M&O design control program	Bernero to Dreyfus ltr, 10/13/94	A. Segrest	S. Dana	Dreyfus to Bernero ltr, 11/14/94. Broccom to Bell ltr of 9/25/96, requesting NRC to close. Stablein to Broccom ltr., 10/29/97, closes item 1.	Closed
2	Closed	ESF design and construction phasing.				Holonich to Milner ltr, 03/09/95, closes item 2.	Closed
3	2	Potential of construction work to impact site characterization or the waste isolation capability of the site.	Bernero to Dreyfus ltr, 10/13/94	S. Broccom	S. Dana	Dreyfus to Bernero ltr, 11/14/94. Broccom to Bell ltr. of 9/25/96, requesting NRC to close. Stablein to Broccom ltr., 10/29/97, closes item 3.	Closed
4	3	Request for more details regarding QA concerns as well as the design of the ESF.	Bernero to Dreyfus ltr, 10/13/94	S. Broccom	P. Auer	Dreyfus to Bernero ltr, 11/14/94. Broccom to Bell ltr. of 9/25/96, requesting NRC to close. Stablein to Broccom ltr., 10/29/97, closes item 4.	Closed
5	Closed	Validation of acquired software.				Austin to Milner ltr, 03/06/96, closes item 5.	Closed
6	Closed	Electronic Scientific Notebooks.				Holonich to Milner ltr, 02/17/95, closes item 6.	Closed
7	4	License Application Annotated Outline (LAO) incomplete and editorially poor.	Holonich to Milner ltr, 08/15/95	A. Gil	J. Clark	Broccom to Thoma ltr, 03/21/97, requesting NRC to close. Bell to Broccom ltr., 8/29/97, closes item 7.	Closed
8	5	LAO Chapter 10 headings do not reflect NRC guidance.	Holonich to Milner ltr, 08/15/95	A. Gil	J. Clark	Broccom to Thoma ltr, 03/21/97, requesting NRC to close. Bell to Broccom ltr., 8/29/97, closes item 8.	Closed
9	6	Quality controls applied to the LAO.	Holonich to Milner ltr, 08/15/95	A. Gil	J. Clark	Broccom to Thoma ltr, 03/21/97, requesting NRC to close. Bell to Broccom ltr., 8/29/97, closes item 9.	Closed

Item #	NRC QA Issue #	Issue Item	Reference	Responsible (Affected Organization) Individual	Responsible (QATSS) Individual	Comments	Status
10	7	USGS technical review process effectiveness.	Holovich to Milner ltr, 11/02/95	D. Miller	R. Powe	The referenced letter refers to OCRWM Audit YM-ARP-95-20 conducted 9/11-14/95. This audit resulted in issuance of CAR YM-96-C-002 to address the subject. The CAR has been subsequently closed and a follow-up surveillance, YMP-SR-96-025, was performed 10/7-9/96. The surveillance resulted in a recommendation that YMSCO conduct a technical review of three USGS documents. YMSCO has committed to conduct a technical review. The technical review is approximately 75% complete. Preliminary report indicates no problems to date.	Open
11	Closed	Lack of QARD requirements for the qualification of scientific investigation methods.	Austin to Milner ltr, 04/08/96			Horton to Austin ltr, 04/25/96, closes Item 11 (w/draft ltr Milner to Austin)	Closed
12	9	Level of quality of work products.	YM-ARP-96-14, 10/28/96; NRC Observation Audit Report of LANL, 10/24/96	T. Sullivan	S. Dana	As a result of the LANL audit, DOE wrote four Deficiency Reports. Corrective action to close these Deficiency Reports is scheduled for completion in July 1997. If this corrective action satisfactorily addresses the NRC open item, it can be closed. Corrected action relating to all but one affected Deficiency Report has been completed and verified to be adequate. Corrective action relating to DR-YM-96-D-107 is being rejected.	Open
13	Closed	Applicability of QARD, Supplement I, "Software," to statistical analysis programs.	NRC Observation Audit Report OA-97-01, 12/17/96.			W. Belke closed in NRC OR Report, Section 4.0, 03/12/97	Closed See Item 15

