



Department of Energy

Nevada Operations Office
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Las Vegas, NV 89193-8518

WBS 1.2.9.3
QA

MAR 26 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

ACCEPTANCE OF RESPONSE TO STANDARD DEFICIENCY REPORT (SDR) 418, REVISION 0,
RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY
ASSURANCE (QA) AUDIT 89-04 OF U.S. GEOLOGICAL SURVEY (USGS)

The Project Office QA staff has evaluated and accepted your response to
SDR 418, Revision 0, generated as a result of Project Office QA Audit 89-04 of
USGS. The SDR will be closed after verification of satisfactory completion of
the specified corrective actions. A copy of the SDR is enclosed for your
information.

Verification of completion of your corrective action will be performed after
May 1, 1990, as requested in your letter of February 28, 1990. Extensions to
due dates must be requested in writing with appropriate justification prior to
the due date. Please send a copy of extension requests to Nita J. Brogan,
Science Applications International Corporation, 101 Convention Center Drive,
Las Vegas, Nevada 89109, and Ralph W. Gray, U.S. Department of Energy,
P.O. Box 98518, Las Vegas, Nevada 89193.

If you have any questions, please contact either Catherine E. Hampton at
(702) 794-7973 or FTS 544-7973, or Daniel A. Klimas at (702) 794-7881 or
FTS 544-7881 of Yucca Mountain Project QA.

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

YMP:CEH-2563

Enclosure:
SDR 418, Revision 0

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

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Larry R. Hayes

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MAR 26 1990

cc w/o encl:

K. G. Sommer, HQ (RW-3) FORS
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
D. A. Klimas, SAIC, Las Vegas, NV, 517/T-06
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06
D. O. Porter, SAIC, Golden, CO
J. W. Gilray, NRC, Las Vegas, NV

YMP STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date August 17, 1989		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 3
	3 Discovered During Audit 89-4		3a Identified By Mario R. Diaz/J. E. Clark		4 SDR No. 418 Rev. 0
	5 Organization USGS		6 Person(s) Contacted Peg Warner and Ben Zeigler		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) USGS-QMP-12.01, Revision 3, Para. 5.1.15, a QA calibration form is completed by the PI or delegate for each equipment requiring calibration after each calibration. The form is sent to the YMP-USGS QA office prior to an				
Completed by Originating QA Organization	9 Deficiency Contrary to the above numerous QA calibration forms were found in the Local Records Center that did not comply with the following requirements:				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Review all QA calibration forms located at LRC to ensure that they do comply				
	Aprvl.	11 QAE/Lead Auditor/Date <i>AA Caldwell 8/28/89</i>	12 Division Manager/Date <i>Robert Hedge F-26-89</i>	13 Project Quality Mgr./Date <i>James Blaylock 8/28/89</i>	
Completed by Organization in Block 5	14 Remedial/Investigative Action(s) See attached response.				15 Effective Date 11-30-89
	16 Cause of the Condition & Corrective Action to Prevent Recurrence See attached response.				17 Effective Date Complete
	18 Signature/Date <i>JR Wellmon / 10/10/89</i> Quality Assurance Manager, USGS, Yucca Mtn. Project				
Comp. by Orig. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date <i>Paisa Bar 3/15/90</i>	Division Manager/Date <i>N/A</i>	Project Quality Mgr./Date <i>Cathy [Signature] 3/15/90</i>	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks: <i>File dtd 10/10/89 - changes to Party Request Amended Response 4/15/90 - YMP.RBC-2001 Rec'd Amended Response 2/11/90 - [Signature] to Norton. RESPONSE ACCEPTED BASED ON REVISED RESPONSE 3/15/90</i>				
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

ENCLOSURE

STANDARD DEFICIENCY REPORT
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8 Requirement (continued)

equipment's use. USGS-QMP-17.01, Revision 3, Para. 5.1.7.2.6, the record shall be recorded with an indelible medium preferably black ink, against a light background. Para. 5.1.8, the correction shall include the date and initials or signature of the record source making the correction.

9 Deficiency (continued)

Records not completed such as:

RECORD ID

NONCOMPLIANCE

GS.89.Q.000541

Corrections made without required date and ID of person(s) doing it. Calibration performed 2/28/89, reported on 3/7/89 and received by QA on 3/14/89 which is after equipment's use.

