



Department of Energy

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WBS 1.2.9.3
QA


MAY 08 1990

Larry R. Hayes
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CLOSURE OF STANDARD DEFICIENCY REPORTS (SDRs) 156 and 161, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE AUDIT 88-04 OF U.S. GEOLOGICAL SURVEY

SDRs 156 and 161, Revision 0, have been closed based on satisfactory verification of completed corrective actions. Copies of the SDRs are enclosed for your files.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973, or Terry W. Noland at (702) 794-7212 or FTS 544-7212 of Yucca Mountain Project QA.


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

YMP:CEH-3215

Enclosures:
SDRs 156 and 161

cc w/encl:
Ralph Stein, HQ (RW-30) FORS
D. E. Shelor, HQ (RW-3) FORS
T. H. Chaney, USGS, Denver, CO
S. W. Zimmerman, NWPO, Carson City, NV
K. R. Hooks, NRC, Washington, DC

cc: w/o encl:
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
J. E. Clark, SAIC, Las Vegas, NV, 527/T-12
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08
T. W. Noland, W, Las Vegas, NV, 517/T-06
D. O. Porter, SAIC, Golden, CO
J. W. Gilray, NRC, Las Vegas, NV

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WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization	1 Date June 22, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 28
	3 Discovered During WMPO Audit 88-4		3a Identified By Hans/Clark/Camp		3b Branch Chief Concurrence Date
	4 SDR No. 158		Rev. 0		
	5 Organization USGS-Denver		6 Person(s) Contacted Darrell Porter		7 Response Due Date is 20 Working Days from Date of Transmittal
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) NNWSI-USGS-QAPP-01, R4, Section 5.1 Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, and (or) plans or drawings, of a type appropriate to the				
	9 Deficiency Contrary to the above requirement, with the exception of QMPs 5.03 R1, and 8.01, R2, procedures have not been developed/updated to fully describe quality activities covered by Revision 4 of NNWSI-USGS-QAPP-01.				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective (1) Determine procedures needing development/revision to fully implement the Quality Assurance program in NNWSI-USGS-QAPP-01, Rev. 4.				
	11 QAE/Lead Auditor Date Daniel Kumas 7-25-88		12 Branch Manager Date Mark R. HRC 7/25/88		13 Project Quality Mgr. Date James Blaylock 7/25/88
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s) See attached response for Blocks 14-17.				
	15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____				
	18 Signature/Date Larry R. H... 8/31/88				
Comp. by Orig. QA Org.	19 Response <input type="checkbox"/> Accept <input checked="" type="checkbox"/> Amended Response		QAE/Lead Auditor/Date Dan Kumas 12-5-88		Branch Manager/Date Mark R. HRC 5 Dec 88
	20 Amended Response <input checked="" type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date Dan Kumas 5-11-89		Branch Manager/Date Mark R. HRC 19 May 89
	21 Verification <input checked="" type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date T.D. N... 4/25/90		Branch Manager/Date Mark R. HRC 4-27-90
	22 Remarks See Page 8 for Verification				
23 QA CLOSURE		QAE/Lead Auditor/Date T.D. N... 4/25/90	Branch Manager/Date N/A	PQM/Date 4-27-90	

ENCLOSURE



PO STANDARD DEFICIENCY REPORT
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8 Requirement (continued)

circumstances.

9 Deficiency (continued)

The lack of implementation of Rev. 4 of USGS QAPP resulted in other SDR problems, specifically (1) lack of trend analysis (SDR #144) - no objective evidence was presented during the audit that USGS has a deficiency document trending program in place as required by NNWSI-USGS-QAPP-01, Rev. 4, Section 15, Para. 15.5, (2) lack of position descriptions (SDR #145), (3) field notebook documentation (SDR #153), (4) lack of unusual occurrence review and reporting (SDR #160).

10 Recommended Actions (continued)

- (2) Develop/revise procedures implementing the Revision 4 QA program.
- (3) Perform comprehensive review of all project activities to determine impact on the QA program.

BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

The individual SDRs (144, 145, 153 and 160) and the USGS responses were reviewed and evaluated to determine the impact of QMPs not being revised to address QAPP-01, R4, dated 1-5-88. This evaluation revealed that there was no adverse impact on quality. In fact, the evaluation results support the USGS decision to stop processing QMP revisions until the QAPP-01, R5, is approved. QAPP-01, R4, Preface, page 1, lists the significant changes that were included in that revision and the following summarizes the impact of those changes:

Section 1, Organization, identified a more stringent requirement which was already met by the current revision of QMP-1.01.

Section 2, QA Program, included changes involving a "Q List" (WMPO responsibility), requirements expansion in five areas, a leniency possibility for QA Level II items and activities, and clarification of content and approval of the QAPP. Revision of the associated QMPs will need to be evaluated against the requirements of QAPP-01, R5.

Section 3, Scientific Investigation and Design Control, contained clarification statements and an option to allow the use of scientific notebooks in place of technical-implementation procedures. This option is not being exercised by the USGS, and therefore required no new procedure. Section 3 also contained a reference to surveillances which is currently covered by QMP-10.01. Finally, this section addressed peer reviews which are the responsibility of WMPO.

Section 5, Instructions, Procedures, Plans and Drawings, and Section 6, Document Control, included revisions that allow the use of plans as documents prescribing activities affecting quality. Except for the QAPP itself, the USGS uses procedures, not plans, for this purpose. Section 5 also included a requirement that implementing procedures identify the QA records that are generated. QMP-5.03 was revised in February 1988 to incorporate this requirement. For technical procedures, the current revision of QMP-5.01 includes the QA record requirement. Section 7, Control of Purchased Items and Services, was revised to allow more leniency concerning commercial-grade items than the current QMPs allow. Immediate revision to QMPs is not considered necessary.

Section 8, Identification and Control of Items, Samples, and Data, has been expanded to include control of items and data. Control of items needs to be addressed in a QMP based upon approval of QAPP-01, R5. The QMP to control data has been drafted and will be issued based upon approval of QAPP-01, R5. QMP-8.01 was revised in February 1988 to incorporate appropriate requirements.

Section 9, Control of Processes, and Section 10, Inspection, requirements were exempted from the USGS program and no immediate QMP changes are necessary. QMP-9.01 will be deleted based upon approval of QAPP-01, R5, and QMP-10.01 is being converted to QMP-18.02.

Section 18, Audits, has been changed to include surveillance requirements. The present revision of QMP-10.01 includes the appropriate requirements.

The distribution requirements for various documents has changed. Although this change has not been fully addressed, it will not have a direct affect on quality and any additional distribution changes will be addressed in QAPP-01, R5.

BLOCK 14 (continued):

The USGS QMPs that are to be developed or revised in order to comply with the NNWSI-USGS-QAPP-01, R5, will be identified in the WMPO-provided matrix developed for that purpose. The delay in developing procedures has had no adverse effect on quality.

While the USGS agrees that QMP revisions are necessary to assure compatibility with the QAPP, the USGS does not agree that the changes resulting from NVO-196-17, Rev. 5, and QAPP-01, R4, necessitated immediate revision to QMPs other than QMP-5.03 and QMP-8.01. The USGS was notified of changes in the WMPO QA Plan, NVO-196-17, Rev. 5, in March 1987. Subsequently, the revised USGS QAPP-01, R4, was submitted to WMPO in August 1987. Comments and comment resolution phases continued until final approval in January 1988. QMP-5.03 and QMP-8.01 were revised and issued in February 1988 based upon the revised QAPP. By this time the USGS was fully aware of additional revisions to the NVO-196-17 (now 88-9). Due to the changing upper-tier requirements, a management decision was made not to continue with full QMP revisions. For instance, in order for the USGS to proceed, QMP-5.03 must again be revised to address the requirement for obtaining WMPO approval on USGS management procedures. Based upon recent discussions with WMPO, it is apparent that this requirement may change again. These fluctuations in the basic QA Plans serve to amplify the USGS decision to hold QMP revision/processing pending full approval of NNWSI-USGS-QAPP-01, R5.

