



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
QA

MAR 02 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

CLOSURE OF STANDARD DEFICIENCY REPORT (SDR) 157, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE AUDIT 88-04 OF U.S. GEOLOGICAL SURVEY (USGS)

SDR 157, Revision 0, has been closed based on satisfactory verification of completed corrective actions. A copy of the SDR is enclosed for your files.

If you have any questions, please contact Robert B. Constable of my staff at (702) 794-7945 or FTS 544-7945, or Daniel A. Klimas of Science Applications International Corporation at (702) 794-7881 or FTS 544-7881.

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

YMP:RBC-2233

Enclosure:
SDR 157, Revision 0

cc w/encl:
Ralph Stein, HQ (RW-30) FORS
D. E. Shelor, HQ (RW-3) FORS
Tom Chaney, USGS, Denver, CO
D. A. Klimas, SAIC, Las Vegas, NV, 517/T-08
S. W. Zimmerman, NWPO, Carson City, NV
J. E. Kennedy, NRC, Washington, DC

cc w/o encl:
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08
K. G. Sommer, HQ (RW-3) FORS
D. O. Porter, SAIC, Golden, CO
Alan Flint, USGS, NTS
J. W. Gilray, NRC, Las Vegas, NV

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PDR WASTE
WM-11 PNR

FULL TEXT ASCII SCAN

ADD: J Kennedy

Ltr. Encl.
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WM-11
102.7
NH03

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date June 9, 1988	2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 4
3 Discovered During AUDIT - 88-4	3a Identified By S. Mans	3b Branch Chief Concurrence Date	4 SDR No. 157 Rev. 0
5 Organization USGS/Denver	6 Person(s) Contacted Jim Robison/Ron Spaulding		7 Response Due Date is 20 Working Days from Date of Transmittal
8 Requirement (Audit Checklist Reference, if Applicable) NNWSI-USGS-QMP-6.01, R1, Para. 4 states in part, "Details of this procedure pertain to the control of preparations and issuance of...procedures...", para. 4.2.2 entitled REVIEW, states in part "Each document is required to show the			
9 Deficiency Contrary to the above requirements, the following procedures used to perform activities that affect quality in SIP-33331G-01, Rev. 0, were not properly reviewed and approved. NWN-USGS-HP-25 Rev.1; HP-39 Rev. 0; HP-60 Rev. 0;			
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective (1) Replace unapproved procedures with approved procedures.			

Apr 11

11 QAE/Lead Auditor Date <i>Daniel Kumas 7-25-88</i>	12 Branch Manager Date <i>Jim Robison 7/25/88</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 _____

18 Signature/Date
Larry R. [unclear] 8/31/88 *J. W. Estell 8/31/88*

Comp. by Orig. QA Org.

19 Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	<input checked="" type="checkbox"/> Amended Response	QAE/Lead Auditor/Date <i>Dan Kumas 12-5-88</i>	Branch Manager/Date <i>J. W. Estell 5 Dec 88</i>
20 Amended Response	<input checked="" type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date <i>Dan Kumas 5-11-89</i>	Branch Manager/Date <i>J. W. Estell 19 May 89</i>
21 Verification	<input checked="" type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date <i>Dan Kumas 8/24/89</i>	Branch Manager/Date <i>J. W. Estell 8/30/89</i>
22 Remarks <i>See dated 8/31/88 - Denver to Denver verified personnel at NTS are on CONTROLLED DISTRIBUTION.</i>				

23 QA CLOSURE	QAE/Lead Auditor/Date <i>Dan Kumas 8/24/89</i>	Branch Manager/Date <i>J. W. Estell 8/30/89</i>	PQM/Date <i>James Blaylock 8/31/89</i>
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ENCLOSURE



8 Requirement (continued)

signature and date denoting technical & QA compliance reviews", para. 4.2.3 states states in part "Each document will be reiewed by the Quality Assurance Office to check for compliance with the appropriate controls, and regulations in accordance with checklists established..."

9 Deficiency (continued)

HP-61 Rev. 0, were not reviewed by the QA office and they were not approved by USGS management.

These improperly approved procedures were physically located at the NTS (Test Cell C) and were the controlling documents for the individual work activities specified.

Discussion:

The NNWSI QAP requires that "The preparation, review, approval, and issuance of documents such as instructions, procedures, plans, and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

- o Documents containing or specifying quality requirements
- o Documents that prescribe activities affecting quality."

It was noted during the audit that USGS had developed measures to control the issuance of documents. A method to assure that only correct documents were used was in place. In fact the USGS QAPP, Rev. 4, required "Methods for Control: The preparation, review, approval, and issuance of documents, such as instructions, procedures, plans, and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

- o Documents that assure technical adequacy,
- o Documents containing or specifying quality requirements, and
- o Documents that prescribe activities affecting quality.

The document control system shall be documented and the QA office shall provide the appropriate review, resolution of comments, and concurrence with respect to quality related aspects of the documents."

Additionally, the USGS QAPP requires "Implementation of Document Control: Implementation of document control shall provide for the following:



9 Deficiency (continued)

- o A method for assuring that the correct and applicable documents are available at the location where they are to be used,

and it requires
- o Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents."

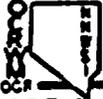
All of the above requirements were included in the USGS implementing procedure, QMP 6-01, Rev. 1. However, as documented above, four of the technical procedures reviewed during the audit had not been subjected to the appropriate review and approvals.