Item #	NRC QA Issue #	Issue Item	Reference	Responsible (Affected Organization) Individual	Responsible (QATSS) Individual	Comments	Status
14	8	Data Qualification.	Austin to Milner ltr. 03/18/96	S. Brocoun	M. McDaniel	In late 1996, in response to the NRC 8/19/96, letter (Austin to Brocoun), DOE organized a working group for improving the requirements and process for qualification of existing data. This was tracked by the ORs, was presented at the 5/12/97, QA meeting, and will be discussed at an Appendix 7 type meeting, if necessary. From the OR perspective this revised methodology appears to be responsive to the NRC position expressed in the above August 19, 1996, letter. Should the review by the NRC HQ staff of this revised methodology be acceptable, this open item will be closed in a subsequent QA meeting and in the monthly OR Report. QARD, Revision 8, when issued, should resolve.	Open
15	11	QARD Supplement 1, Guidance/Requirements unclear for Statistical Analysis Program.	Section 4.0 of NRC OR Feb97 Report	C. Hampton	S. Harris	DOE has discussed the content of a future proposed clarification to the QARD for this open item with the OR at the 5/12/97, QA meeting. From the OR perspective, this proposed QARD clarification should close this open item when the QARD is revised. QARD, Revision 8, when issued, should resolve.	Open
16	12	Due to the quantity of supplier related deficiencies, OR questions the acceptability and qualifications of associated data/products.	Section 4.0 of NRC OR Report Number OR-97-09	R. Dyer	K. Gilkerson	OQA to finalize CAR 98-C-02 and issue.	Open

ATTACHMENT 4

QARD, REV. 8

EFFECTIVE DATE 6/5/98

HIGHLIGHTS OF REVISION

- **Section 2.0, Quality Assurance Program - Revised Subsection 2.2.12, Personnel Qualification to incorporate a graded approach to training and qualification.**
- **Supplement I, Software - Modified, Subsection I.1 to clarify applicability of Supplements I and V.**
- **Supplement III, Scientific Investigation - Subsection III.2.4, Data, Review, Adequacy, and Usage and Subsection III.2.5, Technical Report Review were rewritten. This establishes new categories (qualified, accepted, and existing) for data and adds technical assessment as an alternative method for qualification of data.**

QARD, REV. 8

EFFECTIVE DATE 6/5/98

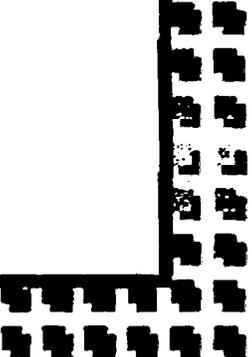
HIGHLIGHTS OF REVISION (Continued)

- **Appendix C, Mined Geologic Disposal System - Added new Subsection C.2.1, to define requirements for conducting expert elicitation.**
- **Glossary - Added definitions of special terms used in Appendix C, Expert Elicitation (i.e., expert elicitation, generalist, normative expert, and subject-matter expert). Added definitions of special terms used in Supplement III (i.e., accepted data, acquired data, developed data, existing data and technical report). Modified definition of "qualified data."**



FY 1998
INTERNAL AUDIT SCHEDULE

- REVISION 1 CURRENTLY APPROVED
BY DIRECTOR, OQA

 - REVISION 2 TO BE APPROVED
FEBRUARY 1998
- 



FY 1998

INTERNAL AUDIT SCHEDULE

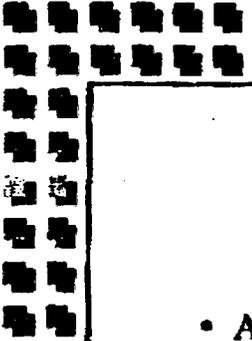
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- ELEVEN COMPLIANCE AUDITS OF
AFFECTED ORGANIZATIONS**

