



Department of Energy

Yucca Mountain Project Office
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WBS 1.2.9.3
QA

NOV 20 1990

Larry R. Hayes
Technical Project Officer
for Yucca Mountain Project
U.S. Geological Survey
101 Convention Center Drive
Suite 860
Las Vegas, NV 89109

ACCEPTANCE OF AMENDED RESPONSE AND CLOSURE OF STANDARD DEFICIENCY REPORT (SDR) 561, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 90-03 OF U.S. Geological Survey (USGS)

The Project Office QA staff has evaluated and accepted your amended response to SDR 561, Revision 0, generated as a result of Project Office QA Audit 90-03 of USGS.

The SDR has been closed based on satisfactory verification of completed corrective action. A copy of the SDR is enclosed for your files.

If you have any questions, please contact either Catherine E. Hampton at 794-7973 or Donald J. Harris at 794-7356 of the Yucca Mountain Project QA staff.

Catherine E. Hampton for
Donald G. Horton, Director
Quality Assurance
Yucca Mountain Project Office

QA:CEH-785

Enclosure:
SDR 561, Revision 0

cc w/encl:
K. R. Hooks, NRC, Washington, DC
D. H. Appel, USGS, Denver, CO
S. W. Zimmerman, NWPO, Carson City, NV
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:
J. W. Gilray, NRC, Las Vegas, NV

FULL TEXT ASCII SCAN

YMP's

9011290349 901120
PDR WASTE
WM-11 PDC

ADD: KHooks

103.7
WM-11
NH03

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date JUNE 29, 1990		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 3		
	3 Discovered During AUDIT 90-3		3a Identified By D. HARRIS/ J.E. CLARK		4 SDR No. 561 Rev. 0		
	5 Organization USGS		6 Person(s) Contacted B. LANGSTEINER, A. WHITESIDE		7 Response Due Date is 20 Working Days from Date of Transmittal		
	8 Requirement (Audit Checklist Reference, if Applicable) USGS-QMP-18.01, Rev. 4, states in part:						
Completed by Organization in Block 5	9 Deficiency The audits program is not being consistently implemented in accordance with cited procedure requirements. Procedure violations were noted as follows: (See Page 3.)						
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective						
	11 QAE/Lead Auditor/Date <i>J.E. Clark 7/16/90</i>		12 Division Manager/Date <i>N/A</i>		13 Project Quality Mgr./Date <i>Catherine [unclear] 7-17-90</i>		
	14 Remedial/Investigative Action(s) See Attached Response.						
Completed by Org. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence						
	17 Effective Date _____						
	18 Signature/Date <i>[Signature] 8/18/90</i>						
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date <i>D. Harris 10/30/90</i>		Division Manager/Date <i>N/A</i>		
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date <i>D. Harris 11/7/90</i>		Division Manager/Date <i>N/A</i>		
	21 Remarks Response, Hayes to Horton, 9-20-90 Request Amended Response 10/5/90 - QA:CEH-133 Request Response Extension 10/16/90 - Hayes to Horton Amended Response 10/29/90 - Hayes to Horton Corrective Action Verification Attached D. Harris 11/7/90						
22 QA CLOSURE		QAE/Lead Auditor/Date <i>D. Harris 11-7-90</i>		Division Manager/Date <i>N/A</i>		PQM/Date <i>Catherine [unclear] 11/7/90</i>	

ENCLOSURE

YMPO STANDARD DEFICIENCY REPORT
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8 Requirement (continued)

1. Para. 5.1.2 INTERNAL AUDITS - Applicable elements of the YMP-USGS QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of an audit shall be established by considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or the QA Program.
2. Para. 5.5.4 As the audit progresses, any identified deficiencies and concerns shall be prepared by the audit team members and recorded on the Audit Finding Report (Attachments 4 and 5) or the Audit Observation form (Attachment 6), as appropriate.
3. Para. 5.9.2 Annual supplier evaluations, supplier performance audits, or source verification shall be identified in the USGS Audit Schedule (refer to Para. 5.1) and conducted as directed by the QA Manager. Applicable procurement-related requirements shall be incorporated into the Audit Checklist.
4. Para. 5.4.1 Audit checklist characteristics or elements that have been selected shall be evaluated against specified requirements or effectiveness indicators and shall include a review of corrective actions taken on deficiencies identified during previous audits.
5. Para. 5.6 Audit Report: The Audit Team Leader, or delegate, shall prepare a written Audit Report that shall include the information shown in Attachment 7, as a minimum.

Attachment 7 requires the following:

AUDIT REPORT: (Include statement of the effectiveness of the QA program elements that were audited.)

9 Deficiency (continued)

1. The Fiscal Year 90 Audit Schedule, Rev. 0, Rev. 1, and Rev. 2, do not reflect scheduled audits to cover QAPP elements 1 and 15.
2. In Audit 90-07, conditions documented on Observations No. 2 and 3 were issued as concerns, when they actually cite program violations.
3. The USGS YMP Audit Schedule and Vendor Evaluation Schedule do not contain 3 suppliers due for requalification: ENSECO Rocky Mountain Lab, Stable Isotope Lab, and USGS National Water Lab.

