

MINUTES OF THE JULY 20, 1993, QUALITY ASSURANCE MEETING

A meeting of the staff of the U.S. Nuclear Regulatory Commission and representatives of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), to discuss items of mutual interest with regard to quality assurance (QA), was held at the NRC Headquarters in Rockville, MD on July 20, 1993. An attendance list is included as Attachment 1. The representative of the State of Nevada participated in the meeting by telephone conference.

At this meeting, DOE presented information on the following topics: (1) update on the status of implementation of the Quality Assurance Requirements and Description (QARD) document for the Civilian Radioactive Waste Management Program; (2) update on QA overview and status of field activities, tunnel boring, and core drilling; (3) update on Fiscal Year 93 DOE audit schedule; (4) QA review of study plans; (5) responses to NRC's comments on the DOE QARD document; (6) QA applicability to resolution of Site Characterization Plan (SCP) issues hierarchy; and (7) status of the new QA support contractor for the DOE/OCRWM. The NRC staff presented information on the Open Items List and summaries of observations of recent DOE audits and surveillances.

The meeting began with the introduction of the attendees followed by introductory remarks. The NRC staff expressed concern about DOE postponing the Exploratory Studies Facility (ESF) Title II Design Technical Exchange planned for July 27-28, 1993, in Las Vegas, Nevada. As a result of recent feedback from the NRC Nevada On-Site Licensing Representatives, DOE audit findings, and NRC staff Observation Audit Report findings, the NRC staff is concerned that problems are surfacing in the design area that could require immediate attention from DOE. The NRC staff is uncertain whether these design problems are of a serious nature or just require clarification. The ESF Technical Exchange would have provided the NRC staff an opportunity to learn more about the design process for the revised Title II Design, what role QA played, associated problems, significance, corrective actions, and effects upon the overall design review process. The NRC staff encouraged DOE to consider a special audit where DOE would take a vertical slice of the design process to determine whether a serious problem exists. The NRC staff stated that it would formally address its concerns in a letter to DOE.

In response to the NRC concerns, DOE stated that DOE and the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O) have identified problems in the design area. The M&O is a relatively new contractor that acquired the work of previous contractors in addition to developing its own design strategies. Consequently, this process has been carefully scrutinized by DOE and it recognizes design problems exist. Some of these design problems may be items or activities that have been conservatively classified as quality-related when they should have been classified as non-quality related. DOE further stated that the rationale for postponing the ESF Technical Exchange was to provide the M&O the opportunity to develop corrective actions for this problem. DOE has also assigned several of its personnel to integrate with the M&O to assist in the corrective action effort. In view of these actions, the DOE audit of the M&O originally scheduled for

August 23-27, 1993, has been cancelled. DOE further reiterated that the existing problems surfaced as a result of the QA program effectively performing its function. Lastly, DOE stated that it does not intend to stop work at this time, because the findings are not sufficiently significant.

Following the introductory discussion, DOE provided an update on the QA overview and status of field activities, tunnel boring, and core drilling (Attachment 2) conducted within the past three months. This presentation included information on the following topics: (1) completed boreholes to date; (2) in-progress boreholes; (3) other borehole activities; (4) job packages and test-planning packages reviewed; (5) ESF status; (6) surveillances of field activities; and (7) QA activities related to participant field work. DOE indicated that the information in the viewgraphs did not reflect the daily QA surveillance activities (rock-bolt testing, shotcrete testing, etc.) conducted in the field in the presence of DOE and M&O representatives.

The next agenda item included a discussion of how QA reviews of study plans are conducted by the originating participant, Yucca Mountain Site Characterization Project Office (YMPO), and OCRWM. DOE noted that, until November 1991, DOE QA reviewed and approved study plans. Based on the redundancy of the review process between the participant and DOE, the study plan review process by DOE QA was discontinued until March 1993. It was decided that since study plans were technically oriented, rather than QA oriented, the participant's QA review was sufficient and, therefore, there was no need for DOE QA to duplicate these reviews. In March 1993, it was found that the study plan review process was not being performed as intended and, consequently, a CAR was issued. DOE agreed to send the NRC staff an information copy of this CAR. On July 1, 1993, the CAR was closed and all future study plans will be reviewed and approved by the DOE Yucca Mountain QA Division in accordance with Revision 6 of YMPO Administrative Procedure (AP) 1.10Q, "Preparation, Review, Approval, and Revision of Site Characterization Plans." The NRC staff inquired about those controls to assure that proper QA controls will be applied to the study plan activities. DOE's reply was that the documented review of job packages and test packages will assure that proper controls have been incorporated into these packages and are applied to the activities. Both the participant's line organization and DOE will review this process to assure implementation.

The next topic discussed was applicability of QA to resolution of the issues described in Chapter 8 of the SCP (issues hierarchy) and how resolution of these issues is being tracked. DOE indicated these issues were being tracked by the M&O through the Technical Requirement Information Management System (TRIMS). In addition to being tracked by the TRIMS system, DOE stated that the SCP issues were also being addressed in study plans. DOE agreed to transmit a package to the NRC staff that explains the TRIMS system. The NRC staff inquired whether the issues hierarchy will be subject to the same QA controls as flowdown for design requirements and whether they will be evaluated at each step to arrive at the specific performance objective. DOE emphasized that the SCP is subject to management/administrative controls, rather than QA controls. The NRC staff QA concern in the issues hierarchy process is with the design-data input from the design process. The QA organization does not oversee the issues hierarchy, since this is a management

function, but the QA program does focus QA attention on the data that goes into the system to resolve issues. DOE agreed to look into the similarities of this process and determine whether similar controls are applied to design requirements and the SCP issues hierarchy.

