

Department of Energy

Washington, DC 20585

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QA: L

R. W. Craig, Technical Project Officer for Yucca Mountain Site **Characterization Project** U.S. Geological Survey 1261 Town Center Drive Building 12, Room 1249, M/S 423 Las Vegas, NV 89134

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-040 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQÁ) AUDIT USGS-ARC-97-15 OF U. S. GEOLÓGICAL SURVEY

The OOA staff has evaluated the response to DR YM-97-D-040. The response has been determined to be unsatisfactory because of reasons stated in the enclosed DR.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Kristi A. Hodges at (702) 734-0871.

> R.W.Ch To Donald G. Horton, Director

Office of Quality Assurance

OQA:JB-1773

Enclosure: DR YM-97-D-040

cc w/encl:

J. O. Thoma, NRC, Washington, DC

S. W. Zimmerman, NWPO, Carson City, NV T. H. Chaney, USGS, Denver, CO

D. J. Sinks, OQA/USGS, Denver, CO

A. M. Whiteside, OQA/USGS, Denver, CO

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV

K. A.Hodges, OQA/QATSS, Las Vegas, NV

D. G. Sult, OQA/QATSS, Las Vegas, NV

R. W. Clark, DOE/OQA, Las Vegas, NV

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8 □Performance Report

■ Deficiency Report

NO. YM-97-D-040

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PERFORMANCE	DEFICIENCY RE	PORT	
1 Controlling Document:		2 Related Report No.	
AP 17.1Q, "Record Source Responsibilities for Inclusionary Records," Revision 0		USGS-ARC-97-15	
3 Responsible Organization:	4 Discussed With:		
U.S. GEOLOGICAL SURVEY (USGS)	R. Craig, T. Chaney ar	d M. Mustard	·
	,		
5 Requirement/Measurement Criteria:			
AP 17.1Q, Section 2.0, Applicability, states: "This pro Records in progress before the effective date of this p records' initiation; however, records begun on or after	rocedure may continue u	nder the procedure in effect at the	time of the
AP 17.1Q, Revision 0, was issued with an effective da Distribution) was transmitted to Affected Organizations cancellation of existing record source procedures with AP 17.1Q, nor has it canceled its QMP-17.01 procedu Several records/record packages were recently transmit records were prepared and submitted in accordance with the recent transmittals, which are part of a backlog permeet AP-17.1Q requirements.	s (including USGS) direct in 90 days (February 20, are. nitted by USGS to the Re with QMP-17.01, Revision	ing implementation of AP 17.1Q a 1997). To date, USGS has not in cords Processing Center (RPC). 9. Based on discussion with RP	nd nplemented These C personnel,
7 Initiator	9 ls condition an isolate	ed occurrence?	
Kristi H. Hodge Date 3/7/97	⊠Yes □ No	□ Unknown; Must be Yes if F	PR
10 Récommended Action: (Not féquired for PR) / / Implement AP 17.1Q and project direction in the 11/22/96 letter. Coordinate concerns with AP 17.1Q implementation with the CRWMS M&O records management organization.			
		•	
11 QA Review, QAR Trusti A. Holge Date 5/7/97	12 Response Due Date 20 working days from k		
13 Affected Organization QA Manager Issuance Approval: (Q/ Printed Name DG Hoについ Signature	AR for PR) Blue	Lord Par	e5/13/97
22 Corrective Action Verified		<u> </u>	A for PR)
QAR	Date •		Date
Exhibit AP-16.1Q.1			Rev. 07/15/96

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14Remedial Actions:

The YMP-USGS has reconsidered its approach to implementing AP-17.1Q. YMP-USGS concerns with AP-17.1Q involve the treatment of individual records within a records package. Originally, the primary USGS concern was in meeting the requirements of AP-17.1Q, RO, sections 5.2.1e) and 5.4 b) for <u>each</u> individual record within a records package. The USGS has not been providing the required information for each individual record that will become part of a package but rather has been providing this information on the table of contents.

In discussing how to meet the requirements of the AP, the issue of temporary storage as required by section 5.3 f) became a more over-riding concern due to manpower and funding limitations. Because of the way that the USGS currently designates records packages within its Quality Management Procedures (QMPs), many of the individual records within those packages would be subject to temporary storage requirements. The USGS does not feel that it is necessary to treat most of those records as individual records; they would normally be retrieved only as part of the record package. They provide supporting information to the primary record but are not necessarily useful documents when separated from the package. The USGS has done a preliminary re-evaluation of the records section of each of our QMPs to determine whether it is feasible to reduce the number of individual records designated within record packages. We anticipate replacing most designated record packages with an individual record requiring specific attachments. With this approach, the USGS will be able to implement the AP as written.

The records sections to the following QMPs will be revised to either eliminate the designation of record packages and to redefine the contents of records packages for records generated as a result of their implementation: QMPs 2.02, 2.07. 2.08, 3.03, 3.04, 4.01, 4.02, 5.01, 5.03, 5.05, and 6.01. These revisions/modifications will entail significant differences in the details of how we do business and therefore it is approriate for them to be fully reviewed prior to implementing them (rather than treat them as expedited modifications.) Upon completion of these revisions, the USGS will rescind QMP-17.01 and add AP-17.1Q to the list of APs recognized as part of the USGS QA Program.

¹⁵Extent of Condition (not required for PR):

Per discussions with Records Management personnel (phone call 6-5-97 between Martha Mustard, USGS, and Bill Smith, M&O and e-mail from Terry Mueller to Martha Mustard dated 6-6-97), there have been no problems in acceptance of USGS records. USGS records show acceptance of the following records sent on or after 11-22-96: MOL.19970303.0116-.0220, MOL.19970304.0165, MOL.19970310.0056-.0107, MOL.19970318.0026-.0251, and MOL.19970331.0029-.0204. Per Bill Smith, the acceptance criteria have not changed since that time.