GS.89.Q.000542

Corrections made without required date and ID of person(s) doing it. Calibration performed 2/28/89, reported on 3/7/89 and received by QA on 3/14/89. No indications or documented evidence that equipment was used after receiving QA calibration form.

GS.89.Q.006661

GS.89.Q.006662

Record was not completed by PI/designee, contains corrections made by QA. Calibration performed by 4/6/89, reported on 4/18/89. No indications of when the record was received by QA, therefore, it is not possible to determine if record was transmitted to QA prior to equipment's use.

GS.89.Q.000841

Does not contain calibration date revision of procedure used is not recorded. Required range and accuracy is missing. Calibration was reported on 6/12/89. However, indications of when the record was received by QA do not exist. Therefore, it is not possible to determine if record was transmitted to QA prior to equipment's use.

GS.89.Q.000831

Serial number, calibration date and expiration date are missing. Procedure revision number is missing. Signature is not complete. Documented evidence form was received does not exist. Not possible to determine if record was transmitted to QA prior to equipment's use.

All Remote Seismic
Telemetry Station
dated 4/25/89

Calibration dates since 1/18/89. However, record written on 4/25/89 and received by QA on 5/1/89 which is after equipment's use. All QA calibration form contain xerox copy of the signature of person completing form.

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9 Deficiency (continued)

"A"

Additionally, QA records provided by USGS Las Vegas Office did not contain information required by the calibration procedure such as technical procedure and revision number used for calibration, name of person performing the calibration, required range and accuracy, etc.

10 Recommended Actions (continued)

with all the requirements of the USGS QA program.

2.

Determine the impact are quality work done to date on YMP.

3.

Determine the cause of the condition noted in this SDR and what action will be taken to prevent recurrence.

4.

Revise procedures to clearly establish requirements for writing QA calibration forms; i.e., time limitation, data required, personnel authorized to authenticate those forms, indicate and clarify records originator, verification of equipment's use, transmittal to LRC, etc.

5.

Any NCR condition detected during item (1) above shall be identified, reported, and controlled by the appropriate NCR program.

6.

Retrain all affected personnel to the current requirements and any changes due to this SDR. Provide documented evidence of this action.

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BLOCK 14 REMEDIAL/INVESTIGATIVE ACTION(S):

NCR-89-27 was issued on 8-22-89 to internally track nonconformances involving QA Calibration Forms that were present in the LRC and that were signed after the issuance of YMP-USGS-QAPP-01, R5 on 5-3-89. QMP-12.01, R3 was modified on 8-23-89 to clarify the submission time requirements for QA Calibration Forms and the review process of forms for compliance as QA Records. In addition, QMP-17.01, R3 was modified on 8-21-89 to require an LRC record verification check upon record receipt. All QA Calibration Forms completed after 5-3-89 shall be corrected to ensure all required information per QMP-12.01, R3 is present and all forms are QA Records per QMP-17.01, R3 requirements. This correction process will be performed by 11-30-89. QA Calibration Forms were used solely to update the calibration status of YMP-USGS equipment and in no way impact calibration data and/or other project data.

Discussion of Specific Items:

- o Records GS.89.Q.006661 and GS.89.Q.006662 are incorrectly numbered within this SDR. The correct numbers are GS.89.Q.000661 and GS.89.Q.000662.
- o All QA Calibration Forms lacked objective evidence that they were submitted to the QA Office prior to an equipment's use. Submission of QA Calibration Forms prior to an instrument's use proved not feasible, particularly in the case of in situ equipment, where calibration and data collection occur on the same day so as to avoid loss of irrecoverable data. As a result of DOE's 89-04 Audit, QMP-12.01, R3 was modified on 8-23-89 to reflect a time requirement for submittal of QA Calibration Forms to the QA Office of 30 days from the date of calibration. The 30 day submission requirement will provide for a timely updating of the calibration status of YMP-USGS Project equipment.
- o Records GS.89.Q.000841 and GS.89.Q.000831 were identified as not having the revision number of the technical procedure used during the calibration. The revision number of the technical procedure was not required on the QA Calibration Forms but was required on the calibration data sheets and/or logbooks maintained by the technical personnel. However, during the 8-23-89 modification to QMP-12.01, R3, Attachment 1, the technical procedure revision number was added as part of the required information on the form to more clearly and consistently approach documentation of calibration information.
- o Record GS.89.Q.000841 was identified as not having the required calibration range and accuracy. The range and accuracy were noted as being specified in HP-23. It is acceptable to refer to a technical procedure for calibration range and accuracy.

