

May 14, 1996

Mr. Ronald A. Milner, Director
for Program Management and Integration
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW 30
1000 Independence Avenue, S.W.
Washington, D.C. 20585

SUBJECT: MINUTES OF THE MARCH 27, 1996, QUALITY ASSURANCE MEETING

Dear Mr. Milner:

Enclosed are the minutes of the U. S. Nuclear Regulatory Commission - U. S. Department of Energy (DOE) quality assurance (QA) meeting that was held on March 27, 1996. This technical meeting, convened at 1:00 p.m. EST, was held by videoconference between DOE contractor facilities in Las Vegas, Nevada, and Washington, D.C., as part of a continuing series of QA meetings.

Other organizations represented at the meeting were the State of Nevada; Clark County, Nevada; Nye County, Nevada; the Nuclear Waste Technical Review Board; DOE's Management and Operating Contractor; DOE's Quality Assurance Technical Support Services Contractor; and the National Council of American Indians.

If you have any questions regarding this letter or the meeting minutes, please contact Jack Spraul of my staff. He can be reached at 301-415-6715.

Sincerely,
[Original signed by:]
John H. Austin, Chief
Performance Assessment and High-Level
Waste Integration Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: See attached list

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R. Milner

- 2 -

CC List for letter to R. Milner dated May 14, 1996 :

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



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 14, 1996

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Other organizations represented at the meeting were the State of Nevada; Clark County, Nevada; Nye County, Nevada; the Nuclear Waste Technical Review Board; DOE's Management and Operating Contractor; DOE's Quality Assurance Technical Support Services Contractor; and the National Council of American Indians.

If you have any questions regarding this letter or the meeting minutes, please contact Jack Spraul of my staff. He can be reached at 301-415-6715.

Sincerely,

John H. Austin for

John H. Austin, Chief
Performance Assessment and High-Level
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Enclosure: As stated

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D. Horton, YMPO
F. Rodgers, DOE/Wash, DC

**MINUTES OF THE MARCH 27, 1996,
U.S. NUCLEAR REGULATORY COMMISSION/U.S. DEPARTMENT OF ENERGY
TECHNICAL MEETING ON QUALITY ASSURANCE**

On March 27, 1996, staff from the U.S. Nuclear Regulatory Commission met with representatives of the U.S. Department of Energy (DOE) to discuss items of mutual interest regarding Quality Assurance (QA) for DOE's site-characterization program for Yucca Mountain. This technical meeting, convened at 1:00 p.m. EST, was held by videoconference between DOE contractor facilities in Las Vegas, Nevada and Washington, D.C. as part of a continuing series of QA meetings. Attachment 1 is the meeting agenda which was generally followed. The numbers in parentheses at the end of some of the agenda items are the attachment numbers assigned to the overheads/handouts presented and discussed at the meeting.

Other organizations represented at the meeting were the State of Nevada; Clark County, Nevada; Nye County, Nevada; the Nuclear Waste Technical Review Board (NWTRB); DOE's Management and Operating Contractor (M&O); DOE's Quality Assurance Technical Support Services Contractor (QATSS); and the National Council of American Indians (NCAI). Attachment 2 is the attendance list.

This was the first NRC-DOE QA meeting with the primary objective of exchanging information that would lead to resolution of open items. The meeting began with opening remarks followed by self-introduction of the attenders. The NRC then referred to Revision 19 of NUREG-0325, "U.S. Nuclear Regulatory Commission Organization Charts and Functional Statements" (January 31, 1996) and presented some of the information from it. The organization of the Office of Nuclear Material Safety and Safeguards (NMSS) was described with emphasis on the Division of Waste Management (DWM). It was pointed out that the new organization has John Austin taking the place of Joe Holonich as NRC's primary point of contact for high-level waste, that John Thoma should be contacted when John Austin is not available, and that Sandra Wastler is now performing the NRC-DOE interface activities formerly performed by Mark Delligatti. As shown in Attachment 3, the NRC noted that John Greeves (Director, DWM) is currently serving as the Acting Deputy NMSS Office Director and that Margaret Federline (Deputy Director, DWM) is serving as Director, DWM. Further, the position of Deputy Director, DWM, is being filled on a 60-day rotational basis by the Branch Chiefs in DWM with Mike Weber currently acting in that capacity.

