

QA: QA

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT USGS-ARC-00-16

OF THE

**U.S. GEOLOGICAL SURVEY
SUPPORT OF THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT**

AT

DENVER, COLORADO

JULY 24-28, 2000

Prepared by: _____

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Date: _____

Approved by: _____

**Robert W. Clark
Director
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Date: _____

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit USGS-ARC-00-16, the audit team determined that the U.S. Geological Survey (USGS) at Denver, Colorado, is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, and the USGS implementing procedures.

QA Program elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 12.0, 15.0, 16.0, 17.0, Supplements I, II, III, V, and Appendix C were determined to be effectively implemented based on the activities evaluated during the audit. Currently, elements 3.0, 8.0, 9.0, 10.0, 11.0, 13.0, 14.0, 18.0, Supplement IV, and Appendices A and B are not implemented by the USGS.

The audit team identified four conditions adverse to quality that are addressed in Deficiency Reports (DR) USGS-00-D-122 through USGS-00-D-124 and LVMO-00-D-125, and two deficient conditions adverse to quality that were considered isolated and corrected during the audit (CDA).

DR USGS-00-D-122 addresses the USGS failure to perform planning by not completing a Development Plan (DP) prior to the creation of a technical product, as required by AP-2.13Q, Rev. 0, ICN 4, *Technical Product Development*. Further, the Review Record completed for the Technical Product did not correspond to DP TDP-EBS-HS-000005, which identified four additional organizations for use of the data.

DR USGS-00-D-123 addresses a Decagon Thermolink Soil Multimeter used to determine material thermal properties that was not calibrated by an OCRWM qualified supplier as required, and the USGS failure to maintain an up-to-date list of Measuring and Test Equipment (M&TE) as required by YAP-12.3Q, Rev.0, ICN 1, *Control of Measuring and Test Equipment and Calibration Standards*.

DR USGS-00-D-124 and LVMO-00-D-125 were issued, respectively, to address record packages transmitted by the USGS and accepted by the Yucca Mountain Site Characterization Project (YMP) Records Processing Center (RPC), with obliterations and other corrections, that did not meet the requirements of AP-17.1Q, Rev. 1, ICN 2, *Record Source Responsibilities for Inclusionary Records*, and LP-17.1Q-M&O, Rev. 0, ICN 1, *Processing Inclusionary Records*.

Two deficient conditions requiring only remedial action were identified and CDA. CDA #1 addressed recent organizational changes in personnel and titles that were not correctly reflected in QMP-1.01, Rev. 6, Mod. 1, *Organization Procedure*. A revised procedure, QMP-1.01, Rev. 6, Mod. 2, was approved and issued to accurately reflect the changes. CDA #2 addressed incomplete Process Control Evaluation forms for the control of electronic data. The forms were rewritten and the missing information added, as required.

2.0 SCOPE

Auditors representing the DOE Office of Quality Assurance (OQA) conducted a compliance-based audit to evaluate the USGS implementation of the OCRWM QA Program as described in the QARD and implementing procedures. The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluations of procedures assessed the adequacy and effectiveness of the USGS implementation of the QA Program.

The audit team did not evaluate the USGS activities that support the Analysis Model Reports (AMR) and Process Model Reports (PMR) which have already been evaluated during performance-based audit M&O-ARP-00-04.

The audit team reviewed the status of open and closed OCRWM deficiency documents that may have been generated during previous OQA audits and surveillances to determine the effectiveness of in-process and completed corrective actions by the USGS. No concerns were identified.

In accordance with the approved audit plan, the following QA Program elements were evaluated:

QA PROGRAM ELEMENTS

1.0	Organization
2.0	QA Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	QA Records
Supplement I	Software (limited to software not related to AMR/PMR development)
Supplement II	Sample Control
Supplement III	Scientific Investigation (limited to review of entries in notebooks since last audit)
Supplement V	Control of the Electronic Management of Data (limited to USGS activities not related to AMR/PMR processes)
Appendix C	Monitored Geologic Repository

The following QA Program elements were not evaluated, since the USGS is not currently implementing them:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage and Shipping
14.0	Inspection, Test and Operating Status
18.0	Audits
Supplement IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Element</u>
Edward P. Opelski, Audit Team Leader, OQA/QATSS	1.0, 2.0, 16.0
Marilyn A. Kavchak, Auditor, OQA/QATSS	4.0, 7.0, Supplements I and V
Patout H. Cotter, Auditor, OQA/QATSS	Supplement II and III, Appendix C
Sam H. Horton, Auditor, OQA/QATSS	12.0, 5.0
Cynthia Humphries-Alder, Auditor, OQA/QATSS	2.0, 6.0, 15.0, 17.0

4.0 AUDIT TEAM MEETINGS

A pre-audit meeting was held at the USGS on July 24, 2000. Daily debriefings were conducted to apprise the USGS management and staff of the progress of the audit and any conditions adverse to quality. A post-audit meeting summarizing the audit was held at the USGS on July 28, 2000. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, the USGS implementation of the QA Program is adequate and effective. The results for each QA Program element evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions as a result of the audit.