Next, DOE presented an update on the status of implementation of the new QARD. DOE stated that there have been some revisions to the transition schedule, but it is expected that the QARD will be fully implemented by DOE and its participants before the end of CY 1993, as indicated in Attachment 3. DOE indicated that there will be a clear commitment to the QARD by each participant through a policy statement accompanied by a matrix delineating how each DOE QARD requirement is met and whether any exceptions are taken. When the process is complete, DOE will transmit this documentation to the NRC staff. The NRC staff plans to review this documentation and provide a response to DOE indicating whether the revised QA programs of DOE and its participants continue to meet the commitments previously accepted by the NRC staff. DOE stated that the NRC staff could be placed on computer access to the QARD matrix and DOE CAR systems by documenting this request in a letter to DOE.

Although the status of the DOE Quality Concerns Program was placed on the meeting agenda, DOE was not prepared to discuss it due to unavailability of appropriate personnel. The NRC staff will request for the next NRC/DOE QA meeting, that appropriate personnel be present to discuss this subject, since it deals with important QA issues associated with the overall DOE QA program.

Three new open items were added to the NRC QA Open Items List (Attachment 4) as a result of a recent NRC surveillance of the Office of Environmental Restoration and Waste Management Vitrification Projects Division (EM-343) and audit observation of the Savannah River Site Defense Waste Processing Facility (DWPF). The first open item is a request for DOE to keep the NRC staff informed of the corrective actions that EM-343 plans to take to prevent a recurrence of the Waste Acceptance Product Specifications for Vitrified High-Level Waste Forms being developed without a procedure. The second open item pertained to EM-343 documenting deviations as Observations and not as Deviation Corrective Action Reports, which appears inconsistent from the OCRWM process. The third open item was that DWPF did not have a listing of items and activities covered by the DWPF scope of work.

Next on the agenda was NRC's update on observations of recent DOE audits and surveillances. The NRC presented summaries of its observations of the following audits: (1) YMPO (YMP-93-09); (2) OCRWM Headquarters, Washington, DC (HQ-93-05); and (3) DWPF Savannah River, Georgia (93-EA-SR-AU-01). It also reported on the surveillances of the M&O program in Las Vegas, Nevada (YMP-SR-93-16) and EM-343 in Germantown, Maryland (HQ-SR-93-01). The summaries presented are excerpts from publicly available NRC reports (Attachment 5). For the update on the Fiscal Year 93 audit schedule, DOE stated that the audit of the M&O planned for August 23-27, 1993, has been postponed indefinitely due to concerns in the design process. A new audit schedule is in process and will be released shortly.

The next discussion focused on the DOE OCRWM May 24, 1993, responses (Attachment 6) to the NRC staff's four comments (March 8, 1993, letter from J. Holonich to D. Shelor) on the QARD. Comment (1) related to the DOE proposal to change auditing DOE's principal contractors from an annual basis to a triennial basis. The NRC staff indicated that since DOE has not yet implemented this proposal, the NRC staff has not had the opportunity to determine acceptability of implementation. Therefore, this issue will remain open. For responses (2) and (3), the NRC staff will review the agreed upon OCRWM responses when they are incorporated into the next revision of the QARD. The response to comment (4) concerning the 10 CFR Parts 21 and 71 issues will be discussed further internally by the NRC staff. The NRC staff agreed to provide a written response to the OCRWM May 24, 1993, letter.

DOE indicated that the procedure consolidation effort is still in process. Quality Assurance Administrative Procedures will become Quality Assurance Procedures and Implementing Line Procedures will become Line Procedures. The process for classifying items and activities for quality-affecting activities is also underway. DOE stated that certain items and activities may have been classified with an approach that was too conservative. DOE is presently taking a second look at many of these items and activities to determine whether the previous approach was too conservative. The revised list of these items and activities is expected to be released on or before September 30, 1993.

A representative of the new support contractor for the OCRWM Office of QA gave a brief overview of the new organization (Attachment 7). The new contractor will provide support to both the OCRWM Headquarters and the Yucca Mountain Site Characterization Project QA organizations.

The State of Nevada and affected unit of local government did not present any comments, questions, or raise any items of concern after being invited to do so.

The NRC staff explained that it is concerned that the M&O QA line organization does not appear to be developing and following its procedures in a totally adequate manner. The NRC staff further stated that it could be a sign that M&O management should become more involved. The M&O representative indicated that this problem is presently being discussed within the M&O organization and between DOE and more corrective actions are forthcoming.

DOE noted that the NRC staff accepts and endorses the services of the National Institute of Standards and Technology as an accredited institution for calibration services. DOE requested a response on the NRC staff position on whether the Department of the U.S. Navy and the facility used by the State of Nevada for calibration services would also be acceptable for calibration services. The NRC requested DOE to document its specific concerns and the NRC will provide a response.

There were no closing remarks.

The meeting was adjourned after the participants tentatively set Tuesday, October 26, 1993, as the next NRC/DOE QA meeting date.



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July 20, 1993 NRC/DOE QA Meeting

ORGANIZATION/NAME

PHONE NUMBER

NRC

J. Linehan	301-504-3406
J. Holonich	301-504-3387
Ken Hooks	301-504-2447
Bill Belke	301-504-2445
M. Nataraja	301-504-3459
C. Abrams	301-504-3403
R. Johnson	301-504-2409
Pauline Brooks	301-504-3465
J. Gilray	702-388-6125
John Jankovich	301-504-2454
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DOE

Donald Horton	202-586-8858
Sharon Skuchko	202-586-4590
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L. Desell	202-586-1462
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CLARK COUNTY, NEVADA

E. v. Tiesenhausen	702-455-5175
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M&O

R.J. Brackett	703-204-8760
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Tom Colandrea	619-487-7510
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Ray Wallace	202-586-1244
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SAIC/OATSS