¹⁶Root Cause Determination (not required for PR): Required □ Yes KNo A root cause determination is not necessary because it is unique to implementation of AP-17.1Q.

17Action to Preclude Recurrence (not required for PR):

Required XYes DNo

The USGS did not consider the direction provided in the 11-22-96 letter from J.J. Adams and H.H. Brandt to distribution to be the appropriate means of conveying requirements concerning the extent of the Quality Assurance Program; the USGS felt that it was meeting the QARD requirements through implementation of USGS-QMP-17.01 (as supported by the results of

OQA audit USGS-ARC-97-15). The USGS recognized the letter as project guidance and was planning to implement the AP upon its revision. (We were told during the December 1996 Records Management teleconference that several implementation problems had been identified with the new procedure and a new revision was planned. The records management personnel present listened to our concerns regarding section 5.2.1 e) and agreed that the wording could be changed to indicate that the specified information was required for individual records only if individual retrievability was necessary for them.)

In retrospect, it would have been more appropriate for the USGS to document its concerns with the AP using a Document Action Request and will do so in the future if the case arises again.

¹⁸ Corrective Action Completion Due Date: September 15, 1997	19 Response by: Solution G. Louis Ducret, Jr, USGS, YMPB, 6/9/97, 303 236-5050 ext234	
²⁰ Response Accepted:	²¹ Response Accepted (N/A for PR):	
QAR Date	AOQAM Date	

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EVALUATION OF RESPONSE FOR DEFICIENCY REPORT (DR) YM-97-D-040

The submitted response is unacceptable based on the following evaluation:

Remedial Action:

Based on the DR response, at issue is the treatment of individual records within designated records packages, and whether significant modifications of USGS procedures are required prior to AP implementation. Also at issue is a manpower and funding concern with establishing temporary storage for supporting documentation that would become part of a record package.

The AP requires specified information for retrievability to be included on each individual record within a record package; whereas, the USGS has indicated in its response that this information has been provided only on the Table of Contents (TOC). It is not understood by this QAR why procedures must be modified when information that is already included on the TOC can be transferred to individual records within designated record packages. The transferring of this retrievability information is not perceived as a significant diversion from former practice, nor a laborious task that would have precluded or would continue to preclude implementation of the AP.

Although manpower and funding are important issues, they are considered irrelevant in the resolution of this deficiency. In-process records have historically been afforded protection, although the degree of protection was not specified. Records that were deemed complete, but considered as part of an in-process package, have traditionally been afforded interim storage protection. The submitted response states a concern with individual records that are not perceived as meaningful when separated from the primary record, and an intent to replace designated records packages with individual records with attachments. This is perceived as a means of avoiding the adding of traceability information to individual records, and will inevitably preclude individual records, retitled "attachments," from independent retrieval. With no TOC, there will be no tie to supporting documentation, and also limited ability to omit record duplicates. OQA does not perceive that the intent of the AP was to minimize retrievability.

The USGS was included in the initial/final review of AP 17.1Q, and resolved all of its mandatory and nonmanditory review comments prior to issuance of the procedure. This DR documented a failure to implement the AP and to cancel the existing USGS QMP, as directed by YMSCO. Compliance with the QARD was not at issue, since the USGS QMP meets current QARD requirements; however, the decision to implement the AP was a Project-level decision, made by YMSCO, and implementation was not an option for the USGS or other affected organizations. There was documented concurrence with the draft AP and no attempt was made to implement it after issuance. A conclusion that the procedure was inadequate is therefore unjustifiable.

Extent of Condition:

It was recommended in the DR that the USGS coordinate the response with the records management personnel. This occurred, however, there has not been a consistent records management position upheld. The position understood prior to the initiation of the DR was that records submitted by the USGS that fail to meet the AP would be unacceptable; however, based on recent discussion with records management personnel, the Records Processing Center (RPC) has limited acceptance criteria, e.g., line-outs/crossouts, legibility, page count, etc. The RPC does not reject records that do not meet the AP for forms, format, or even retrievability information on each individual record. The statement that there are no perceived problems with the acceptance of USGS records is with understanding that the submittals do not meet the AP. Based on discussion with records personnel, compliance with the AP is a record source and not an RPC responsibility. This is perceived as an inconsistency between the AP and the RPC accept/reject criteria that needs further evaluation.

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Also, overlooked in this Extent of Condition is an evaluation to determine whether there are other APs that are applicable to USGS that have not been implemented.

Action to Prevent Recurrence:

The response stated that "The USGS did not consider the direction . . . to be the appropriate means of conveying requirements concerning the extent of the Quality Assurance Program." There is an apparent misunderstanding in whether there is latitude in implementation of Project procedures/direction if one perceives that the QARD requirements are being adequately implemented. USGS needs to address how it receives Project direction and when such direction can be interpreted as "guidance." The referenced letter directed all affected organizations to cancel their record source procedures by the specified date, and to implement the AP. It is unrealistic to interpret that definitative direction as only guidance. Likewise, informal, undocumented discussions cannot replace the established process for initiating a procedure change. As stated earlier, USGS was included in the AP review process and had no remaining review comments prior to its issuance. An acceptable response would address increased involvement in the AP review process, implementation of APs as directed by YMSCO, and a commitment to document proposed procedure changes (not concerns) via the QAP 5.1 DAR process.

Kristi A. Hodges, QAR

0/18/97 Date