5.3 QA Program Implementation

Attachment 2, "Summary Table of Audit Results," provides results for each QA Program element audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Conditions Adverse to Quality

Four DRs with conditions adverse to quality were issued as a result of the audit. Details of these DRs are documented in Section 5.5.2 of this report. Two deficient conditions identified required only remedial actions and were CDA. These are described in detail in Section 5.5.3 of this report.

5.5.1 Corrective Action Requests

None.

5.5.2 Deficiency Reports (DR)

USGS-00-D-122

DP TDP-EBS-HS-00005, Rev. 00, was not approved and issued until July 20, 2000, and after the associated work, the measurement of thermal properties using the Decagon Thermolink Soil Multimeter and Thermal Properties Sensor for selection of potential backfill material was completed.

Furthermore, the Review Record associated with the technical product did not reflect the review of all required affected organizations, whereas the aforementioned DP identified four other organizations for use of the data.

USGS-00-D-123

The Decagon Thermolink Soil Multimeter, serial number TL2774S, used in the determination of material thermal properties, was calibrated by the manufacturer, who was not on the OCRWM Qualified Supplier List.

In addition, Mettler balances (serial numbers K59633 and G429891), Satorius Balance (serial number 71203370), Cahn Balance (serial number 75791), and Linkham Heating Stage Unit (serial number THMSG 600) were not included in the USGS list of M&TE. Although these specific conditions were corrected prior to the post-audit meeting by the list being updated, the number of cases identified is not considered isolated and requires more than remedial action.

USGS-00-D-124

Approximately 80 individual record packages totaling 294 pages were transmitted June 30, 2000, by the USGS to the YMP RPC in Las Vegas, Nevada. The packages contained numerous obliterations and strike-outs/corrections that did not include the initials and date of the person(s) making the corrections contrary to the requirements of AP-17.1Q. Examples of deficient conditions can be found in record packages contained in Batch Number MOY-000705-05-09.

LVMO-00-D-125

Record packages sent to the RPC in Las Vegas, Nevada, on June 30, 2000, by the USGS included corrections that did not contain the initials and date of the person(s) making the corrections, as well as obliterations, and did not meet the requirements of AP-17.1Q. Record screening requirements of LP-17.1Q-M&O failed to identify the deficient conditions. Examples of the condition can be found in Batch Number MOY-000705-05-09.

5.5.3 Deficiencies Corrected During the Audit (CDA)

Deficiencies considered isolated in nature and requiring only remedial action can be CDA. Two deficiencies meeting this criteria were CDA and are identified below.

1. QMP-1.01, Rev. 6, Mod. 1, "Organization Procedure," which describes the internal and external organizational structures, requirements, and responsibilities did not correctly reflect a recent reorganization that resulted in changes in personnel and organizational titles. The referenced procedure was updated July 27, 2000, to reflect the changes.

2. Work activities for hydrologic testing in the C Holes and for performing tracer tests using prototype pressure transducer assemblies had incomplete Process Control Evaluations forms (for Supplement V). The forms were rewritten to combine related activities and to include the missing information.

5.5.4 Follow-up of Previously Issued Deficiency Documents

No concerns were identified during the follow-up of previously identified deficiencies.

6.0 RECOMMENDATION

One recommendation resulting from the audit is presented below for the USGS management's consideration:

The USGS should review all tasks to assure the electronic data controls, identified in the Process Control Evaluation forms, are adequate and effectively described in the planning documents or procedures. The DPs reviewed during the audit contained only minimal information related to the electronic data controls. A procedure with sufficient detail should be written to control electronic data.

7.0 LIST OF ATTACHMENTS

Attachment 1: "Personnel Contacted during the Audit"

Attachment 2: "Summary Table of Audit Results"

Attachment 1

Personnel Contacted During the Audit

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Anderson, Alexandra	USGS/Administrative Secretary		X	
Chaney, Thomas H.	USGS/Chief, Regulatory and Quality Support Team	X	X	X
Craig, Robert W.	USGS/Branch Chief	X	X	X
Doyle, John R.	QATSS-Las Vegas/QA Specialist		X	
Ducret, G. Louis	USGS/Associate Branch Chief	X		X
Eron, Angela	USGS-PMT/Quality Assurance Specialist	X		X
Flint, Alan L.	USGS/Principal Investigator		X	
Futa, Kiyota	USGS/Chemist		X	
Golos, Joyce L.	USGS/Administrative Officer	X	X	X
Hall, Valerie	USGS/Staff			X
Hersh, Barbara	USGS-PWT/QA Specialist	X	X	X
Hudson, David	USGS/Principal Investigator		X	
Jensen, Emily S.	QATSS-Las Vegas/Senior Quality Assurance Specialist		X	
Jhoon-Yen, Anne	USGS/Records Management Specialist	X	X	X
Jordan, Jeff	USGS-PWT/Quality Assurance Specialist	X	X	
Kurzmack, Mark	USGS/Senior Scientist	X	X	X
Kwak, Loretta	USGS/Chemist		X	
Larsen, Kate	USGS/Quality Assurance Specialist	X		
Losasso, Jacqueline	USGS/Instructional System Specialist			X
Marshall, Brian D.	USGS/Research Hydrologist		X	
McKinley, Patrick W.	USGS, Data Coordinator			X
Miller-Corbett, Cynthia	USGS/Hydrologist	X	X	X
Moscato, Richard	USGS/Geologist		X	X
Motyl, Pamela	USGS-PMT/Quality Assurance Specialist	X		X

