

Department of Energy

Yucca Mountain Project Office P. O. Box 98608 Las Vegas, NV 89193-8608

WBS 1.2.9.3 QA

OCT 2.0 1996

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 RESPONSES TO OBSERVATIONS 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 the responses to Observations 90-03-01 through 90-03-10, generated as a result of Project Office QA Audit 90-03 of USGS. The responses to these observations are acceptable. Copies of the observations are enclosed for your information.

If you have any questions, please contact either Catherine E. Hampton at 794-7973 or Richard L. Maudlin at 794-7290 of the Yucca Mountain Project QA staff.

Donald G. Horton, Director Quality Assurance Yucca Mountain Project Office

QA:CEH-547

YMP-5

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Enclosures: Observations 90-03-01 through 90-03-10

cc w/encls: K. R. Hooks, NRC, Washington, DC S. W. Zimmerman, NWPO, Carson City, NV D. H. Appel, USGS, Denver, CO

N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encls: J. W. Gilray, NRC, Las Vegas, NV D. D. Porter, SAIC, Golden, CO

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FULL TEXT ASCII SCAN

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1	YUCCA MOUNT			N-QA-012 4/89			
ц	2Noted During: YMP-90-03	³ Identified	 By: R.Weeks/M.Meyer	4 Date: 6-28-90			
ganizati	5Organization: USGS	6 Person (s Peggy Wa) Contacted: rner	7 Response Due Date is 20 Days from Date of Transmittal			
Completed by Originating Organization	CRF stating that 786 pages wer the CRF stated the page count the LRC Record Transmittal for attempted to resolve the discr page counts.	12 was transmitted from the USGS LRC to the were present in the record package; however, ant to be 601 pages on the returned copy of form. There is no indication that the LRC iscrepancy that existed between the different					
	PQAE/Lead Auditor	Date / / / / / / /	10 Branch Manager	Date 1-17-90			
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	12 Signature: Lang R. Have	<u>`</u>	Date: S	1/20/90			
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ENCLOSURE

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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-10 Page 1 of 1

BLOCK 11 RESPONSE:

An investigation of this condition revealed that in fact USGS LRC had counted 786 pages and DOE/YMP CRF had counted 601 pages. Nothing was missing or lost. This discrepancy is attributable to the fact that each organization counted the copied pages from a scientist's logbook differently.

The LRC copied the logbook with two logbook pages per sheet. Therefore, when counting logbook pages to record on the Table of Contents, the LRC counted the actual logbook pages, not the number of copy pages. The CRF counted each sheet of copy paper received. Therefore, the portion of the record packages including logbooks was counted differently than the LRC count. CRF changed the page count on the LRC transmittal, but did not change or justify the change on the Table of Contents, or notify LRC of the change.

The LRC will watch for changes of this nature when CRF returns LRC transmittal records. LRC will contact CRF and obtain explanations when possible.

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	YUCCA MOU		OJECT OFFICE 0. 90-03-09	N-QA-012 4/89
, no	2Noted During: Audit 90-03	³ Identifi	ed By: C.C. Warren	4 Date: 6-26-90
ganizati	5Organization: USGS	⁶ Person	(s) Contacted: J. Ziemba	7 Response Due Date is 20 Days from Date of Transmittal
Completed by Originating Organization	⁸ Discussion: Procedure YMP-USGS-QMP-16. in the description (part 4 specific conditions, if im None of the CARs reviewed actions taken although the require immediate action.	ent of immediate actions f tions were necessary. audit included a statemer	taken to remedy nt of immediate	
0	⁹ QAE/Lead Auditor	Date	¹⁰ Branch Manager /	Date
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	(continued)			
CAR 89-14, 89-10, 89-	"ADVERSE TREND IN CALIE 11, 89-12, 89-13, 89-14,	BRATION OF EQUIPMENT" and 90-01.	CARs reviewed wer	e
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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-09 Page 1 of 1

BLOCK 11 RESPONSE:

The response to CAR-89-14, signed less than two weeks after its issuance, included the results of an initial evaluation and also the statement "Remedial actions are being taken for each deficiency document identified and are not warranted as a result of this CAR."

The USGS is considering modifying the CAR form to include a box or area for identifying immediate actions or for explaining why no immediate actions are needed.

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u	2Noted During: Audit 90-03	³ Identifi	ed By: C.C. Warren	4 Date: 6-26-90
ganizati	⁵ Organization: USGS	⁶ Person	n(s) Contacted: J. Ziemba	7 Response Due Date is 20 Days from Date of Transmittal
Completed by Originating Organization	identify cause and pro recurrence or provide A cause/corrective act	pose appropriat a plan describi tions to prevent	requires responsible mate te corrective action to ing future actions to re recurrence or a plan of clearly identified in th	prevent esolve the CAR. describing future
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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-08 Page 1 of 1

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BLOCK 11 RESPONSE:

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The cause statement for CARS is required in the initial issue of the CAR, not in the response. Five root causes were identified in CAR-89-11. The response to the CAR is the plan describing actions to resolve the CAR.