The next topic on the agenda was the list of QA open items generated by the NRC in the 1994-1996 time period. These 11 open items are shown on Attachment 4. While the items marked "Closed" on Attachment 4 received little attention during the meeting, the status and responsibilities for closing the other items on the attachment were discussed at some length. It was generally agreed that the resolution of the first three items shown as "Open" on the list would not occur until after DOE submitted its response to the request for additional information requested by the NRC in its letter to DOE dated December 14, 1995 (Bell to Milner). The schedule for this submittal had been discussed at the videoconference concerning the Exploratory Studies Facility (ESF) on February 15, 1996. At that time, DOE had reported its response to NRC was scheduled for submittal to DOE by the M&O in mid-April 1996 and then to the NRC for review and potential item resolution. DOE noted there has been no change to that schedule. In order to help resolve these open items, NRC

Enclosure

requested that DOE submit the revised drawings of the ESF interface with the Geologic Repository Operating Area. DOE indicated that these revised drawings will be supplied. However, this was the first time the request had been made (NRC had planned to review these drawings in Las Vegas at a later date), and thus a schedule for submission was neither expected nor provided.

Open items 7, 8, and 9 on Attachment 4 all relate to DOE's license application annotated outline (LAAO). DOE indicated that a response to these open items - including a revised LAAO Chapter 10 - was in preparation and that NRC could expect the response in about one month. NRC noted that Open Item 9 on Attachment 4 regarding the LAAO quality controls and qualification of data appeared to the NRC to also apply to DOE's Total System Performance Assessment - 1995 (TSPA-95) currently being reviewed by the NRC. Thus, DOE should not be surprised if such a comment is included in NRC's response to TSPA-95.

DOE questioned the need of Open Item 10 since corrective action by USGS regarding its technical review process had been requested. NRC indicated the problem was evident at two DOE audits and the open item was issued to ensure that the individual corrective action requests would result in the identification and correction of the fundamental root causes. DOE indicated that its response to this open item is in-work.

Open Item 11 drew forth significant discussion during the meeting. NRC pointed out that USGS reports continue to use the uranium-trend dating technique in spite of a USGS report (USGS - Yucca Mountain Project Branch 1995 Milestone Report 3GCH510M, "Progress Report on Dating Quaternary Surficial Deposits") having words like: "Some of the problems inherent (to uranium-trend dating) ... became apparent during ... the late 1970's. ... The method has never received wide-spread use by the Quaternary geochronologic community." And, later: "... uranium-trend dating methods are considered fundamentally flawed from a technical viewpoint. ... we recommend in the strongest terms that all subsequent reference to and consideration of previously-published uranium-trend 'ages' from soil profiles at Yucca Mountain and elsewhere be abandoned with regards to numerical age significance. No other uranium-series geochronologists have ever come to the defense of the technique or the published results resulting from its application." The consensus of those participating in the discussion seemed to be that selection of methodologies, field and analytical techniques, technical approaches, and overall scientific design for characterizing the site are subject to technical reviews in, among other places, Study Plans. Requirements in the Quality Assurance Requirements and Description document (QARD, DOE/WR-0333P) pertain to how scientific investigations are conducted and documented, but DOE's Office of Quality Assurance has no *a priori* role in the selection process for what technique is applied for licensing. The potential applicant ultimately defends these decisions based on their technical merit. NRC indicated it would consider the discussion as it assesses DOE's response to the open item.

The next agenda item resulted in a discussion of the qualification of existing data. Between the time the meeting agenda was established and the meeting, NRC had responded to the DOE (Brocoum) letter of January 31, 1996, to NRC

(Holonich) in the NRC (Austin) letter of March 6, 1996, to DOE (Brocoum). The NRC letter noted that the qualification of existing data by verifying equivalent QA programs should be done by looking at equivalent procedure steps required by today's standards rather than by looking at a programmatic level. DOE indicated that it is costly, time consuming, and of limited value to merely compare process steps followed in obtaining information or data. The DOE will evaluate the documentation associated with the collection, development, and technical reviews of the data to be qualified to ensure consistency with QARD requirements and defensibility of the data through the License Application evaluation process. If both the DOE subject matter experts and the DOE Office of Quality Assurance determine that the data to be qualified were collected and/or developed and adequately documented consistent with QARD requirements, the data will be considered defensible and therefore qualified. The NRC letter also suggested using the term "accepted data" for data that were the best data (or only data) available. However, NRC's letter had indicated that "accepted data" must at some point be replaced by "qualified data." All present agreed that this is not necessarily the case as there are many useful and necessary data sources that cannot and will not be submitted to a qualification process for use in the development of the License Application. Examples include (but are not limited to) U.S. Weather Service data, Waste Form Characteristics data compiled by the DOE and the nuclear utilities outside of the QARD, and earthquake data or information compiled before current practices were instituted. Attachment 5 provides DOE's concepts regarding the qualification of existing data and agrees with the use of the term "accepted data." NRC also referenced its Request for Additional Information (RAI) 19 in the NRC (Austin) letter of March 18, 1996, to DOE (Milner) regarding Revision 5 of the QARD. RAI 19 states:

QARD Section III.2.5C, "Data considered as established fact by the scientific and engineering community do not require qualification" conflicts with Section II of NUREG 1298 that states: "All data used in support of the license application that is important to safety or waste isolation must ultimately be qualified to meet the requirements of 10 CFR 60, Subpart G." This conflict should be resolvable (and resolved) with the understanding by both DOE and NRC that the "weight" given to data during the licensing process will be dependent upon its documented quality and reliability or "goodness." Since this item is beyond the scope of QARD review, it will be carried as a separate open item in NRC's Open Item Tracking System until resolution.

While DOE objected to use of the term, "goodness," there did appear to be agreement with the concept that the "weight" given to data during the licensing process would be dependent upon its documented quality and reliability. Further, there appeared to be agreement that the source and classification (existing, qualified, or accepted) of data used in licensing must be clearly identified in order for its quality and reliability to be

1 No resolution was reached regarding DOE's use of the term "unqualified data" in the QARD versus the NRC's use of the term "existing data" in NUREG 1298.

assessed. DOE indicated it is preparing its response to both the March 6 and 18, 1996, NRC letters.

The NRC distributed its draft "HLW Procedure on the Use of Existing Data" (Attachment 6) to the meeting participants and called attention to the fact that Sections 1 through 4 of the draft refer to the use of data during precicensing while Section 5 refers to the use of data during licensing. While the paragraphs above reflect the discussions and understandings on data qualification, comments were solicited on the draft document. Since most meeting participants saw Attachment 6 at the meeting for the first time, comments at the meeting were neither expected or received.

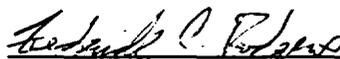
Changes to DOE's audit schedule, Attachment 7, were discussed, and there was mention made of Attachment 8, the summary reports of NRC's observation of DOE audits YMP-ARP-95-20 and YM-ARP-96-01 (U.S. Geological Survey - September 6-14, 1995 and October 23-27, 1995) and YM-ARP-95-19 (Sandia National Laboratories - January 22-26 1996). Generally, those at the meeting agreed that Attachment 8 is not very useful since it is only a summary of information issued previously. Future meetings will not include these summaries.

There were no items of concern noted by representatives of the State of Nevada or affected local governments.

After noting that the next NRC-DOE QA meeting had recently been scheduled for Wednesday, July 31, 1996, the meeting was adjourned at about 3:00 p.m. EST.



John G. Spraul
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

**NRC-DOE VIDEO CONFERENCE AGENDA
HIGH-LEVEL WASTE QUALITY ASSURANCE**

490 L'Enfant Plaza, Suite 7200
Washington, DC

Bank of America Building, Room 663
101 Convention Center Drive, Las Vegas, NV

March 27, 1996

OBJECTIVE - Technical meeting leading toward issue resolution for items listed below.

1:00 EST (10:00 PST)	Opening Remarks DOE, NRC, NV, AULG
1:10 EST	NRC/DWM reorganization NRC (3)
1:20 EST	Resolution status of NRC open QA issues DOE/NRC (4)
2:00 EST	DOE (Brocoum) letter of January 31, 1995, to NRC (Holonich) - "U.S. Department of Energy (DOE) Position on Qualification of Existing Data." NRC/DOE (5)
2:15 EST	Draft NRC position on the use of existing data for issue resolution NRC (6)
2:30 EST	DOE (Milner) letter of February 7, 1996, to NRC (Travers) regarding QARD application to 10 CFR Part 72 - "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste" DOE
2:50 EST	Changes to DOE audit schedule DOE (7)
3:00 EST	Closing Remarks and Discussion . . . DOE, NRC, NV, AULG (8)
3:10 EST (12:10 PST)	Adjourn