BLOCK 15: EFFECTIVE DATE: As mandated by WMPO (See attached for current WMPO schedule).

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

The cause of the condition was an unstable QA Plan, with planned revisions announced concurrently or before issuance of each revision. These changes resulted in a management decision not to actively pursue development and/or revision of QMPs. Corrective action for the changing conditions is beyond the control of the USGS, however, the situation is expected to stabilize when Nuclear Regulatory Commission (NRC) concurrence/endorsement of NNWSI/88-9 is attained.

BLOCK 17: EFFECTIVE DATE: Not Applicable.

REVISION OF PARTICIPANT QA ADMINISTRATIVE PROCEDURES

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB
TRANSMIT 88-9 PROCEDURE MATRIX TO PARTICIPANTS		8/12 ◇						
PARTICIPANTS TO COMPLETE MATRIX		▬						
SUBMIT COMPLETED MATRIX TO WMPO			9/12 ◇					
SUBMIT SCHEDULE FOR PROCEDURE REVISION			9/12 ◇					
WMPO INTEGRATE SCHEDULE			9/26 ▬					
PARTICIPANT REVISION OF PROCEDURES		▬	▬	▬				
WMPO REVIEW OF PARTICIPANT PROCEDURES				▬	▬			
COMMENT RESOLUTION					▬			
COMMENT INCORPORATION BY PARTICIPANTS					▬			
TRANSMIT PROCEDURES AND VERIFIED MATRIX FOR WMPO APPROVAL						12/15 ◇		
TRAINING					▬	▬	▬	