Attachment 1

Personnel Contacted During the Audit

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Mustard, Martha H.	USGS/Hydrologist	X	X	X
Oliver, Thomas	USGS/Hydrologist	X	X	
Paces, James	USGS/Hydrologist	X	X	
Parks, Bruce	USGS/Assistant Chief YMPBO	X		X
Peterman, Zell	USGS/Chief, Environmental Science Team		X	
Sanchez, Alexander J.	USGS/Technician		X	
Scofield, Kevin	USGS-PWT/Geologist		X	
Sheaffer, Patricia	USGS/Supervisor/QA Implementation			X
Sinks, Donna J.	USGS, QATSS On-Site Representative	X	X	X
Striffler, Peter	USGS/Hydrologist	X	X	
Whelan, Joseph	USGS/Hydrologist		X	

Attachment 2

Summary Table of Audit Results

QA Element/Activities	Document Review	Checklist Pages	Deficiencies	Recommendation	Program Adequacy	Procedure Compliance	Overall
1.0	YMP-USGS-QMP-1.01, R 6, M 1 DOE/RW-033P, R 10	1-5	CDA #1		SAT	SAT	SAT
2.0	AP-2.1Q, R 1, ICN 0 AP-2.2Q, R 0, ICN 0 AP-2.3Q, R 0, ICN 0 AP-2.12Q, R 0, ICN 0 AP-2.13Q, R 0, ICN 4 AP-2.14Q, R 0, ICN 1 AP-2.15Q, R 0, ICN 1 AP-2.16Q, R 0, ICN 0 AP-2.17Q, R 0, ICN 0 AP-2.19Q, R 0, ICN 0	6-8 9-10 11-13 14-17 18-19 20-22 23-24 25-26 27-29 30-31	USGS-00-D-122		SAT SAT N/A N/A SAT SAT N/A N/A N/A SAT	SAT SAT N/A N/A SAT SAT N/A N/A N/A SAT	
4.0	YMP-USGS-QMP 4.01, R 10 YMP-USGS-QMP 4.02, R 8, M 1	32-35 36-38			SAT SAT	SAT SAT	SAT
5.0	YMP-USGS-QMP 3.07, R 6 YMP-USGS-QMP 5.01, R 8 YMP-USGS-QMP 5.03, R 10	39-48			SAT SAT SAT	SAT SAT SAT	SAT
6.0	YMP-USGS-QMP-6.01, R 7 AP-6.1Q, R 4, ICN 0 AP-6.28Q, R 0, ICN 0	48-58			SAT SAT SAT	SAT SAT SAT	SAT
7.0	AP-7.4Q, R 4, ICN 0	59-62			SAT	SAT	SAT
12.0	YAP-12.3Q, R 0, ICN 1	63-70	USGS-00-D-123		SAT	SAT	SAT
15.0	YAP-15.1Q, R 5, ICN 0	71-73			SAT	SAT	SAT
16.0	AP-16.1Q, R 4, ICN 1 AP-16.4Q, R 0, ICN 0	74-78			SAT SAT	SAT SAT	SAT
17.0	AP-17.1Q, R 1, ICN 2 LP-17.1Q-M&O, R 0, ICN 1	79-82	USGS-00-D-124 LVMO-00-D-125		SAT SAT	SAT SAT	SAT
Supplement I	AP-SI.1A, R 2, ICN 4	83-94			SAT	SAT	SAT
Supplement II	YAP-SII.4Q, R 2, ICN 1 YMP-USGS-QMP 8.01, R 4, M 1	95-101			SAT	SAT	SAT
Supplement III	SP-SIII.1Q, R 0, ICN 1	102-108			SAT	SAT	SAT
Supplement V	AP-SV.1Q, R 0, ICN 1	109-110	CDA #2	Recommendation	SAT	SAT	SAT
Appendix C	DOE/RW-033P, R 10 <i>Quality Assurance Requirements & Description</i>	111-112			SAT	SAT	SAT
TOTALS		112 PAGES	4 DRs 2 CDAs	Recommendation	SATISFACTORY		