NRC/DOE QA MEETING

MARCH 27, 1996

ATTENDANCE LIST

NAME	ORGANIZATION	PHONE
(Las Vegas, Nevada)		
Therien, John	QATSS	(702) 794-7862
Hudson, Woody	QATSS	(702) 295-9184
Dana, Steve	QATSS	(702) 294-7176
Warren, Charles	QATSS	(702) 794-7248
Diaz, Mario	DOE	(702) 294-7974
Zimmerman, Susan	State of Nevada	(702) 687-3744
Williams, Albert	DOE	(702) 794-7591
Humphries, Cindy	QATSS	(702) 794-7742
Spence, Richard	DOE	(702) 794-7504
Greene, Hank	QATSS	(702) 794-7369
von Tiesenhausen, E.	Clark County, NV	(702) 455-5175
Barton, Bob	DOE	(702) 794-7957
Belke, Bill	NRC	(702) 388-6125
Ruth, Ron	M&O	(702) 295-5074
Horton, Donald	DOE	(702) 794-7675
Schmit, Jim	QATSS	(702) 794-7709
Snell, Richard	M&O	(702) 295-5168
Bailey, Jack	M&O	(702) 794-7266
Geer, Tom	M&O	(702) 794-7868
LeRoy, S. E.	M&O	(702) 295-5563
Bodnar, Steve	M&O	(702) 295-4844
Gil, April	DOE	(702) 794-7622
Stellovato, Nick	Nye County	(702) 295-6142
Newbury, Claudia	DOE	(702) 794-7942
Bjerstedt, Tom	DOE	(702) 794-7590

NAME	ORGANIZATION	PHONE
(Washington, D.C.)		
O'Conner, Stephen	NRC	(301) 415-7878
Spraul, Jack	NRC	(301) 415-6715
Wagner, Lester	QATSS	(202) 488-5420
Clark, Bob	DOE	(202) 586-1238
Morgan, Robert	M&O	(703) 204-8761
Dossett, John	NCAI	(202) 466-7767
Einberg, Chris	DOE	(202) 586-8869
Chu, Sherwood	NWTRB	(703) 235-4473
Peck, Richard	QATSS	(202) 488-5438

ROTATIONAL ASSIGNMENTS

- * John Greeves Acting Deputy NMSS Office Director
- * Margaret Federline Acting DWM Division Director
- * Michael Weber Acting Deputy DWM Division Director
- * John Surmeier Detailed to Strategic Assessment
- * Robert Nelson Acting Branch Chief for LLDP

NRC OPEN ITEMS (ISSUES) FOR DISCUSSION @ 03/27/96 QA MEETING

	ISSUE (ITEM)	REFERENCE	STATUS
1	M&O design control program.	Bernero to Dryfus ltr, 10/13/94	Open
2	ESF design and construction phasing.	Holonich to Milner ltr, 03/09/95	Closed
3	Potential of construction work to impact site characterization or the waste isolation capability of the site.	Bernero to Dryfus ltr, 10/13/94	Open
4	Request for more details regarding QA concerns as well as the design of the ESF.	Bernero to Dryfus ltr, 10/13/94	Open
5	Validation of acquired software.	Austin to Milner ltr, 03/06/96	Closed
6	Electronic Scientific Notebooks.	Holonich to Milner ltr, 01/27/95	Closed
7	License Application Annotated Outline (LAAO) incomplete and editorially poor.	Holonich to Milner ltr, 08/15/95	Open
8	LAAO Chapter 10 headings do not reflect NRC guidance.	Holonich to Milner ltr, 08/15/95	DOE resubmitting
9	Quality controls applied to the LAAO.	Holonich to Milner ltr, 08/15/95	Open
10	USGS technical review process effectiveness.	Holonich to Milner ltr, 11/02/95	Open
11	Lack of QARD requirements for the qualification of scientific investigation methods.	Milner to Austin ltr, 02/26/96	In Work (NRC)

QUALIFICATION OF EXISTING DATA

**DATA DETERMINED TO BE TECHNICALLY CORRECT,
SUITABLE FOR THEIR INTENDED USE, AND ACCEPTED AS
FACTUAL FOR USE IN SUPPORT OF QUALITY-AFFECTING
ACTIVITIES SHALL BE IDENTIFIED AS ACCEPTED DATA.**