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CONTINUATION SHEET**

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9 Deficiency (continued)

4. US Bureau of Reclamation Audit 90-07 and USGS Internal Audit 90-02 took credit for determining implementation of program elements when the audit records indicated that those criteria were not audited.
5. Audit 90-02 Audit Report did not contain an effectiveness statement.

USGS RESPONSE TO YMPO STANDARD DEFICIENCY REPORT (SDR) NO. 561

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BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

Investigative actions revealed the following:

1. FY 90 Audit Schedule, Rev. 0, 1, and 2 did include a scheduled audit in Menlo Park which was to have "covered" QAPP elements 1 and 15. Limited implementation was available at that location. Therefore these elements will be covered in Audit USGS-90-13 scheduled for 9/10 - 9/21/90 in Denver, CO.
2. No remedial actions are warranted.
3. ENSECO Rocky Mountain Analytical Laboratory has been dropped from the AVL due to lack of continued need. The Stable Isotope Lab and the USGS NWQL are now listed in the vendor evaluation schedule.
4. No remedial actions are warranted.
5. No remedial actions are warranted.

BLOCK 15: EFFECTIVE DATE: Complete.

BLOCK 16: CAUSE OF THE CONDITION & CORRECTIVE ACTION TO PREVENT RECURRENCE:

1. Not Applicable - not a violation.
2. Observations are not well defined. QMP-18.01 will be changed to clarify the intent of observations and audit finding reports.
3. Two of the three labs identified were scheduled to be reviewed by another entity, BQA, on behalf of the QA Office. The surveillance schedule which generally accompanies the audit schedule was annotated. There was no effect on quality. All vendors requiring requalification will continue to be listed on the vendor evaluation schedule for as long as the requirement remains in effect.
4. This finding is the result of inconsistent terminology. The audit reports "took credit" for auditing those elements because those elements were reviewed during the audits to determine level of activity (implementation). The checklists recorded "not audited" meaning "no activity." Appropriate terminology will be decided during the audit and surveillance workshop to be held August 28-30, 1990. There is no affect on quality and the QMP-18.01 will be changed accordingly.
5. This finding was the result of lack of attention to details. All audit and surveillance personnel will be reminded of this requirement during the audit and surveillance workshop to be held August 28-30, 1990.

BLOCK 17: EFFECTIVE DATE: October 15, 1990.

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This 10-29-90 response is intended to supplement the 8-20-90 response.

BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

Sub-part 1 (Audit Schedule not identifying full QA program coverage): The Audit Schedule had included "implementing QMPs" for the Menlo Park audit and the audit plan for the Menlo Park audit included both criterion 1 and 15. Because there was limited or no implementation of these criterion available at Menlo Park, they were both added to the scope of the internal audit 90-13 for the Denver/Golden area. Revision 4 of the audit schedule for FY90 and Revision 0 of the FY91 audit schedule will specify the criteria (by criteria number) to be included.

Sub-part 2 (Observations used to document program violations): For QA program violations, a determination is needed regarding the basis for the requirement and the impact on quality. The two cited Observations have been re-evaluated. Neither Observation represents the violation of a specific USGS QAPP (and DOE/YMP 88-9) requirement, nor do the conditions represent an adverse impact on quality. Hence, the USGS documented the conditions on Observations. No remedial actions are needed.

Sub-part 3 (Scheduling supplier requalifications): The Audit Schedule was updated to reflect supplier requalification information.

ENSECO, Rocky Mountain Analytical Laboratory: This supplier is no longer needed for the analytical service, therefore the supplier requalification was dropped from the Approved Vendors List.

National Water Quality Laboratory (NWQL) and the Stable Isotope Laboratory were added to the Audit Schedule via the Vendor Evaluation Schedule (attached to audit schedule).

Sub-part 4 (determining audit coverage for applicable QA program criteria): QMP-18.01 requires that "audits shall be scheduled at a frequency commensurate with the importance or status of the activity or task...". The audit coverage for FY90 is considered adequate.

Ltr dtd 10/29/90 - Hayes to Hoston

USGS AMENDED RESPONSE TO YMPO SDR 561

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Sub-part 5 (effectiveness statement): Audit Report 90-02 has been re-evaluated to determine if effectiveness was addressed. Although the effectiveness statement was not explicit in Audit Report 90-02, the report clearly indicates that the results were generally satisfactory and that the QA Program was being implemented properly with the exceptions noted. Therefore, the effectiveness is considered to be adequately, if not explicitly, covered and no further clarification of the audit report is necessary at this time.

BLOCK 15: EFFECTIVE DATE:

October 31, 1990 - Audit Schedule FY90, R4 and FY91, R0 to be issued

BLOCK 16: CAUSE OF THE CONDITION & CORRECTIVE ACTION TO PREVENT RECURRENCE: (Reference part 4)

The need for additional audits and/or redefinition of the scope of planned audits must be evaluated based in part on the outcome of the audits performed (reference QMP-18.01, R5, para. 5.1.1.1). If no implementation of a criterion is found during an internal audit, further evaluation during a subsequent audit will be considered.

BLOCK 17: EFFECTIVE DATE:

Not applicable.

BLOCK 18: SIGNATURE/DATE:

W. J. [Signature] 10/29/90