R. Keele	702-794-7442
S. Horton	702-794-7399
L. Wagner	703-841-7011

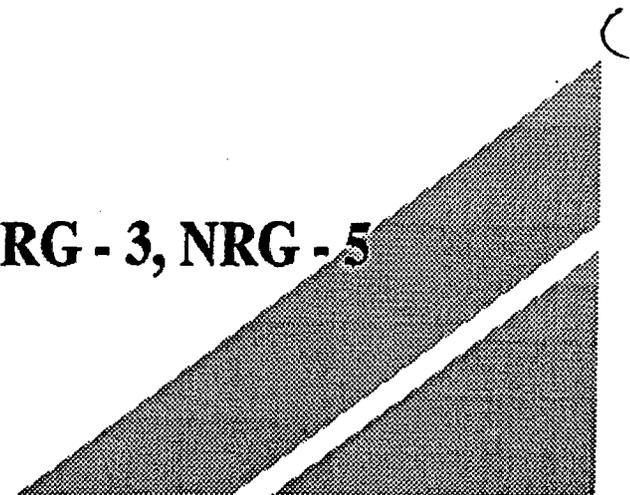


FIELD ACTIVITIES UPDATE

FIELD ACTIVITIES UPDATE

Completed Boreholes to Date

- ▶ **Total footage drilled to date (completed holed) -9412.0 feet**
- ▶ **Neutron - 23 - 3016.9 feet (N11, N15, N16, N17, N27, N31, N32, N33, N34, N35, N36, N37, N38, N53, N54, N55, N57, N58, N59, N61, N62, N63 and N64)**
- ▶ **UZ - 16 - 1686.2 feet**
- ▶ **JF - 3 - 1298 feet**
- ▶ **NRG Holes - 6 - (NRG - 1, NRG - 2, NRG - 2a, NRG - 3, NRG - 5 and NRG - 6)**

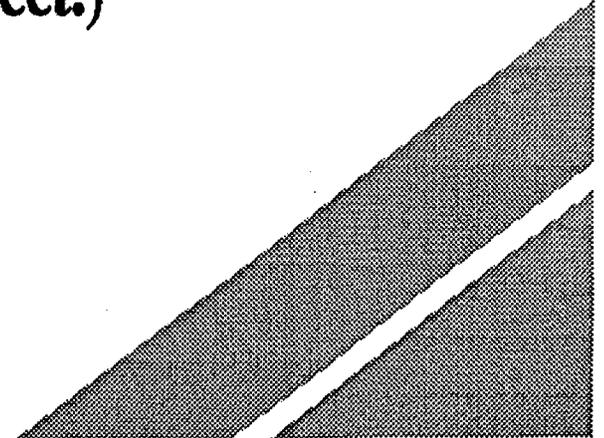


FIELD ACTIVITIES UPDATE

(continued)

In-Progress Boreholes

- ▶ **UZ #14: Cored to 1002 feet. as of July 14, 1993
(planned total depth = 2000 feet)**
- ▶ **UE - 25 NRG - 4: Cored to 603 feet. as of July 14, 1993
(planned total depth is approximately 725feet.)**



FIELD ACTIVITIES UPDATE

(continued)