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rganizati	5Organization: USGS	⁶ Person	(s) Contacted: J. Ziemba	7 Response Due Date is 20 Days from Date of Transmittal
Completed by Originating Organization	⁸ Discussion: Procedure YMP-USGS-QMP-16. corrective action for CARs management review of the a	be accompl iffected act	ished by audit, surveilla ivity.	ance, or
Completed b	Verification of completion by surveillance and found 89-13 was issued to docume corrective action was spec	"not to be int this uns	adequate or effective". atisfactory verification.	Revision 1 to CAR No additional
Ŭ	⁹ QAE/Lead Auditor	Date	¹⁰ Branch Manager	Date
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Completed by QA Org.	¹⁴ Remarks:			Page _1of_2

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8 Discussion: (continued)

although this response was accepted and closed by USGS Quality Assurance. Verification action on CAR 89-13, Rev. 1 was then marked "N/A - No Action". Therefore, CARs 89-13 and 89-13, Rev. 1 were closed out without a satisfactory verification of corrective action being performed. In addition, there was no documented justification for acceptance of the Revision 1 response without additional corrective action being specified.

USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-07 Page 1 of 1

BLOCK 11 RESPONSE:

CAR-89-13, RO, did not pass verification because some of the actions were not complete. When a CAR does not pass verification, procedure requires that a new revision be issued. The reissue of CAR-89-13 as R1 was the result specifically of some original response commitments not being fulfilled as written; R1 did not indicate a significant condition adverse to quality existed.

The commitment actions that had not passed verification were re-evaluated and deemed unnecessary. Therefore, the response to the reissued CAR deleted these commitments. This response was accepted by the acting QA Manager and there were no further actions requiring verification.

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			DJECT OFFICE	N-QA-012 4/89	
on o	2Noted During: AUDIT 90-03 (USGS)	³ Identifie	ed By: J.E. CLARK	4 Date: JUNE 27, 1990	
ganizati	5Organization: USGS	1	(s) Contacted: J. ZIEMBA, EY, A. WHITESIDE, ET AL	7 Response Due Date is 20 Days from Date of Transmittal	
Completed by Originating Organization	⁸ Discussion: The NCR system established in QMP-15.01, Rev. 4, is applied to both hardware and programmatic deficiencies. The dispositioning process requires assigning resolutions such as "rework," "repair," and "use-as-is," which do not help identify corrective actions necessary for programmatic deficiencies. A dedicated programmatic deficiency documentation system (possibly an adaptation of the system used for audit findings) would facilitate corrective action identification and implementation by eliminating the force-fitting of irrelevant dispositioning terms.				
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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-06 Page 1 of 1

BLOCK 11 RESPONSE:

The YMP-USGS uses NCRs to document hardware, programmatic, and data-related deficiencies for simplification (only one system). The YMP-USGS "product" is data, and the disposition of data is most important. An NCR system which just addressed hardware would have limited use on the YMP-USGS because very little "hardware" is used. The dispositioning of programmatic deficiencies is appropriate, although the interpretation of the disposition (especially rework, repair) can be confusing.

During an audit and surveillance workshop, the revision of the NCR form (to clarify and simplify the disposition process) and the NCR system will be discussed. After subsequent discussions with technical personnel, a final decision will be made on the NCR system and possible changes to it.

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uo	2Noted During: Audit 90-03	³ Identified By: R. L. Maudlin		4 Date: 07/02/90
ganizati	5Organization: USGS	⁶ Person	(s) Contacted: R. Luckey	7 Response Due Date is 20 Days from Date of Transmittal
Completed by Originating Organization	⁸ Discussion: During the review of calibrat the NTS, it was observed that procedural revision used to p all future entries in the low revision used to do the calib	t the log perform t gs at the	s did not, in all case he calibration. It is	s, identify the recommended that
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	12 Signature: Zam R. Huy	<u>h</u>	Date:	8/20/90
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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-05 Page 1 of 1

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BLOCK 11 RESPONSE:

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We agree with the recommendation noted above. The QMP-12.01 does state that the procedure number and revision level will be noted. If discrepancies are noted, such as that mentioned, we are confident that using our Document Control System, we easily can determine which revision of the procedure was used.