**(e.g. engineering handbooks, density tables, gravitational
laws, etc.)**

**EQUIVALENT QA PROGRAM IS A QA PROGRAM SIMILAR IN
SCOPE AND IMPLEMENTATION TO A 10CFR 60, SUBPART G
QA PROGRAM.**

HLW PROCEDURE ON THE USE OF EXISTING DATA¹

1. For the purpose of conducting prelicensing reviews, resolving issues at the staff level, or providing comments to DOE and others during pre-licensing consultation (including DOE's viability assessment), NRC staff shall document its understanding of the qualification of the data used in its review. NRC staff should:
 - a. use qualified data² supplied by DOE.
 - b. use existing data supplied by DOE that DOE believes can be qualified.
 - c. use other sources of data if the data are technically defensible; that is, if the NRC staff believes the data can be qualified. For example, the table on the next page identifies non-DOE sources of data used by NRC in its analysis of extreme erosion at Yucca Mountain.
2. NRC staff may identify existing data from other sources which, if qualified, could lead to issue resolution for licensing.
3. NRC staff should ensure that DOE advises NRC of the qualification status of the data DOE uses for pre-licensing issue resolution, for its viability assessment, and for other licensing interactions. (If DOE uses data that NRC staff believes cannot be qualified for its application or uses a scientific approach that NRC staff believes is inappropriate as applied, NRC staff shall comment accordingly.)
4. NRC staff should ensure that DOE supplies the NRC with qualified data and existing data that DOE believes can be qualified that are applicable for resolving a given issue or sub-issue. For example, with respect to extreme erosion and cosmogenic dating, DOE should have provided (1) all data and parameters necessary for a consistent recalculation of the exposure age and (2) a summary of the radiogenic and magnetic results from Black Cone, including recent ⁴⁰Ar/³⁹Ar ages, ¹⁰Be data, and paleomagnetic site-mean results.

¹ Existing Data = Data developed prior to the implementation of a 10 CFR 60, Subpart G, quality assurance (QA) program by DOE and its contractors; data developed outside the DOE repository program (such as by oil companies, national laboratories, or universities); or data published in technical or scientific publications. Existing data does not include information that is accepted by the scientific and engineering community as established facts - for example, data in engineering handbooks, density tables, and gravitational laws (from NUREG-1298, "Qualification of Existing Data for High-Level Waste Repositories", February 1988)

² Qualified Data = Data initially collected under a 10 CFR 60, Subpart G, QA program or existing data qualified in accordance with NUREG-1298 (from NUREG-1298, "Qualification of Existing Data for High-Level Waste Repositories", February 1988)

5. NRC staff shall ensure that data used by DOE at licensing either is qualified or (as noted in footnote 1) is information that is accepted by the scientific and engineering community as established facts - for example, data in engineering handbooks, density tables, and gravitational laws³.

OTHER SOURCES OF DATA USED BY NRC TO EVALUATE EXTREME EROSION	
REFERENCE	SOURCE
Dorn, R. and D. Krinsley. 1994. New perspectives on colluvial boulder deposits in the southwestern Great Basin, USA. <i>Physical Geography</i> 15: 62-79.	Research supported by NSF PYI Award and by State of Nevada.
Liu, T. and R. Dorn. In Press. Understanding spatial variability in environmental change in drylands with rock varnish microlaminations. <i>Annals of the Association of American Geographers</i> .	Research probably supported by State of Nevada.
Morrison, R.B. 1995. <i>Preliminary Draft "Quaternary and Pliocene Geology of Tecopa Valley, California: A Five-Million-Year Stratigraphic, Tectonic, Climatic, Erosion, Hydrologic, and Hydrogeologic Record."</i> Morrison and Associates Ltd. Golden, Colorado. 49 p.	Research probably supported by State of Nevada.
Peterson, Frederick F., J. H. Bell, R. T. Dorn, A. R. Ramelli and T. Ku. 1995. Late Quaternary geomorphology and soils in Crater Flat, Yucca Mountain area, southern Nevada. <i>GSA Bulletin</i> 107: 379-395.	Research supported by State of Nevada.
Spaulding, W.G. 1995. <i>Effects of Climate and Hydrologic Changes in the Vicinity of Yucca Mountain Fortymile Canyon Records</i> . Dames and Moore, 4220 S. Maryland Parkway, Suite 108, Las Vegas, Nevada 89119. 4 p.	Research supported by State of Nevada.

Spraul, 03/19/96
P:\MLW-Proc.R00
March 19, 1996

³ DOE (Brocoum) letter of January 31, 1996, to NRC (Holonich) describes DOE's position on the qualification of existing data. This position does not totally agree with the NRC position given in NUREG-1298. The NRC is currently developing its response to this DOE letter.