Other Borehole Activities

Down Hole Logs

NRG- 6

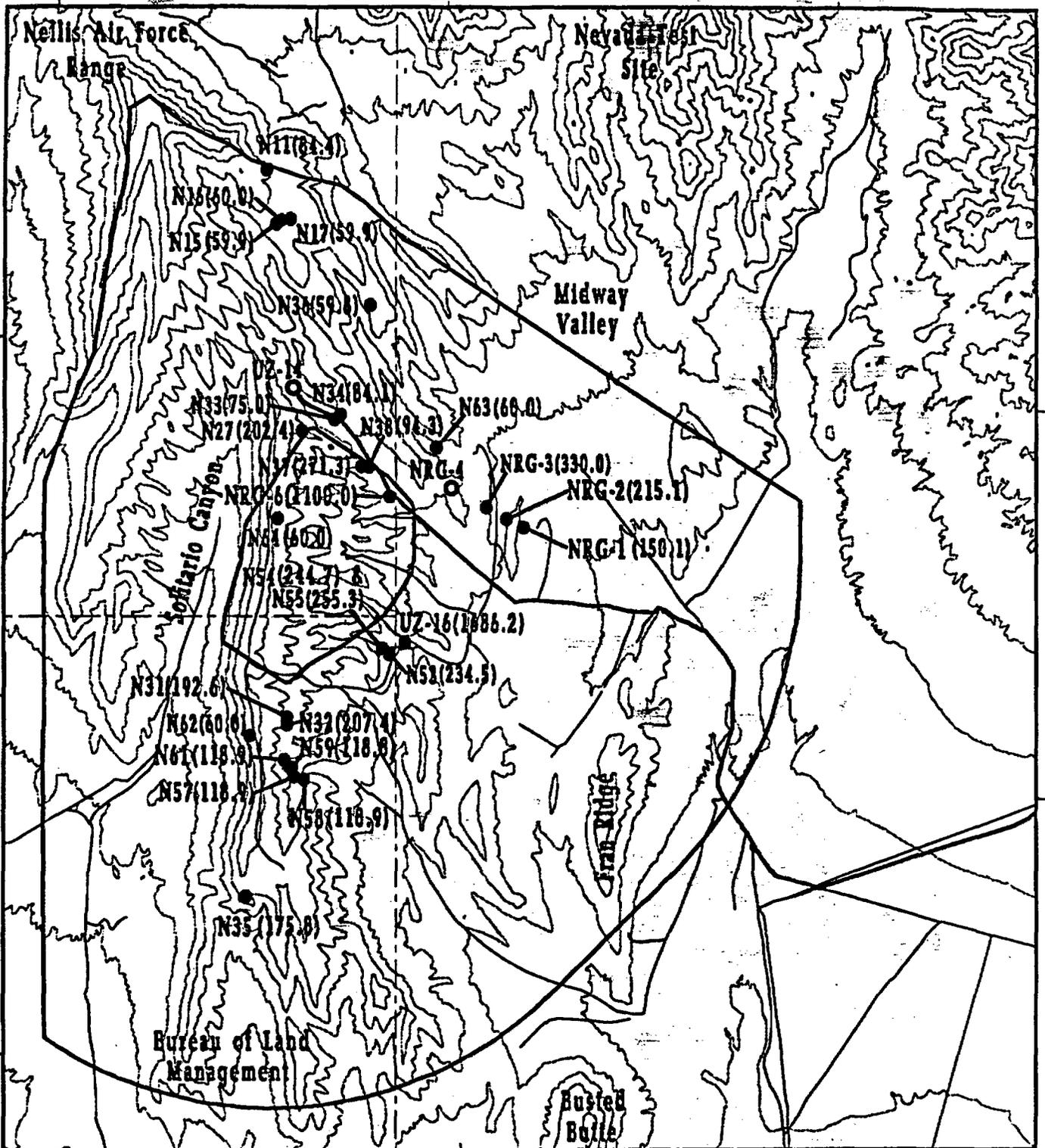
Geophysical logging completed



8302431
8303000

8304001
8305000

8307001
8308000



Neellis Air Force Range

Nevada Test Site

Midway Valley

Solitario Canyon

Iron Ridge

Busted Butte

Bureau of Land Management

116° 25' 00" 116° 27' 30" 116° 30' 00" 116° 32' 30"



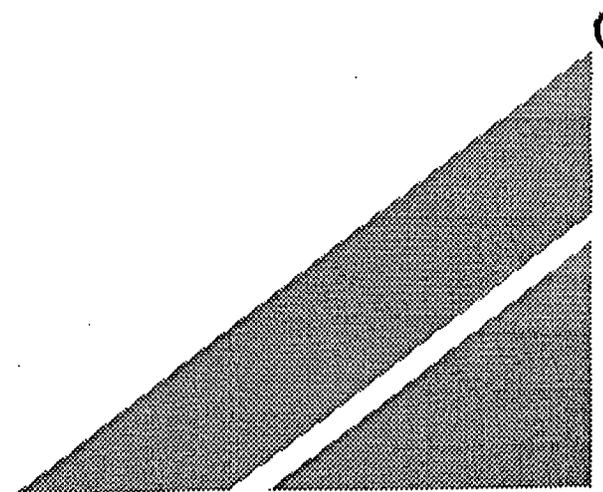
**FIELD ACTIVITIES UPDATE
(continued)**

EXPLORATORY STUDIES FACILITY (ESF)

STATUS

Upper half of ESF north portal

entrance complete to 200 feet



FIELD ACTIVITIES UPDATE

(continued)

Surveillances of Field Activities

▶ **Seven surveillance reports issued or in-preparation**

93-021 First line Inspection Activites (REECo)

93-022 FCR Document Control Process (YMPO)

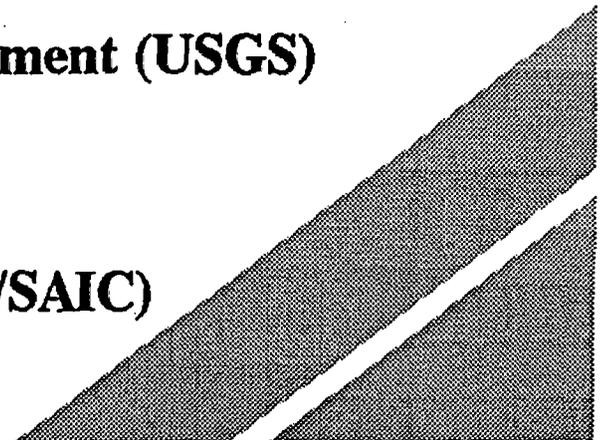
93-023 Submittal of completed JP Documentation (RSN/REECo)

93-024 Sub-surface moisture content measurement (USGS)

93-026 Calibration of measuring and test equipment (USGS)

93-027 Traceability of samples (YMPO/SAIC)

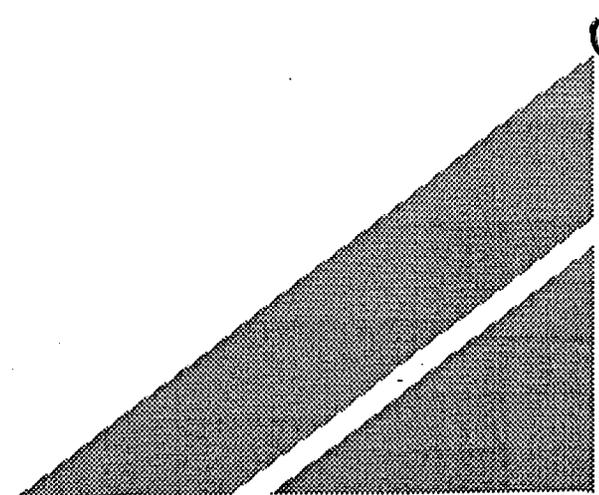
93-030 Geophysical logging at NRG - 6 (YMPO/SAIC)



FIELD ACTIVITIES - ACTIVITIES

Q.A. Activities of Field Activities by Participants

	Completed Audits/Surveillances	Planned Audits/Surveillances
M&O	1	2
LANL	0	0
LLNL	0	0
REEC _o	9	2
RSN	3	0
SNL	1	1
SAIC	9	3
USGS	4	1



QARD Implementation Status

Org.	Submit Traceability Matrix/ Description of Org.	Ready to Impl.
LANL	7-31-93	8-30-93
LLNL	8-14-93	8-14-93
M&O	8-30-93	8-30-93
REEC _o	7-30-93	7-30-93
RSN	5-10-93	In Process
SNL	7-31-93	7-31-93
T&MSS	7-30-93	7-30-93
USGS	Extention Pending	
YMPO	9-30-93	9-30-93



STATUS of QARD IMPLEMENTATION PLANS

(HQ PARTICIPANTS)

■ M&O

- *On Schedule.*

■ EM

- *Incorporated OQA comments.*
- *Original submission of plan indicated completion by end of June - Obvious slip.*
- *Estimated revised completion - September 1993*

■ OAK RIDGE

- *OQA has not received plan.*
 - *Last two months were spent performing cost/benefit analysis - Revise Oak Ridge QA program vs. work to M&O QA program.*
 - *Decision made (OQA concurs) to revise existing Oak Ridge QA program.*
 - *Implementation plan due to OQA August 31, 1993*
- 

COPIES TO:

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J.L.
J.H.
K.H.
J.S.
J.B.
P.B.

