



Department of Energy

Washington, DC 20585

QA: L

AUG 13 1997

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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORT (DR) YM-97-D-040 RESULTING FROM OFFICE OF QUALITY
ASSURANCE (OQA) AUDIT USGS-ARC-97-15 OF U.S. GEOLOGICAL SURVEY

The OQA staff has verified the corrective action to DR YM-97-D-040 and determined the results to be satisfactory. As a result, the DR is considered closed.

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

R.W. Horton
for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2136

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
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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
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8 Performance Report
 Deficiency Report

NO. YM-97-D-040

PAGE 1 OF 2
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
AP 17.1Q, "Record Source Responsibilities for Inclusionary Records," Revision 0

2 Related Report No.
USGS-ARC-97-15

3 Responsible Organization:
U.S. GEOLOGICAL SURVEY (USGS)

4 Discussed With:
R. Craig, T. Chaney and M. Mustard

5 Requirement/Measurement Criteria:

AP 17.1Q, Section 2.0, Applicability, states: "This procedure applies to all individuals within Affected Organizations... Records in progress before the effective date of this procedure may continue under the procedure in effect at the time of the records' initiation; however, records begun on or after the effective date of this procedure must comply with this procedure."

6 Description of Condition:

AP 17.1Q, Revision 0, was issued with an effective date of 11/22/96. Also on 11/22/96, a letter (Brandt & Adams to Distribution) was transmitted to Affected Organizations (including USGS) directing implementation of AP 17.1Q and cancellation of existing record source procedures within 90 days (February 20, 1997). To date, USGS has not implemented AP 17.1Q, nor has it canceled its QMP-17.01 procedure.

Several records/record packages were recently transmitted by USGS to the Records Processing Center (RPC). These records were prepared and submitted in accordance with QMP-17.01, Revision 9. Based on discussion with RPC personnel, the recent transmittals, which are part of a backlog pending processing, will be unacceptable to the RPC, since they do not meet AP-17.1Q requirements.

7 Initiator
Kristi A. Hodges Date 5/7/97

9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required 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 *Kristi A. Hodges* Date 5/7/97

12 Response Due Date
20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)
Printed Name DG HORTON Signature *James Blaylock*

Date 5/13/97

22 Corrective Action Verified
QAR *Kristi A. Hodges* Date 8/6/97

23 Closure Approved by: (N/A for PR)
AOQAM *R.W.C.* Date 8/12/97

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PR/DR NO. YM-97-D040
PAGE 2 OF
QA:L

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 each 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 appropriate 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 No

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 Yes No

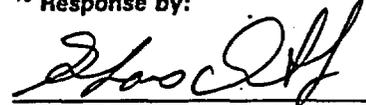
The USGS did not consider the direction provided in the 11-22-96 letter from J.J. Adams and H.H. Brandt to distribution to be the appropriate means of conveying requirements concerning the extent of the Quality Assurance Program; the USGS felt that it was meeting the QARD requirements through implementation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

¹⁸Corrective Action Completion Due Date:

September 15, 1997

¹⁹ Response by:



G. Louis Ducret, Jr, USGS, YMPB, 6/9/97, 303 236-5050 ext234

²⁰Response Accepted:

N/A

OAR

Date

²¹ Response Accepted (N/A for PR):

N/A

AOQAM

Date

EXHIBIT AP-16.1Q.2

REV.07/15/96

6/9/97 Craig Co Hester

Exhibit AP-16.1Q.1

REV. 07/03/95
P. 2 of 6

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

NO. YM-97-D-040

PAGE _____ OF _____

QA: L

PR/DR CONTINUATION PAGE

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 nonmandatory 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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NO. YM-97-D-040

PAGE ____ OF ____

QA: L

PR/DR CONTINUATION PAGE

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 definitive 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

6/18/97

Date

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PR/DR NO. YM-97-D040

PAGE ____ OF ____

QA:L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

¹⁴Remedial Actions:

AMENDED RESPONSE

The USGS will implement AP-17.1Q and rescind YMP-USGS-QMP-17.01 by August 1, 1997. This will provide adequate time for appropriate instruction on the procedure prior to implementation.

¹⁵Extent of Condition (not required for PR):

AMENDED RESPONSE

This is an isolated instance.

The USGS agrees with the QAR that compliance with the QARD is not an issue; therefore, there has been no impact on quality.

¹⁶Root Cause Determination (not required for PR):

Required

Yes

No

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

Required

Yes

No

AMENDED RESPONSE

The USGS will remain involved in the AP review process, implement APs as directed by YMSCO, and will propose procedure changes using the Document Action Request from QAP-5.1 when necessary.

¹⁸Corrective Action Completion Due Date:

August 1, 1997

¹⁹Response by:

Initial

Amended

Date 7/3/97

303
Phone 236-5050

²⁰Response Accepted:

QAR

H. R. Hedges

Date

6/11/97

²¹Response Accepted (N/A for PR):

AOQAM

[Signature]

Date

7/2/97

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NO. YM-97-D-040

PAGE _____ OF _____

QA: L

PR/DR CONTINUATION PAGE

YM-97-D-040 Verification of Corrective Action

Remedial Action:

USGS memorandum (T. H. Chaney to The RECORD), dated July 15, 1997, directed, effective August 1, 1997, implementation of Project AP-17.1Q, Rev. 0, "Record Source Responsibilities for Inclusionary Records" and rescission of YMP-USGS-QMP-17.01, Rev. 9, "Records Management." YMP USGS Document Transmittal Notice, dated August 1, 1997, directs document holders to destroy or mark YMP-USGS-QMP-17.01, Rev. 9 "rescinded." All remedial actions have been completed, as committed.

Action to Preclude Recurrence:

USGS has committed to remain involved in the AP review process, implement APs as directed by YMSCO, and to propose procedure changes via the QAP-5.1 Document Action Request when necessary. An active role in the process and the meeting of the said commitments should preclude this type of deficiency from recurring.

Based on the above verification, this DR is closed.

QAR: Justin R. Hodges Date: 8/6/97