A basic premise for licensing the NNWSI Project is that activities which affect quality are controlled through procedures. These procedures define the actions required to carry out tasks and assure that tasks are done in accordance with those procedures. When this basic premise is fulfilled, there is increased assurance that actions are done properly and in a controlled environment. In order to achieve this controlled environment, several subsystems are necessary: (1) procedures must be written and reviewed, (2) they must be approved, (3) they must be distributed, (4) there must be records that the work/task were accomplished in accordance with the procedure (QA records), and (5) the work is verified independently (QC inspection).

All of the attributes outlined above form an administrative system which supports the concept of quality of workmanship. As problems occur in the work place and specific controls are violated or invalidated, confidence is lost that the tasks were performed in a controlled environment.

In the case of this SDR, several of the control elements which should have been in place to create the controlled environment, were not operating effectively. Specifically: (1) Document Control, Criteria 6 - The review and approval cycle was not followed, (2) Document Control, Criteria 6 - The issuance process for controlled documents was not followed, (3) Document Control, Criteria 6 - No management control, (4) QA Program, Criteria 2 - The indoctrination of individuals in QA requirements was ineffective because the working level personnel doing the task were willing to work to improperly approved procedures indicating lack of knowledge. The approval process or lack of discipline in that they were willing to knowingly violate basic tenets of QA.

When these controlling elements were not in place as required, and confidence in proper performance of tasks is reduced. The ability of regulating quality to accept the resultant data is also reduced, and this reduced ability may severely challenge the successful compliance with the NWPA.



WYMO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 157

Rev. 0

Page 4 of 4

9 Deficiency (continued)

At the time of the audit only limited work activities were being accomplished at the NTS. These activities are limited to the monitoring of natural events and the measuring of ground water elevation. Only one SIP was used to audit the document control system used at NTS. The audit attempted to establish that controlled instructions which had been properly developed, reviewed, approved, and issued were available to the working level personnel. It was found that four of the 10 instructions reviewed by the auditor had not been subject to all of the appropriate controls required by the USGS management.

10 Recommended Actions (continued)

- (2) Assess the impact on the quality of data gathered under unapproved procedures.
- (3) Determine if other unapproved procedures are in use.

BLOCK 14: REMEDIAL/INVESTIGATIVE ACTION(S):

The USGS agrees there is a document control discrepancy, but not as stated in the SDR. The USGS investigation revealed that the cited procedures were not the governing documents in use for technical work, but were available in the office at Test Cell C for information. One of the draft procedures (HP-25, R1) cited in this SDR was in the possession of the field technician for the purpose of his technical review; it was not in use. Another of the technical procedures cited is nonexistent (HP-61, R0). A third technical procedure (HP-39) was suspended before approval by the Principal Investigator because it would not be needed for any QA level I or II work. The fourth technical procedure (HP-60, R0) was approved.

Previous investigation conducted by USGS personnel to determine technical procedures in use before their approval resulted in several internal USGS NCRs, including one covering the use of HP-60. All NCR responses included consideration of the effect on quality.

Test Cell C personnel will be notified to mark uncontrolled copies of controlled documents as "information only".

BLOCK 15: EFFECTIVE DATE: October 1, 1988.

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

The cause of the condition was a misunderstanding by NTS personnel regarding information copies of controlled documents. Test Cell C personnel will be reminded of the requirements as part of the remedial action. QMP-6.01 will be revised to strengthen requirements for distinguishing between documents to be used for work and documents retained for information. The QMPs will be revised in accordance with the WMPO schedule. (Reference response to SDR 156.)

BLOCK 17: EFFECTIVE DATE: See SDR 156.

AMENDED RESPONSE TO SDR-143, -144, -145, -146,
-147, -148, -155, -156, and -157
February 10, 1989

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.

Str dtd 2/10/89 - Wayne to Gerty



United States Department of the Interior



GEOLOGICAL SURVEY
BOX 25046 M.S. 421
DENVER FEDERAL CENTER
DENVER, COLORADO 80225

IN REPLY REFER TO:

WBS 1.2.9.3
QA: "QA"

February 15, 1989

QA RECEIVED

FEB 22 1989

Carl P. Gertz
Project Manager
Yucca Mountain Project Office
U.S. Department of Energy
P.O. Box 98518
Las Vegas, NV 89193-8518

Atten: James Blaylock

SUBJECT: CORRECTION TO AMENDED RESPONSE TO SDR-151

REFERENCE: Larry R. Hayes letter to Carl P. Gertz, atten: James Blaylock, dated February 10, 1989, subject: AMENDED RESPONSES TO SDRs -143, -144, -145, -146, -147, -148, -151, -153, -154, -155, -156, -157, -161, and -162

The subject amended response contained an error. In the remedial actions (block 14) "QMPs" should read "technical procedures". Please consider this letter as a correction to the amended response.

If you have any questions concerning this matter, please contact the Quality Assurance Office at FTS 776-1418.

Sincerely,

Larry R. Hayes,
Chief, Branch of YMP

LRH/MHM

cc: J.R. Willmon, USGS, QA
J.J. Brogan, SAIC, Las Vegas, NV
R.W. Gray, MED, NV
A.D. Boyce, MED, NV
QA Logbook
QA File 3.16.01 YMPO SDR-151
USGS Local Records Center
R.R. Luckey