FROM: B. Belke

SUBJECT: STATUS OF NRC/DOE QA OPEN ITEMS - JULY 20, 1993
(Bracketed items = new items added since last QA meeting)

<u>ITEM</u>	<u>DESCRIPTION</u>	<u>STATUS</u>	<u>RECOMMENDATION FOR CLOSURE/REMARKS</u>
1-93	Response to NRC Observation Audit Report 93-01 for USGS dated 12/7/92	OPEN	DOE should respond within 60 days of the date of the NRC Observation Audit Report transmittal. (1) Weakness 5.10 (b) (1) - Audit technical evaluations and criteria for conducting technical evaluations are not prescribed by documented instructions or procedures.
2-93	Response to NRC Observation Audit Report 93-04 for EM-343 dated 2/17/93	OPEN	(1) Weakness 5.9.2 - No list of items and activities covered by the EM-343 QA program scope of work.
3-93	Responses to NRC Observation Audit Report 93-07 for M&O, NV dated 4/6/93	OPEN	(1) Weakness 5.9.2 - Personnel knowingly not following procedures. (2) Weakness 5.9.2 - Numerous deficiencies combined into single CAR may be difficult to accurately track for corrective action.
4-93	Response to NRC Observation Surveillance Report 93-S3 for EM-343 dated 7/1/93	OPEN	(1) Waste Acc. Product Specifications for Vitrified High-Level Waste Forms performed without procedure. NRC requests DOE inform NRC of actions taken by EM-343 to preclude this type of recurrence.
5-93	Responses to NRC Observation of Sav., Riv. Audit dated 6/25/93	OPEN	(1) Deviations documented as Observations and not DCARs. (2) No list of items and activities covered by the DWPF QA program scope of work (See Item 1-93 above)

YMPO

1.0 INTRODUCTION

During April 5-9, 1993, members of the quality assurance (QA) staff of the NRC Division of High-Level Waste Management (HLWM) observed a U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD) audit of the Yucca Mountain Site Characterization Project Office (YMPO). The audit, YMP-93-09, was conducted at the YMPO offices in Las Vegas, Nevada and at the Sample Management Facility (SMF) on the Nevada Test Site Mercury, Nevada. The audit evaluated the adequacy and effectiveness of the YMPO QA program. Eight programmatic areas were audited. No technical activities and no YMQAD activities were audited during this audit; YMQAD activities will be audited later by the OCRWM OQA.

This report addresses the effectiveness of the YMQAD audit, and the adequacy of implementation of the QA controls in the audited areas of the YMPO QA program.

2.0 OBJECTIVES

The objectives of the audit by YMQAD were to determine whether the YMPO QA program and its implementation meet the applicable requirements and commitments of the OCRWM Quality Assurance Requirements Document (QARD), the OCRWM Quality Assurance Program Description (QAPD), and associated implementing procedures.

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

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the YMPO implementation of the OCRWM QA program on direct observations of the auditors; discussions with audit team, YMPO, and YMPO contractor personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents. The NRC staff has determined that YMQAD QA Audit YMP-93-09 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. Audit team members were independent of the activities that they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team finding that YMPO implementation of the OCRWM QA program is generally adequate. Four preliminary Corrective Action Requests (CARs) were discussed by the YMQAD audit team at the post-audit meeting: three against YMPO and one against the Management and Operations contractor (M&O). Also, several other potential CARs were acceptably resolved by the YMPO organization during the audit. None of the preliminary CARs identified by the YMQAD audit team is significant in terms of the overall OCRWM QA program as implemented by YMPO and the M&O.

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

5.8 Summary of NRC Staff Findings

5.8.1 Observations

The NRC staff did not identify any observations relating to deficiencies in either the audit process or the OCRWM QA program as implemented by YMPO.

5.8.2 Good Practice

YMPO senior management demonstrated its interest in YMPO's implementation of its QA program by the YMPO Associate Director's presentation at the entrance meeting and by the attendance of the YMPO and other involved management at the daily audit status meetings. This was reflected in YMPO's acceptance of CARs and follow-up recommendations where improvements can be made to the YMPO quality system.

OCRWM

1.0 INTRODUCTION

During May 10-13, 1993, members of the quality assurance (QA) staff of the NRC Division of High-Level Waste Management (HLWM) observed a U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Headquarters Quality Assurance Division (HQAD) audit of OCRWM. The audit, HQ-93-05, was conducted at the OCRWM offices, Forrestal Building, in Washington, DC. The audit evaluated the adequacy and effectiveness of the OCRWM QA program in three programmatic areas.

This report addresses the effectiveness of the HQAD audit, and the adequacy of implementation of the QA controls in the audited areas of the OCRWM QA program.

2.0 OBJECTIVES

The objectives of the audit by HQAD were to determine whether the OCRWM QA program and its implementation meet the applicable requirements and commitments of the OCRWM Quality Assurance Requirements Document (QARD), the OCRWM Quality Assurance Program Description (QAPD), and associated implementing procedures.

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

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the HQAD audit process and implementation of the OCRWM QA program on direct observations of the auditors; discussions with audit team and OCRWM personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents. The NRC staff has determined that QA Audit HQ-93-05 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. Audit team members were generally independent of the activities that they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary HQAD audit team finding that implementation of the OCRWM QA program in the areas audited is generally adequate. Five preliminary Corrective Action Requests (CARs) were discussed by the HQAD audit (exit) team at the post-audit meeting. Several other potential CARs were acceptably resolved by the OCRWM organization during the audit. None of the preliminary CARs identified by the HQAD audit team is significant in terms of the overall OCRWM QA program.

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

5.8 Summary of NRC Staff Findings

5.8.1 Observations

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

5.8.2 Good Practices

Including an auditor from the Yucca Mountain Quality Assurance Division to serve as ATL, should it have become necessary to review items that had been worked on by the ATL, was good contingency planning.