**CHANGES TO FY 1996 OCRWM INTERNAL AUDIT SCHEDULE
(REVISION 1 TO REVISION 2)**

AUDITED ORGANIZATION	DATES	CHANGE(S)
M&O	2/5-16/96	COMBINED COMPLIANCE AUDITS OF VA M&O AND LV M&O INTO AUDIT HQ-ARC-96-01. INCREASED AUDIT DURATION TO TWO WEEKS.
M&O/SNL	6/5-14/96	TOTAL PERFORMANCE ASSESSMENT (WBS 1.2.5.4.1) ADDED TO AUDIT SCOPE. AUDIT DURATION EXTENDED TO 8 DAYS TO ALLOW FOR SITE EVALUATIONS. AUDIT DATES CHANGED AT REQUEST OF AUDITED ORGANIZATION.
M&O/SNL	7/8-12/96	PERFORMANCE-BASED EVALUATION OF SITE PERFORMANCE ASSESSMENT (WBS 1.2.5.4.4) ADDED TO AUDIT SCOPE. AUDIT DATES CHANGED AT REQUEST OF AUDITED ORGANIZATION.

**CHANGES TO FY 1996 OCRWM INTERNAL AUDIT SCHEDULE
(CONTINUED)**

AUDITED ORGANIZATION	DATES	CHANGE(S)
USGS	4/29-5/3/96	COMBINED PERFORMANCE-BASED AUDIT OF USGS UZ HYROCHEMISTRY (WBS 1.2.3.3.1.2.7) WITH THIS PERFORMANCE-BASED AUDIT OF USGS PRELIMINARY SITE SATURATED ZONE MODEL (WBS 1.2.3.3.1.3.3).
VA M&O	12/11-15/95	PERFORMANCE-BASED AUDIT OF DESIGN REQUIREMENTS FLOWDOWN CANCELLED.
EM-323	3/11-15/96	PERFORMANCE-BASED AUDIT OF TECHNICAL REVIEW GROUP PROCESS CANCELLED.
VA M&O	7/29-8/2/96	PERFORMANCE-BASED AUDIT OF SYSTEM ENGINEERING DESIGN CONTROL INTERFACES CANCELLED .
EM	1/8-12/95	PERFORMANCE-BASED AUDIT OF INTERFACES BETWEEN WASTE ACCEPTANCE DOCUMENTS CANCELLED.

**CHANGES TO FY 1996 OCRWM INTERNAL AUDIT SCHEDULE
(SUBSEQUENT TO REVISION 2)**

- **COMPLIANCE AUDIT OF GENERAL ATOMIC SCHEDULED FOR 3/25-29/96
HAS BEEN CANCELLED.**

- **ALL CHANGES SUBSEQUENT TO REVISIONS WILL CONTINUE TO
BE REFLECTED IN WORKING SCHEDULE UPDATES.**

**CHANGES TO FY 1996 OCRWM INTERNAL AUDIT SCHEDULE
(CONTINUED)**

- **AN ADDITIONAL FIVE CHANGES INVOLVED ADJUSTMENTS TO SCHEDULED AUDIT DATES ONLY.**
- **ALL CHANGES ARE REFLECTED IN REVISION 2 AND ARE IDENTIFIED BY REVISION BARS.**

YMQAD AUDIT YM-ARP-95-20 OF U.S. GEOLOGICAL SURVEY

INTRODUCTION - Members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) and geosciences staff observed the 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 selected technical activities of the U.S. Geological Survey (USGS). The audit, YM-ARP-95-20, was conducted at Yucca Mountain (YM), Nevada on September 6-7, 1995, and at the USGS offices in Denver, Colorado from September 11-14, 1995.

The objective of the audit by YMQAD was to evaluate selected USGS scientific investigation activities and the quality of the resultant end products associated with the series of activities leading to the development of the unsaturated zone (UZ) hydrologic model of YM.

MANAGEMENT SUMMARY - This audit evaluated the implementation of the USGS QA program for activities associated with the flow of data from field geologic and hydrologic investigations through development of a UZ hydrologic model for YM. The State of Nevada was not represented at this audit.

The NRC staff determined that the audit was effective. The audit team found that the USGS QA program had been effectively implemented in the areas audited, with the exception of the activities associated with the UZ model development, which was indeterminate. The NRC staff agrees with these conclusions. One draft Corrective Action Request (CAR) was discussed at the exit meeting. It identified deficiencies in applying appropriate QA controls (including no software QA controls applied to the TOUGH2 code), inadequate personnel training, and inadequate technical reviews associated with the modeling efforts. In addition, three draft Deficiency Reports (DRs) and one draft Performance Report (PR) were initiated as a result of the audit.