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1YMPO OBSERVAT		N-QA-012 4/89
2Noted During: Audit 90-03	³ I dentified By: Bob Constable-Ken Gilkerson	4Date: 6/29/90
⁵ Organization: USGS	<pre>6Person(s) Contacted: Tom Chaney, W. Rodman, M. Mustard</pre>	7 Response Due Date is 20 Days from Date of Transmittai
for QA records for certain "co acceptance of "commercial grad addressed to delineate the fol a) who receives "commercial g b) how are these items receiv c) what documentation is gene	ommercial grade" items. Requirement de" items not requiring calibration lowing: grade" items not requiring calibrat: red. erated upon acceptance.	ts for the should be
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12 Signature: Lang R. Hen	N 8/20/90 Date:	
13 Response Receipt Acceptable Initiator <i>Maudl: 16</i> 14 Remarks:	Date Date Date Date DA/Lead Auditor DA/Lead Auditor DA/Lead Auditor	Date 10-12-90 Page 1 of 2
	Audit 90-03 ⁵ Organization: USGS ⁸ Discussion: Modification to QMP 7.01, Rev. for QA records for certain "co acceptance of "commercial grad addressed to delineate the fol a) who receives "commercial grad d) whore these items receives b) how are these items receives c) what documentation is gene d) where does this documentat ⁹ OAE/Lead Auditor Moder Development 11 Response: See Attached Response. See Attached Response. ¹² Signature: ¹³ Response Receipt Acceptable M Initiator Maduddia 10	Audit 90-03 Bob Constable-Ken Gilkerson 5Organization: 6Person(s) Contacted: Tom Chaney, W. Rodman, M. Mustard 8Discussion: Modification to QMP 7.01, Rev. 4, dated 6/8/90 eliminated the rec for QA records for certain "commercial grade" items. Requirement acceptance of "commercial grade" items not requiring calibration addressed to delineate the following: a) who receives "commercial grade" items not requiring calibration addressed to delineate the following: a) who receives "commercial grade" items not requiring calibration addressed to delineate the following: a) who receives "commercial grade" items not requiring calibration addressed to delineate the following: a) whore these items received. c) what documentation is generated upon acceptance. d) where does this documentation go. 9OAE/Lead Arckior Date Vokent Double 11Response: See Attached Response. 12Signature: Xin Multimut Side 13Response Receipt Acceptable M Maudtion Initiator Date UMaudti 10-12-80

	-	YMPO Objervation NO. 90-03-04 CONTINUATION PAGE		N-QA-012 1/89
8	Dis e) f)	cussion: (continued) how is it processed and sent to the LRC. how/when does USGS-QA verify the adequacy of this documentation.		
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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-04 Page 1 of 1

BLOCK 11 RESPONSE:

The standard USGS practice regarding receiving and acceptance of items is for the "receiver" to sign either a copy of the purchase order or the shipping slip to denote that the correct item was received undamaged.

QMP-7.01 will be changed to include this standard receiving practice, however, the QMP will not require submittal of these documents as QA records. Verification of implementation will be performed during audits and surveillances.

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cu ,	2Noted During: Audit 90-03	³ ldentifie Gilkers		4Date: 06/29/90
rganizati	⁵ Organization: USGS	⁶ Person(s) Contacted: Martha Mustard		7 Response Due Date is 20 Days from Date of Transmittal
Completed by Originating Organization	⁸ Discussion: QMP 4.01, Rev. 3, Par. 5.4.1 not award a QA Level I or II review of final procurement Review of the Procurement Do assure that the C.O. release Surveillance 90-S05-OBS1 door recommended that USGS conside approving that QA requirement	I final pr documenta ocumentati s POs onl cuments th der having hts have b	cocurement document until re- tion. (Attachment 3, QA & on.) No procedural control y after QAs documented rev: he occurrence of such an and the QA organization sign (been met, or instituting oth	eceipt of the Technical ls exists to iew. USGS omaly. It is off on the PO her similar
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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-03 Page 1 of 1

BLOCK 11 RESPONSE:

QMP-4.01 does contain procedural requirements to ensure that QA will review applicable purchase orders before their issuance. However, the date of issuance of the purchase order has not always been clear. A typed date on a purchase order reflects the dates of preparation, not the date of issuance. The contracting officer dealing with YMP purchase orders now corrects this date when the purchase order is signed. The dated signature of the contracting officer is sufficient objective evidence to indicate the purchase order issuance date.

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zation		R. Weeks, B. Hurley, K. Kersch	6/27/90	
	⁵ Organization:	⁶ Person(s) Contacted:	7 Response Due Date is 20 Days from Date of Transmittal	
gan	USGS	T. Chaney, R. Spengler	of Transmittal	
Ŭ Ŭ	⁸ Discussion:		1	
Completed by Originating Organization	YMP Adminiistrative Procedure AP 1.100 requires that each Study Plan contain a list of the procedures necessary to implement that Plan. It is USGS practice to include the revision number for each procedure as well. This has resulted in apparent discrepancies between the Study Plan-listed revision numbers and those found in the List of Controlled Documents at the time of comparison. The USGS should amend their existing Study Plans to list procedures without revision number and with a statement that the activity will be performed in accordance with the revision in force at the time the activity is performed. 9QAE/Lead Auditor Date 10Branch Manager Date			
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USGS RESPONSE TO YMPO OBSKRVATION NO. 90-03-02 Page 1 of 1

BLOCK 11 RESPONSE:

The USGS initiated NCR-90-26 to document discrepancies noted with the tables of technical procedures in Study Plans.