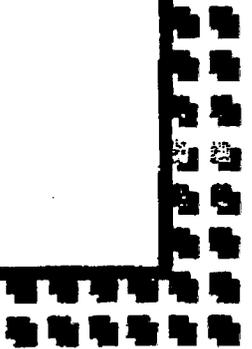
 - THIRTEEN PERFORMANCE-BASED
AUDITS OF PRODUCTS/ACTIVITIES**
- 

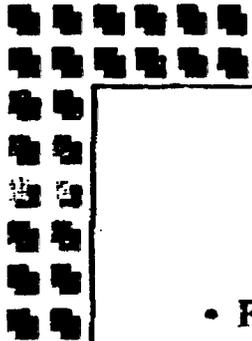
FY97 QAMA RECOMMENDATIONS

- The responsible OCRWM and M&O line manager should closely monitor the EA organization to ensure that the EA role is clearly defined and implemented.
- Management leadership, vision and authority are needed within the OCRWM and the M&O in order to address the design interface control and integration issue on a program-wide basis.
- The M&O should use, to the extent possible, the information developed as a result of earlier requirement research efforts.
- OCRWM and M&O management need to identify what is needed to control baseline changes, articulate the policy, streamline the process and define a single system for the entire OCRWM Program.
- Ensure that policy and upper-tier procedure for documenting key decisions is reviewed by people with NRC licensing experience so that the process will effectively identify meaningful thresholds and avoid over-commitments.
- OCRWM should have an integrated Commitment Management Program in place to effectively manage all regulatory commitments from inception to closure.

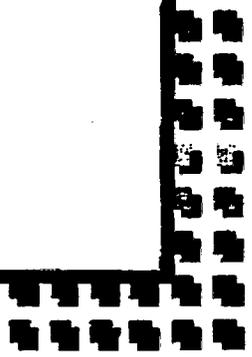


FY97 QAMA RECOMMENDATIONS (Continued)

- Adequate resources and authority need to be given to the TSPA task force, along with continued M&O senior management support to complete the cultural change that is needed in the organization's performing PA activities.
 - The "record submittal" control feature of the Records Management Program should be evaluated to determine if it will adequately support OCRWM's need during the licensing process.
 - OCRWM management should evaluate the organizational structure and corresponding responsibilities to ensure that ownership of functions and processes are clearly defined and communicated and responsibilities do not overlap.
 - M&O management should evaluate the current organizational structure and remove any barriers to horizontal communication.
 - M&O management in consultation with OCRWM management should evaluate the need for a Chief Engineer, taking into account the need for the licensee to establish design authority and consistency within each project.
- 

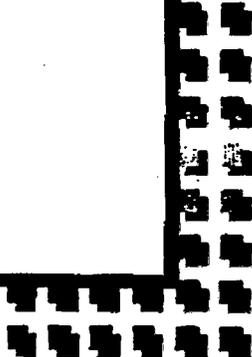


FY97 QAMA RECOMMENDATIONS (Continued)

- For the procurement of commercially available items and services, OCRWM and the M&O should identify and endorse those nationally recognized QA standards that have a proven track record for adequate controls.
 - The construction specifications for common building materials should be revised to remove the excessive QA requirements in favor of commercial requirements.
 - M&O management should provide the Director, OCRWM, with a response to the recommendations identified in the FY 1996 QA Management Assessment of the M&O.
- 

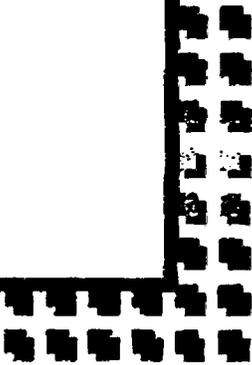


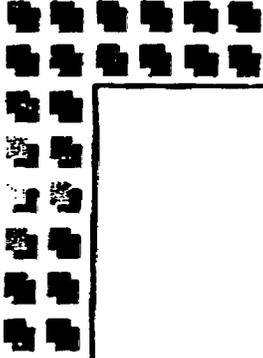
M&O ENGINEERING ASSURANCE ORGANIZATION

- ESTABLISHED AS A RESULT OF TRANSITION OF QA FUNCTION TO THE OQA
 - M&O LINE ORGANIZATION RESPONSIBLE FOR:
 - IN-LINE REVIEW OF M&O DOCUMENTS
 - VERTICAL SLICE REVIEW OF M&O DOCUMENTS
 - METRICS AND EVALUATION OF M&O ACHIEVEMENT OF QUALITY
 - STAFFED WITH PERSONNEL WHO HAVE EXPERIENCE IN QUALITY ASSURANCE AND WHO ARE FAMILIAR WITH M&O TECHNICAL WORK PRODUCTS
- 