5.8.3 Weaknesses

- Although the audit was intended to be performance-based, the process seemed to be mainly a programmatic, compliance-based audit. This was at least partly due to the nature of, and scarcity of, work products.
- Compared to other OCRWM audits observed by the NRC staff the auditors had more problems in reaching agreement with the auditees on the rationale for findings.
- Some of the deficiencies identified appeared to result from lack of understanding of the OCRWM QA program by the OCRWM staff, particularly concerning applicability of procedures and the need to document and retain records of decisions. The NRC observers did not detect the across-the-board awareness of the QA program requirements that now seems to generally prevail at long-time program participants.
- Although many of the personnel are genuinely striving to improve their quality system and their resulting products, in a few areas of the OCRWM HQ organization, key staff did not seem too interested in the audit until it was apparent that a CAR would be written.

W.B.

OBSERVATION OF THE U.S. DEPARTMENT OF ENERGY AUDIT OF THE SAVANNAH RIVER SITE DEFENSE WASTE PROCESSING FACILITY

The audit evaluated the adequacy and effectiveness of implementation of the DOE Savannah River Operations Office Defense Waste Processing Division (DWPD) and the Westinghouse Savannah River Company (WSRC) QA Program Descriptions as applied to the waste acceptance activities associated with high-level waste form production at the DWPF.

The EM-343 audit team consisted of 16 DOE and DOE contractor personnel, namely, 11 programmatic auditors, 4 auditor/technical specialists, and the Audit Team Leader. Audit checklists addressed the 19 programmatic elements of the DWPD and WSRC QA programs and some technical items, and were used throughout the audit. The audit objective was to verify procedural compliance as opposed to being a performance based audit (which focuses on results), or a qualification audit (which essentially qualifies the QA programs for continued activities).

In general, the NRC staff observers determined that the audit appeared to be effective from a programmatic aspect. The technical activities audited were waste container canister design and procurement and waste acceptance; however, these were not identified in the audit plan. Since the NRC observer staff did not include any technical specialists, no NRC technical evaluation was made of the technical adequacy of work products.

As a result of the audit, seven preliminary Deviation Corrective Action Requests (DCARs) were issued and 32 Observations were noted by the EM-343 audit team. Overall, the NRC staff generally agrees with the audit team's conclusion that the implementation of the DWPD and WSRC programs is adequate with the exception of three criteria the audit team considered to be marginally effective (Criterion 5, "Instructions, Procedures, and Drawings"; Criterion 15, "Nonconformances"; and Criterion 18, "Audits"). The adverse conditions identified in the DCARs during the audit do not appear to be significant in terms of the overall QA program as implemented by DWPD and WSRC.

The audit commenced with DWPD and WSRC presenting comprehensive overviews of their organizational structures and of the completed and ongoing activities. The information presented was beneficial to the NRC staff observers and appeared to contribute to better organizing the logistics of the audit. DWPD/WSRC explained that qualification runs for the vitrification process may be delayed two or more months due to a flooding incident in the melter during cold chemical runs and the associated corrective action implementation to resolve this and other issues. The audit team indicated that it would not review the melter incident, since a separate investigation team was presently looking into this matter.

The DWPD and DWPF procedures appear to address the QA program elements applicable to their activities, and their staffs appear to be generally familiar with QA program requirements. The DWPF technical staff members observed seemed particularly comfortable with their QA program as a routine part of their work practices. Implementation of the DWPF QA program for scientific investigations and design control appear effective.

The audit books which contained the audit plan, team selection, checklists, open items from the previous audit, EM-343 audit and corrective action procedures, and audit team and observer forms, were received on the opening day of the audit. The NRC staff needs to have the audit plan and the technical checklists at least one week prior to commencement of an audit, to make a determination whether NRC staff technical observers should observe the audit. This matter has been discussed several times with DOE and documented in a previous NRC Observation Audit Report (see Section 5.9.2 of NRC Observation Audit Report, J. Holonich to J. Roberts dated February 17, 1993, for Audit HQ-93-02 of EM-343 January 11-15, 1993). The NRC staff requests for all future audits, that it receive at least one week in advance, as a minimum, copies of the audit plan and technical portion of the checklists (even if in draft form).

As a result of the audit conducted of DWPf by EM-343 during September 14-18, 1992, 5 DCARS were issued and 14 Observations were noted. All of the findings from the September 14-18, 1992, audit were still open and were scheduled to be verified and closed during this audit. Several of the findings were relatively minor in nature (e.g., procedural deficiencies requiring a revision to a procedure) and could have been closed out in "timely manner" as required by Section 16.1.(8) of the EM-343 Quality Assurance Program Description and Section 16.4 of the DOE Quality Assurance Requirements Document DOE/RW-0214. The NRC staff inquired why corrective action took so long (about eight months), especially for the items relatively minor in nature. The EM-343 QA Manager explained that its policy is to verify the corrective action taken to resolve the discrepancy at the point of origin of the finding. The EM-343 QA Manager indicated that EM-343 will consider revising its corrective action procedure to allow minor deficiencies, such as procedure revisions, to be verified and closed in a more timely manner when the documented evidence is received.

During the auditing of the equipment storage areas and canister design and testing, the auditee indicated that there had been 13 internal and external audits and surveillances of the equipment storage area from August 1992 to February 1993, and over 20 internal and external audits and surveillances of the canister design and testing area in the past 12 months. Based on its experience and "lessons learned" in audits for nuclear reactors, the NRC staff recommends that DOE consider combining audits where possible, to avoid the adverse impacts of excessive audits.

The NRC staff noticed that the DWPf/WSRC QA implementing procedure structure may be redundant or excessive. A similar type of comment was noted during the NRC staff observation of the EM-343 July 27-31, 1992, audit of the West Valley Demonstration Project (WVDP) (see letter from J. Holonich to J. Roberts dated September 24, 1992). The auditors noted two examples where audited personnel were unaware that a particular procedure or specific requirement existed. Due to the multiplicity of implementing procedures, certain implementing requirements may be unintentionally overlooked or bypassed. The NRC staff recommends that consolidation of implementing procedures be considered where feasible. This may contribute to more accurate implementation of the DWPf and WSRC QA programs.