NRC STAFF FINDINGS - The QA programmatic and technical portions of the audit were conducted in a professional manner, and the audit team adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the USGS QA program as applied to UZ hydrologic model development activities.

Although previously recognized good auditing practices were not always followed, no adverse impacts resulted. The NRC staff did not observe any deficiencies in the audit process.

The NRC staff agrees with the preliminary YMQAD audit team findings.

Observation - The NRC staff is concerned that technical reviews conducted under the USGS QA program may not adequately assure the correctness, technical adequacy, completeness, accuracy, and compliance with established requirements of technical documents. This will be listed as an open item (10) in the NRC Open Item Tracking System until satisfactorily resolved.

Recommendations -

- The YMP-USGS Training Database appears to provide an excellent system for storing and retrieving training information, and DOE should consider adopting it for all participants.
- DOE should ensure through appropriate training that previously recognized good audit practices are followed.

AUDIT TEAM FINDINGS

The application of QA controls was determined to be effective except for the activity for developing the UZ hydrologic model. Based on the CAR and DRs identified, the effectiveness of QA controls for this modeling activity were indeterminate.

At the post-audit meeting the audit team presented the CAR, DRs, and PRs listed below.

CAR - UZ model development performed by LBL was not suitably controlled under the USGS QA program. Specifically, the TOUGH2 code was not controlled; the technical reviews of the LBL/USGS report LBL-37358/US-814, "Preliminary Development of the LBL/USGS Three-Dimensional Site-Scale Model of Yucca Mountain, Nevada," did not identify significant errors; the data package for this report was not updated after final comment resolution; LBL personnel lacked required training; and qualification records were incomplete.

DRs -

- The report, "Stratigraphic Relations and Hydrologic Properties of the Paintbrush Tuff Nonwelded Hydrologic Unit, YM, Nevada," was classified as not qualified, but the activity had been classified as quality affecting.
- Technical reviews of the report, "Fracture Character of the Paintbrush Tuff Nonwelded Hydrologic Unit, Yucca Mountain, Nevada," did not include reviews for consistency with the supporting data.
- LBL personnel working on USGS UZ model development activities were not trained/indoctrinated as required.

PR - A calibration record did not identify the company that actually performed the calibration.

YMQAD AUDIT YM-ARP-96-01 OF U.S. GEOLOGICAL SURVEY

INTRODUCTION - Members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) and geosciences staff observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) audit of selected technical activities of the U.S. Geological Survey (USGS). The audit, YM-ARP-96-01, was conducted at the University of Nevada, Reno, Seismological Laboratory (UNRSL), Reno, Nevada on October 23-24, 1995, and at the USGS offices in Lakewood, Colorado on October 25-27, 1995.

The objective of the audit by YMQAD was to evaluate USGS scientific investigation activities and the quality of the resultant end products associated with the seismic data collection and analysis.

MANAGEMENT SUMMARY - This audit evaluated the implementation of the USGS QA program for activities associated with seismic data collection and its use to support seismicity and earthquake studies. The State of Nevada was not represented at this audit.

Although the NRC staff determined that the audit was effective, several weaknesses in the audit process were identified. The audit team found that the USGS QA program had been effectively implemented in the areas audited. The NRC staff agrees with these conclusions. Four preliminary Deficiency Reports (DRs) were initiated by the audit team.

During this audit, the NRC staff recognized that the DOE QARD does not require the qualification of scientific methods which are not generally accepted by the technical community involved. Requirements for scientific method qualification should be equivalent to those for qualifying data and software. This condition is identified as an open item, and it will be tracked in the NRC Open Item Tracking System (II) until satisfactorily resolved.

NRC STAFF FINDINGS - The QA programmatic and technical portions of the audit were conducted in a professional manner, and the audit team adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the USGS QA program as applied to seismological activities. The NRC staff agrees with the preliminary YMQAD audit team findings.

Strength - The Technical Specialists were well qualified and communicated well with UNRSL and USGS personnel.

Weaknesses -

- The PIs should have been questioned in more depth regarding the rationale and justification for choosing certain parameters in the PI's analyses and models.
- The evaluation of the critical process steps during the audit contributed little to the audit and the determination of QA program effectiveness.

- The integration of QA into the technical portion of the audit was poor.

Recommendation - DOE should review the objectives of, implementation of, and training for its performance-based audits.

AUDIT TEAM FINDINGS - The application of QA controls was determined to be effective. At the post-audit meeting the audit team presented the preliminary DRs listed below.