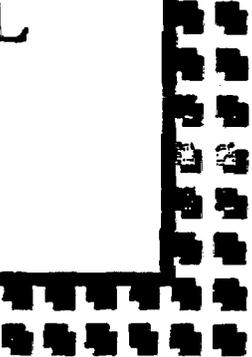
BASELINE REVIEW OF SUPPLIERS QA PROGRAM

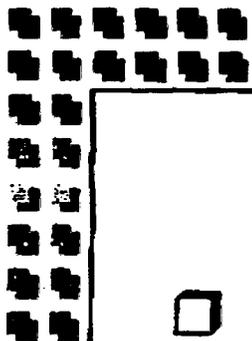
- REVIEW SUPPLIERS QA PROGRAM TO DETERMINE EXTENT OF QARD APPLICATION
 - A TOTAL OF 47 SUPPLIERS ON QSL AS OF SEPTEMBER 9, 1997
- 



REVIEWS

- PERFORM REVIEW OF FY97 PURCHASE ORDERS ISSUED BY AOS**

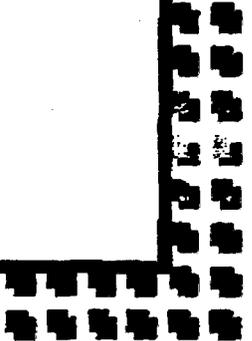
 - PERFORM REVIEW OF SUPPLIER QA PROGRAM AGAINST GRADED QARD CRITERIA AS LISTED ON PURCHASE ORDERS OR GUIDELINES DOCUMENT FOR CALIBRATION AND ANALYTICAL SERVICES**
- 

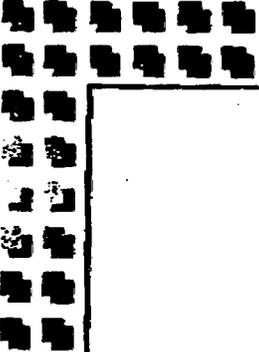


RESULTS

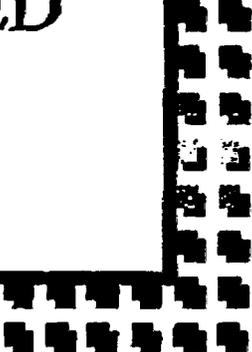
- PROCUREMENT DEFICIENCIES HAVE BEEN IDENTIFIED AT EACH AO PROCURING ORGANIZATION**

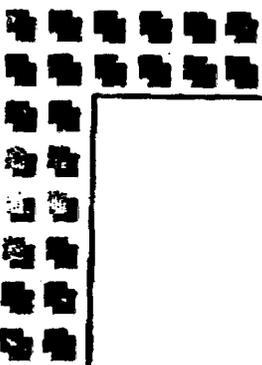
 - SUPPLIER QA PROGRAM REVIEWS IDENTIFIED:**
 - 27 SUPPLIERS WERE FOUND TO HAVE PROGRAMS THAT MEET APPLICABLE CRITERIA**

 - 20 SUPPLIERS WERE FOUND TO HAVE PROGRAMS THAT DO NOT MEET APPLICABLE CRITERIA**
- 



CORRECTIVE MEASURES

- ISSUE CAR TO DOCUMENT PROCUREMENT PROBLEMS**
 - ADJUST STATUS OF SUPPLIERS ON QSL**
 - AS OF JUNE, 1997, OQA REVIEWS ALL Q PROCUREMENT DOCUMENTS TO ENSURE GRADED QARD CRITERIA ARE INCLUDED IN PRs and POs**
- 



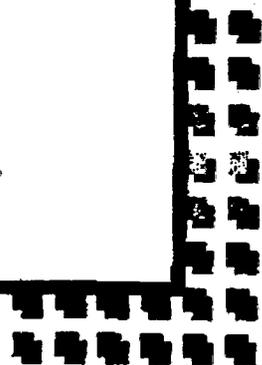
**TRANSITION OF TSPA
FROM
NON-Q TO Q**

□ TRANSITION PLAN

**- IMPLEMENTATION OF PERFORMANCE ASSESSMENT
QUALITY ASSURANCE PROGRAM**

□ ADMINISTRATIVE PROCEDURE

- CONDUCT OF PERFORMANCE ASSESSMENT



PROGRAM DOCUMENTATION