REVISION OF PARTICIPANTS QAPPs

TRANSMIT 88-9 REV. 1 TO PARTICIPANTS

**COMMENT RESOLUTION MEETING ON
88-9 R0 AND DISCUSSION ON 88-9 R1**

PARTICIPANT REVISION OF QAPPs

TRANSMIT CHECKLIST TO PARTICIPANTS

**TRANSMIT DRAFT QAPP TO WMPO FOR REVIEW
ALONG WITH COMPLETED CHECKLIST**

WMPO REVIEW COMPLETE BY 8/26

**COMMENT RESOLUTION MEETINGS COMPLETE
BY 9/2**

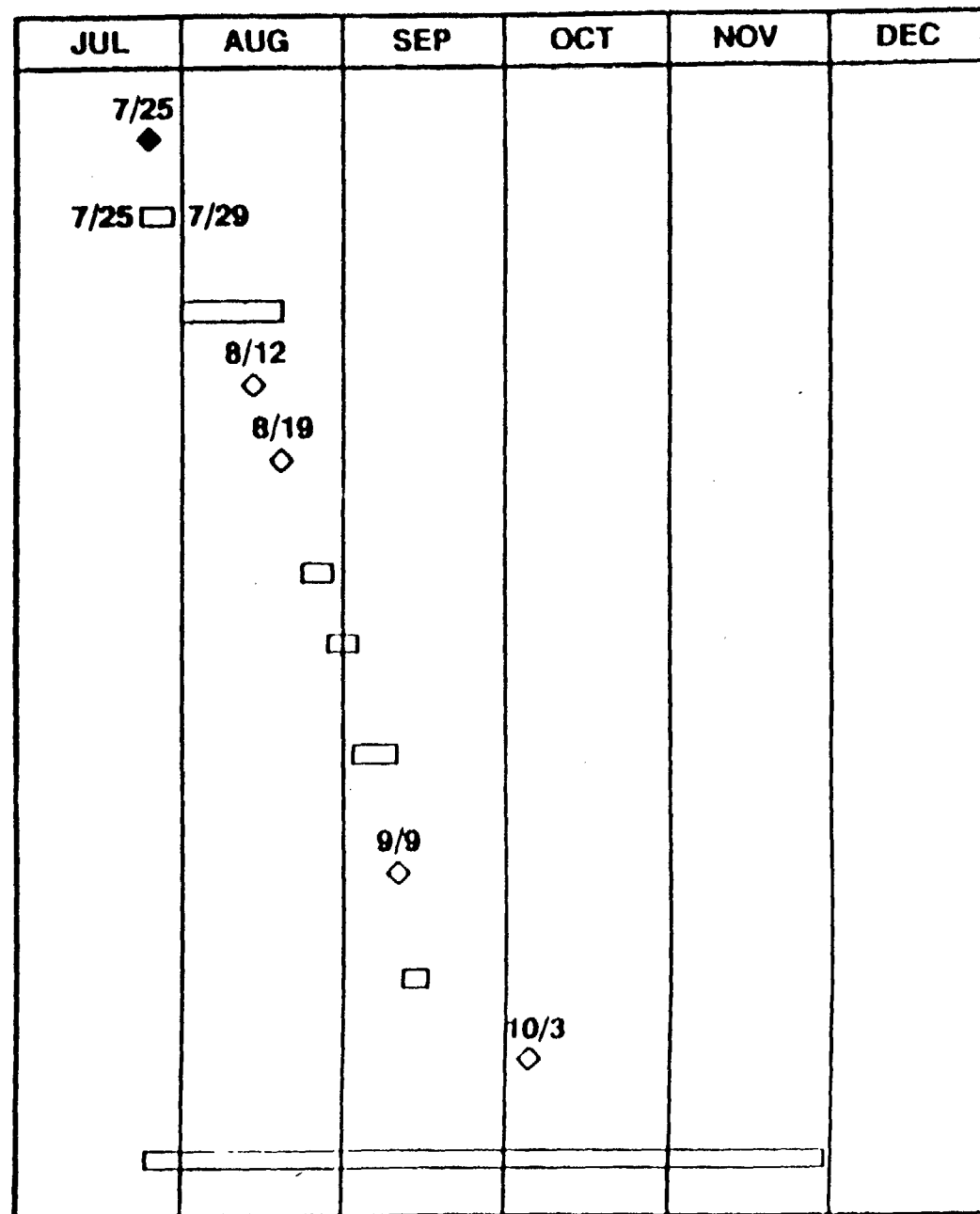
INCORPORATION OF COMMENTS BY PARTICIPANTS
RY 9/9

TRANSMIT REVISED QAPP AND VERIFIED CHECK-
LIST TO WMPO

FINAL REVIEW BY WMPO COMPLETED BY 9/10

**TRANSMIT QAPPs TO OCRWM FOR REVIEW/
APPROVAL**

TRAINING TO REVISED QAPP



REF ID: A66772

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AMENDED RESPONSE TO SDR-143, -144, -145, -146,
-147, -148, -155, -156, and -157
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BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

Part of the "fully qualified QA program" described in block 16 will be the establishment of a qualification process for data that is intended for use in the Project Office licensing process and that had been developed by the USGS before the implementation of this "fully qualified QA Program". This process will be consistent with the Project Office AP-5.9Q.

BLOCK 15: EFFECTIVE DATE:

Thirty days subsequent to issuance of AP-5.9Q.

BLOCK 16: CAUSE OF THE CONDITION AND PREVENTIVE ACTION TO PREVENT RECURRENCE:

The USGS is currently in the process of establishing a Quality Assurance Program which meets the requirements of NNWSI/88-9, Rev.2. The establishment, implementation, and verification of this "fully qualified QA Program" will provide the corrective action to prevent recurrence for the SDRs.

BLOCK 17: EFFECTIVE DATE:

Progress on the "fully qualified QA Program" is tracked for the Project Office bi-weekly and reported as part of the Gold Star Schedule. Please refer to this schedule for current dates. A specific date cannot be accurately projected at this time because parts of the USGS QA Program are dependent upon Project Office APs.

YMPO verification of the USGS Program is scheduled by the Project Office.

Verification

- o USGS QAPP-01, Rev. 5 became effective 5/3/89 and was approved by the Project Office as meeting 88-9 Rev. 2 requirements. USGS did write implementing procedures to implement QAPP-01, Rev. 5. These implementing procedures were verified to meet 88-9 Rev. 2 requirements by the Project Office Task Force Surveillances YMP-SR-89-030, -89-031, -89-091, -89-092, -89-093, -89-094, -89-095, -89-109, and -89-110 of USGS.
- o Verified by sampling that appropriate USGS personnel had been trained to appropriate USGS implementing procedures.
- o USGS letter Chaney to Gertz dated 2/23/90 commits the USGS to use YMP0 AP-5.9 for qualification of any data or data analyses completed prior to 5/3/89 that will be needed in support of licensing.