The intent of the tables in the Study Plans is to identify methodology, not delineate "current" practices. The Study Plans are planning documents intended to identify planning elements for the scientific activity. Due to the nature, complexity, and lengthy preparation time, the technical procedure tables only were intended to show the status of the procedure at the time of development of the table in the Study Plan. The controlled document system is relied upon for identification of current technical procedures available for use.

YMPO OBSERVAT 2Noted During: Audit 90-03 5Organization: USGS 8Discussion: The audit effort related to QM Personnel) reported that the In implemented in an acceptable ma is marginal as reported by the Personnel were encountered who application of the requirements 2.07, a review of the Indoctrial	<pre>3Identified By: A.E. Cocoros 6Person(s) Contacted: P.Warner, T.Chaney, K.Kohn Ps 2.02 & 2.07 (Indoctrination/Tra indoctrination/Training Program was manner. However, the effectiveness auditors of Criteria 3, 4, 7, 15, did not appear to fully understand s documents. During the audit of a nation/Training Records of personn</pre>	being of the program 16 & 17. d the intent and QMPs 2.02 and		
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⁸ Discussion: (continued)

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directed predominately toward "required reading" type of effort as opposed to a formal classroom effort.

Since a "required reading" approach tends to only familiarize personnel with procedural steps rather than facilitating a complete understanding of the application of the procedure, it is recommended that USGS give strong consideration to conducting formal classroom Training/Indoctrination Programs for all personnel who are required to understand and implement specific requirements documents.

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USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-01 Page 1 of 2

BLOCK 11 RESPONSE:

The YMP-USGS reading assignments are made when management determines that personnel must be advised of changes and formal classroom instruction is not required. Formal classroom instruction has been used, and will continue to be used when deemed appropriate by management.

The SDRs and Observations from this audit and the USGS responses have been re-evaluated concerning "training" effectiveness as summarized below:

- Criterion 3 None of the three SDRs or one Observation indicate a serious generic deficiency in the control of scientific investigations as a direct result of ineffective training. The investigative phase for the SDR involving criteria letters is still underway. To date, none of the deficiency documents warrant in-depth instruction as a preventive measure.
- Criteria 4 & 7 There were no SDRs initiated for these criteria and two Observations concerning the actual issue date for purchase orders and required documentation for receipt of commercial-grade items. Neither of these findings indicate a serious deficiency or a lack of understanding of the responsible personnel involved.
- Criterion 15 One SDR involved NCR deficiencies and questions with the NCR processing phases (initiation, disposition, verification). No deficiencies were noted concerning the actual nonconforming conditions or disposition actions taken to correct the deficient conditions. The Observation questions the workability of the USGS NCR system, not the deficient conditions noted in the NCRs. The investigative phase for the SDR is still underway to determine the cause and preventive actions. To date, none of the corrective actions appear to warrant in-depth instruction as a preventive measure.
- Criterion 16 The SDR was initiated due to interpretation of when a CAR was to be written during the trending program. This deficiency does not indicate a lack of knowledge and the corrective action focuses on clarifying the procedure to reflect the actual practice. Three Observations were initiated concerning specific questions with three USGS CARs. None of the responses indicated a need for instruction.

USGS RESPONSE TO YMPO OBSERVATION NO. 90-03-01 Page 2 of 2

BLOCK 11 RESPONSE continued:

Criterion 17 The three SDRs and one Observation initiated involved record source and LRC responsibilities and practices. Many of the problems noted in the SDRs were attributable to ambiguities and inconsistencies within the QMP, and after revising the QMP, classroom training and reading assignments will be made as deemed necessary.

A recent letter from DOE noted that the LRC had maintained a 99.148% accuracy rate for records submitted to the CRF from 4/1 - 6/30/90 which indicates that implementation of record processing to the CRF has been effective.

An individual's knowledge of a procedure or process is based upon experience (use), not just classroom instruction or reading assignments. Until the level of activity increases within our YMP-USGS program, we expect USGS personnel to be familiar with the procedures and know where to locate them for reference during "work". We will continue to use reading assignments to familiarize personnel with current requirements, and we will emphasize formal classroom training to assure key personnel understand and are ready to implement the requirements of a procedure.