- UNRSL seismological interpretation sheets (QA records in process) were completed in pencil and had erasures.
- UNRSL scientific notebooks documenting the digital seismic network included many loose pages, and was incomplete.
- The revised Study Plan covering the work reported in the "Initial Summary of Geologic, Geophysical, and Seismic Data to Support Earthquake Source Characterization for Seismic Hazard Analyses at the Proposed Nuclear Waste Repository, Yucca Mountain, Nevada" had not been issued by DOE to reflect the current direction of the investigations. The Study Plan is the principal document addressing QARD work control requirements. (This preliminary DR was written against OCRWM.)
- Manufacturers' data was used in seismometer calibrations, however, seismometers were procured from an unqualified source.

YMQAD AUDIT YM-ARP-96-05, OF SANDIA NATIONAL LABORATORIES

INTRODUCTION - Members of the Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) and geotechnical engineering staff observed the 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 selected technical activities of the Sandia National Laboratories (SNL). The audit, YM-ARP-96-05, was conducted on January 22 through 26, 1996, at SNL offices in Albuquerque, New Mexico. The State of Nevada was not represented at this audit.

The objective of this performance-based audit by YMQAD was to evaluate the implementation of the SNL QA program and the quality of the resultant end products associated with the in situ thermo-mechanical properties of Yucca Mountain to determine the degree to which they meet program requirements and commitments.

MANAGEMENT SUMMARY - This audit evaluated the implementation of the SNL QA program for activities associated with the in situ thermo-mechanical properties of Yucca Mountain.

The NRC staff determined that the audit was effective. The audit team found that the SNL QA program had been satisfactorily implemented in the areas audited except for the activities associated with the review of work agreements that were judged to be marginal. The NRC staff agrees with these conclusions. One preliminary Deficiency Report (DR) and one preliminary Performance Report (PR) were initiated by the audit team. DRs are used to report nonsignificant deficiencies, and PRs are used to report isolated conditions that require only remedial actions or minor improvements to meet requirements. The preliminary DR related to the lack of objective evidence of acceptable review and comment resolution of work agreements. The preliminary PR was written because the customer of a work agreement had signed it, indicating approval and that all comments had been resolved, prior to the time that the technical reviewer/quality assurance reviewer had signed it to document the review and resolution of comments.

NRC STAFF FINDINGS - The QA programmatic and technical portions of the audit were conducted in a professional manner, and the audit team adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the SNL QA program as applied to planning for the in situ thermal testing at Yucca Mountain.

The initial checklist questions along with the questions suggested by the NRC staff provided an adequate technical basis to conduct a thorough audit of the SNL ESF in situ thermal testing program. The technical specialist went into sufficient detail during the audit to examine the planning assumptions, the bases for technical analyses, and the adequacy of numerical modeling performed at SNL. Based on the discussions, it appeared that the technical people audited were knowledgeable in their respective fields. The method used by the technical specialist to perform the audit was an appropriate combination of technical discussions with the SNL staff and reviews of project files and other reference material requested by the audit team and provided by SNL.

Previously recognized good auditing practices were followed by the ATL and the audit team, and the NRC staff did not observe any deficiencies in the audit process. The auditor and the technical specialist worked well as a team in that they audited items of mutual interest together but separated to audit items that were only within one's area of interest.

The NRC staff will follow the issue of thermal load selection by DOE and will observe how the preliminary results from the shakedown phase will be input into the conceptual design of the repository and into the waste package design. The NRC staff will also follow the construction and layout of the thermal test alcove and will provide timely feedback on resolving issues related to test-to-test and construction-to-test interference.

The NRC staff agrees with the preliminary YMQAD audit team findings of satisfactory compliance with the SNL QA program except for the activities associated with the review of work agreements that was judged to be marginal.

AUDIT TEAM FINDINGS - The application of QA controls was determined to be satisfactory except for the activities associated with the review of work agreements that was judged to be marginal.

At the post-audit meeting the audit team presented the preliminary DR and PR listed below.

DR - DRs are used to report nonsignificant deficiencies. The preliminary DR related to the lack of objective evidence of acceptable review and comment resolution of work agreements.

PR - PRs are used to report isolated conditions that require only remedial actions or minor improvements to meet requirements. The preliminary PR also related to the lack of objective evidence of acceptable review and comment resolution of work agreements. The PR was written because the customer of a work agreement had signed it, indicating approval and that all comments had been resolved, prior to the time that the technical reviewer/quality assurance reviewer had signed it to document the review and resolution of comments.