T. W. Nohd
4/25/90

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Completed by Originating QA Organization

1 Date June 15, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 25
3 Discovered During Audit 88-4	3a Identified By R. H. Klemens	3b Branch Chief Concurrence Date	4 SDR No. 161 Rev. 0	
5 Organization USGS-Denver	6 Person(s) Contacted Peggy Warner, Joe Willmon		7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) USGS QMP-17.01, R1; QA Records Management. Para. 6.2.4, Records must be sent to the USGS Records Processing Center within 120 days of completion.				
9 Deficiency Contrary to the above requirements, USGS has not been sending completed records to the USGS Records Processing Center within 120 days of completion. In addition, USGS has not been forwarding processed records to the Project				
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective (1) Implement the requirements of QMP 17-01.				

Aprvl.

11 QAE/Lead Auditor Date <i>Daniel Klemens 7-25-88</i>	12 Branch Manager Date <i>Joe Willmon 8/31/88</i>	13 Project Quality Mgr. Date <i>James Blaylock 7/25/88</i>
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Completed by Organization in Block 5

14 Remedial/Investigative Action(s) See attached response for Blocks 14-17.		15 Effective Date _____
16 Cause of the Condition & Corrective Action to Prevent Recurrence		17 Effective Date _____

Comp. by Orig. QA Org.

19 Response	<input type="checkbox"/> Accept <input checked="" type="checkbox"/> Amended Response	QAE/Lead Auditor/Date <i>Dan Klemens 12-5-88</i>	Branch Manager/Date <i>Joe Willmon 5 Dec 88</i>
20 Amended Response	<input checked="" type="checkbox"/> Accept <input type="checkbox"/> Reject	QAE/Lead Auditor/Date <i>Dan Klemens 5-1-89</i>	Branch Manager/Date <i>Joe Willmon 19 May 89</i>
21 Verification	<input checked="" type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory	QAE/Lead Auditor/Date <i>T. Willmon 4/25/90</i>	Branch Manager/Date <i>Joe Willmon 4-27-90</i>
22 Remarks See Page 5 for Verification TUN 4/25/90			
23 QA CLOSURE	QAE/Lead Auditor/Date <i>T. Willmon 4/25/90</i>	Branch Manager/Date <i>N/A</i>	PQM/Date <i>4-27-90</i>



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8 Requirement (continued)

Para. 6.5, The records will be processed at the USGS Records Center and will be forwarded to the PRC for microfilming once all QA reviews are complete.

9 Deficiency (continued)

Records Center (PRC). These activities were interrupted early in 1987 by the high priority work on Discovery Records. Aside from record collection, very little processing of records has been resumed by USGS. Activities which have not been done include processing, examination of packages, evaluation, data entry, processing of data items, preparation for transmittal, and mailing records to the PRC.

While the USGS has not met the above requirements, it has been noted that processing activities are being reactivated. USGS has appointed a new Records Coordinator (as of 1/88) and are currently working to a plan which emphasizes the processing of 1987 records. A schedule has been established for the months of May, June and July, 1988.

AUDIT CHECKLIST REF: Audit Item 17-23, 17-24 and 17-25.

Discussion: This SDR was written because of the failure of USGS to collect and process records as required by USGS QMP 17.01, Rev. 1, during the period of time from early 1987 until the present. Although some activities have resumed within the past four or five months, it is apparent that USGS has not been able to resolve the problems which must be corrected prior to meeting the current records requirement documents.

10 Recommended Actions (continued)

- (2) Investigate to determine if records in various stages of processing are intact and still in usable condition and determine the impact of this deficiency on quality.
- (3) Reinstruct applicable personnel as to procedure requirements.

BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

Record submittal and collection activities to the USGS Records Center are underway and will continue to assure that appropriate documents are on file and available. Additional processing will not proceed until the revisions to the upper-tier QA Plans and the USGS Management Procedures are complete and training is conducted.

BLOCK 15: EFFECTIVE DATE: In Process.

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

The condition was the result of personnel turnover and general confusion regarding the changing plans and project direction for controlling project records.

Records personnel are now assigned to undertake record processing activities that will be required by a revised QMP-17.01.

As a result of an internal audit finding (USGS-8701-AFR01), an amendment to QMP-17.01 was proposed to describe the record management activities that would be conducted until QMP-17.01. This QMP-17.01 Amendment was approved by USGS management and forwarded to WMPO in August 1987 for approval. As of March 1988, the USGS had not received any formal response from WMPO, and since WMPO approval was no longer required on USGS QMPs (ref. USGS-QMP-5.03, R1), the USGS considered the Amendment canceled and requested the return of the Amendment. No response has been received to date. As evidenced by the substance of the Amendment, the USGS Management considered processing records through to the WMPO Records organization too much of a risk in light of the changing requirements and directions. A conscious decision was made to hold all records in order to implement, what we thought at the time, were forthcoming changes, namely as the Information Management System (IMS) instead of QARMS.

Overall, the real probability of adversely impacting quality was minimized by not processing records as opposed to processing records with possibly inadequate direction.

The WMPO 88-9 and the USGS requirements as well as the WMPO Administrative Procedure (AP-1.7Q) concerning records management are changing and the USGS QMP-17.01 will be revised accordingly. The schedule for QMP revisions is a part of the actions required for SDR 156.

BLOCK 17: EFFECTIVE DATE: See SDR 156.

AMENDED RESPONSE TO SDR-161
February 10, 1989

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BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

As given in original response.

BLOCK 15: EFFECTIVE DATE:

Schedule for revision to upper-tier QA Plans and QMPs:

Revision to QAPP - Revised USGS QAPP which meets the requirements of NNWSI/88-9, Rev. 2 submitted to YMPD December 30, 1988. Approval is dependent upon the Project Office.

Revision to QMP-17.01 - Revised (rev. 2) to meet requirements of NNWSI/88-9, Rev 2 effective October 7, 1988.

Records submittals to LRC - currently implemented for correspondence, publications, and supporting packages. To be implemented in February 1989 for QA Office records.

Records type list - in effect (September 16, 1988), to be updated upon need.

Authorized personnel list - in effect, to be updated upon need.

Authorized access list - in effect, to be updated upon need.

Time schedules for records submittals to LRC - in effect for correspondence, publications, and supporting packages. To be determined by March 1, 1989 for the QA Office files.

Record submittals to CRF - dependent upon permission from the YMP Records Administrator and methods to be determined by the YMP Records Administrator.

Training - in process, last training scheduled for February 6, 1989.

BLOCK 16: CAUSE OF THE CONDITION AND PREVENTIVE ACTION TO PREVENT RECURRENCE:

As given in original response.

BLOCK 17: EFFECTIVE DATE:

AP-1.7Q, Rev. 0 - issued August 15, 1988

QMP-17.01, Rev. 2 - effective date October 7, 1988.

Verification

- o USGS QAPP-01, Rev. 5 became effective 5/3/89. USGS QMP 17.01, Rev. 2 became effective 10/7/88. USGS QMP 17.01, Rev. 3 became effective 3/3/89.
- o Verified that formal training to QMP-17.01, Rev. 2 was conducted by observing training attendance forms dated 11/15/88, 11/22/88, 12/5/88, 12/13/88, 1/23/89, 1/30/89, 2/6/89, and 2/7/89. Training of USGS staff to QMP-17.01, Rev. 3 was verified by observing a sample of completed read and understand training forms.
- o Verified that completed QA records were being submitted by the Record Source to the USGS Local Records Center (LRC) within 10 working days by observing a sample of records submitted in April 1990.
- o Verified that USGS LRC accepted QA records were being submitted to the Central Records Center within 10 working days of acceptance by observing a sample of records submitted in April 1990.

T.W. Nald
4/25/90