Auditors and observers experienced some difficulties in integrating their respective roles compared to recent OCRWM audits. The NRC staff recommends that EM-343 auditors attempt to more positively include observers in the audit process by (1) identifying the activities the auditor may wish to observe; (2) keeping the observer apprised of the auditor's approach to the audit, for example, by identifying the checklist items being covered, what objective evidence is to be reviewed, the roles of the auditees being interviewed, and (3) eliciting comments and questions from the observer at appropriate points.

The OCRWM and NRC observers noted an apparent inconsistency in the way deviations were being documented as Observations and not as DCARs. Standard Practice Procedure (SPP) 4.02, Revision 3, "Administration and Conduct of QA Audits," requires adverse findings to be recorded on a DCAR in accordance with SPP 5.01, "Deviations and Corrective Actions." A Deviation as defined in paragraph 3.b.(3) of SPP 5.01, is, "A condition adverse to quality that is a departure from specified requirements." The OCRWM and NRC observers noted that deviations are being documented as Observations and not as DCARs as required to meet the intent of SPPs 4.01 and 5.01. Additionally, it appeared that several of the deviations appeared to be subjective opinions as opposed to basing the findings on specified requirements. The DOE observers cited four examples in the area of software validation and existing data where this procedure was knowingly not being followed or being interpreted differently than OCRWM does. OCRWM requires that existing data used for waste acceptance be qualified. WSRC has used some existing data for designing the vitrification process, and has developed plans for qualification of the data during waste qualification runs. An audit observation was presented that the Waste Form Qualification Report did not identify data requiring qualification, although it was identified in a subsequent "Plan for Qualification of Existing Data for Waste Acceptance." The OCRWM Observers felt that a DCAR was warranted because the data had not been qualified before use. The NRC staff is concerned with this inconsistency in that conditions adverse to quality documented as Observations, do not require a response and do not require a tracking system. This matter was previously discussed and documented in the Observation Report of EM-343 Audit No. 93-WV-AU-01 (Letter from D. Horton to R. Erickson dated March 9, 1993). A written response concerning this practice is requested and it will be carried on the NRC/DOE Open Items list.

Product Composition Control System software predicts waste form acceptability based on melter feed composition. This software is classified as essential; the process cannot operate without it functioning. The software specification includes requirements for an on-line, back-up computer (hardware) system. The audit team identified that this system design requirement was not included in the test plan, nor had it been tested. During the course of the audit, the auditors strongly considered this for a DCAR, however, no specific requirement to test the hardware configuration of this system was found. The preliminary conclusions of the auditors appeared to be based on their judgement that the hardware should be tested, rather than on QA requirements.

An Audit Observer Inquiry was submitted to request a copy of the procedure(s) used to determine those items under the DWPF QA program and a copy of the actual listing of the items. The reply to this inquiry was received just prior to the Post Audit meeting and there was insufficient time for the NRC staff observer to fully understand the detail of the response. However, the response appeared to indicate there was not a standardized list available. This is also of concern to the audit team since two observations were listed which questioned the waste items/activities and the requirements for determining the actual items and activities. The subject matter of the listing of items and activities which fall under the purview of the QA program has surfaced during the audits of West Valley Demonstration Project (see NRC comments for EM-343 Qualification Audit No. 92EA-WV-AU-001, from J. Holonich to J. Roberts dated September 24, 1992), and EM-343 (see Sections 5.3.1 and 5.9.2 of NRC Observation Audit Report 93-04 for the OCRWM performance based QA Audit No. HQ-93-02 of EM-343, from J. Holonich to J. Roberts dated February 17, 1993). This matter was briefly discussed with the EM-343 QA Manager during the audit, and it was indicated that a meeting may be held between EM-343, DWPF, and WVDP to mutually resolve this issue. The NRC staff will continue to carry this item on the NRC/DOE Open Items list and a written response is requested.

M&O

1.0 INTRODUCTION

From March 22-25, 1993, the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) conducted Quality Assurance (QA) Surveillance No. YMP-SR-93-16 of the Civilian Radioactive Waste Management System, Management and Operating contractor (M&O) QA program in Las Vegas, Nevada.

2.0 PURPOSE

The U.S Nuclear Regulatory Commission staff observed and evaluated the YMQAD QA surveillance to gain confidence that YMQAD and the M&O are properly implementing the requirements of their QA programs by assessing the effectiveness of the YMQAD surveillance and determining the adequacy of the M&O QA program in the areas observed. The staff's evaluation is based on direct observations of the surveillance process, discussions with the YMQAD surveillance team and M&O personnel, and reviews of pertinent M&O records.

3.0 SCOPE

The scope of this surveillance was limited to evaluating: 1) M&O procedures for receiving and processing changes to Raytheon Services Nevada (RSN) design documents; 2) M&O acceptance, review, and verification of design documents, engineering analyses and calculations from RSN; 3) M&O use and control of Field Change Requests; 4) M&O procedures for the identification of design documents, and 5) M&O implementation of M&O design procedures.

6.0 NRC CONCLUSIONS

The NRC staff has determined that the DOE/OCRWM surveillance of the M&O QA program was useful and effective. The surveillance team was very familiar with the M&O QA procedures in the areas being surveilled. The NRC staff agrees with the OCRWM surveillance team's preliminary findings as stated in Section 5.0 above.

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1.0 INTRODUCTION

During June 22 through 24, 1993, quality assurance (QA) staff of the NRC Division of High-Level Waste Management observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) QA Surveillance No. HQ-SR-93-01 of the DOE Office of Environmental Restoration and Waste Management Vitrification Projects Division (EM-343). The surveillance team conducted interviews with EM-343 and its contractors' personnel and reviewed pertinent documents in Germantown, MD. A member of the NRC staff participated as an observer on this surveillance.

2.0 SCOPE

The surveillance, HQ-SR-93-01, focused on the development, preparation, review, and issuance of the EM-343 Waste Acceptance Product Specifications for Vitrified High-Level Waste Forms (WAPS). The surveillance team independently verified the flow-down of requirements from the OCRWM Waste Acceptance Systems Requirements Document (WA-SRD) into the WAPS.

3.0 PURPOSE

The NRC staff observed and evaluated the OCRWM QA surveillance to gain confidence that OCRWM and EM-343 are properly implementing the requirements of their QA programs by assessing the effectiveness of the OCRWM surveillance and determining the adequacy of the EM-343 QA program in the areas under surveillance. The NRC staff's evaluation is based on direct observations of the surveillance process; discussions with the OCRWM surveillance team, EM-343 personnel, and EM-343 contractor personnel; and reviews of pertinent EM-343 records. The NRC staff did not evaluate the technical validity, adequacy, or correctness of the WAPS.

7.0 NRC CONCLUSIONS

The NRC staff determined that the surveillance was effective and agreed with the surveillance team that the WAPS adequately addresses the requirements in the WA-SRD but that some corrective actions should be taken. Two preliminary CARs were issued by the surveillance team. The adverse conditions identified in the preliminary CARs are not significant in terms of the overall EM-343 QA program and they do not reflect any major problems with the quality of the WAPS.



Department of Energy

Washington, DC 20585

MAY 24 1993

cc: J. [unclear] 6/9/93

Mr. Joseph J. Holonich, Director
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
Washington, DC 20555

Dear Mr. Holonich:

This is in response to the U. S. Nuclear Regulatory Commission (NRC) review of the U. S. Department of Energy (DOE) Quality Assurance Requirements and Description Document

On December 21, 1992, the NRC was requested to review and accept the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description Document (QARD), DOE/RW-0333P, Revision 0, dated December 18, 1992. The NRC staff documented the results of their review in a letter to Mr. Dwight Shelor, dated March 8, 1993. The letter indicated that the DOE/RW-0333P QARD continues to meet the NRC conditions for acceptance of the OCRWM Quality Assurance (QA) program with the exception of four open issues. The OCRWM responses to the four open issues are described below.

Issue (1) It is the NRC's position that the principal contractors be audited on an annual basis or justification be provided as to why longer time periods would be acceptable. The NRC understands OCRWM's intent for its proposed reduction of auditing frequency to a triennial basis; however, the staff has reservations on completely accepting this new practice until it can monitor its effectiveness. The NRC will monitor this position and indicate, in writing, any unsatisfactory results.

Response: The DOE/RW-0333P QARD, requires that the need for and frequency of all external audits be determined after an affected organization has been selected to perform work for the OCRWM program. The determination is based on the nature of the items or services being performed. External audits for compliance shall be performed triennially, as a minimum. Triennial compliance audits will be supported by performance based audits on selected work products. Annual performance evaluations for all affected organizations are required to be

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conducted and documented. These annual evaluations provide the justification for not performing annual compliance audits. If the annual evaluations cannot justify not performing an audit within the triennial period or indicate the need for additional audits, then an audit will be performed. Based on the QARD requirements, OCRWM will proceed with scheduling audits on a triennial basis, and as always, the NRC is welcome to monitor this practice.

Issue (2) It is the NRC's understanding that OCRWM has agreed to revise Supplement I of the DOE/RW-0333P QARD, to clarify that acquired software must meet the requirements of Supplement I, Section I.2.6, paragraphs A, B, C and D.

Response: OCRWM has agreed to make this change in its next revision of the DOE/RW-0333P, QARD.

Issue (3) It is the NRC's understanding that OCRWM has agreed to revise Supplement III, of the DOE/RW-0333P QARD, to clarify, in Section III.2.6.B, that "Model Validation" is limited to validation by peer review in those instances where data cannot be collected.

Response: OCRWM has agreed to evaluate Section III.2.6.B for a change in its next revision of the DOE/RW-0333P, QARD. We do not recall that specifics were discussed. The proposed change to Supplement III will be coordinated with the NRC staff before making the change.

Issue (4) The NRC Transportation Branch, Division of Industrial and Medical Nuclear Safety, maintains the position that the QARD include a description that the DOE has overall responsibility for quality assurance for the transportation system under the OCRWM program. This is with the understanding that DOE will be supported in this activity by other various organizations and that these organizations will be delegated authority and responsibility to implement the applicable requirements of 10 CFR Parts 71 and 21.

Response: The DOE/RW-0333P, QARD, is applicable to all program elements including transportation. Section 1.3.2.A states that the Director of OCRWM has the overall responsibility for carrying out the program. Section 1.2.4 states that positions or organizations delegating work shall retain overall responsibility for the delegated work. Section 1.3.2.6 states that the OCRWM Office of Storage and Transportation is responsible for managing the transportation system.

OCRWM has maintained its responsibility for Quality Assurance for all program elements, including transportation, by issuance of the QARD and imposition of requirements therein to all program participants.

OCRWM assures compliance with the QARD requirements by required QA overview activities.

With regard to 10 CFR Parts 71 and 21, the QARD, Appendix B, imposes 10 CFR Part 71. 10 CFR Part 21, however, while applicable to the OCRWM program through the OCRWM technical baseline, is not a Quality Assurance requirement and, therefore, will not be referenced in the QARD. This is consistent with NRC guidance contained in NUREG-0302, Revision 1.

Should you have any questions regarding this reply, please contact Donald G. Horton, at (202) 586-7220.

Sincerely,



Dwight E. Shelor
Associate Director for
Systems and Compliance
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**QATSS ORGANIZATIONAL CHART
PERSONNEL STATUS AS OF JUNE 14, 1993**

APPROVED JUNE 22, 1993



**R. KEELE
QATSS PROGRAM MANAGER**

QATSSORG.129.QA/S-22-93