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BLOCK 14 CONTINUED

- o Record GS.89.Q.000831 was identified as not having the serial number of the applicable equipment. The form shows a "#2" in the blank for unique identification number. The form reads, "Unique Identification Number (i.e. Model #, Serial #, and/or other ID #)". "#2" is an acceptable ID number.
- o Record GS.89.000831 was identified as missing the calibration date and the calibration due date. The form shows an "N/A" in both of the entry blanks. These are correct entries since the instrument is identified as "Operator To Calibrate" and is calibrated prior to each use. Entries of specific dates would be inappropriate for instrumentation of this type.
- o Record GS.89.000831 was identified as missing the complete signature of the person completing the form. This form will be corrected to show the complete signature.
- o QA Calibration forms that were listed in this SDR, other than GS.89.000831 and GS.89.000841, were signed prior to 5-3-89, the effective date of YMP-USGS-QAPP-01, R5. These forms will be handled independently of this SDR and will be reviewed as part of the actions associated with SDR No. 416.

BLOCK 15 EFFECTIVE DATE: 11/30/89

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

1. Condition per the referenced requirement, "USGS-QMP-12.01, Revision 3, Para. 5.1.15, a QA calibration form is completed by the PI or delegate for each equipment requiring calibration after each calibration. The form is sent to the YMP-USGS QA office prior to an equipment's use".

Cause: Submission of QA Calibration Forms prior to an instrument's use proved not feasible particularly in the case of in situ equipment, where calibration and data collection occur on the same day so as to avoid loss of irrecoverable data.

2. Condition per the referenced requirement, "USGS-QMP-17.01, Revision 3, Para. 5.1.7.2.6, the record shall be recorded with an indelible medium preferably black ink, against a light background. Para. 5.1.8, the correction shall include the date and initials or signature of the record source making the correction".

Cause: Nonconformances were present because the forms were not reviewed as QA Records for compliance with QMP-17.01, R3 requirements.

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BLOCK 16 CONTINUED

Preventive Actions: QMP-12.01, R3 was modified on 8-23-89 to clarify the submission time requirements for QA Calibration Forms and the review process of forms for compliance as QA Records to meet QMP-17.01 requirements. This modification reflects actual practices, and the implementation of the modification will preclude recurrence of similar nonconformances. QA personnel involved with the review of QA Calibration Forms are aware of the modification requirements and implementation of the requirements is already underway. Additionally, QMP-17.01, R3, was modified to clarify record acceptance requirements and actions are proceeding as addressed in SDR No. 416.

BLOCK 17 EFFECTIVE DATE: Complete

REVISED RESPONSE TO SDR-418
FEBRUARY 6, 1990

This response is to replace the original response dated 10/10/89.

BLOCK 14 REMEDIAL/INVESTIGATIVE ACTION(S):

QMP-12.01, which has been revised to Revision 4, renames the QA Calibration Form to the Notification of Calibration Status form and classifies it as a non-QA record. This revision has been fully approved and its effective date is being coordinated with conduct of necessary instruction. The re-classification to non-QA record status is based on the fact that these forms are used only as input to the Calibration Register.

The internal nonconformance report USGS-NCR-90-14 has authorized the repair condition to mark the QA Calibration Forms as non-QA records.

BLOCK 15 EFFECTIVE DATE:

Issuance of QMP-12.01, R4 is currently scheduled for March 1, 1990.

Other actions to be completed as required by USGS-NCR-90-14.

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

The requirement to send a QA Calibration Form to the QA Office prior to use of the equipment has proved infeasible in the case of in-situ equipment, where calibration and use occur on the same day so as to avoid irrecoverable loss of data. QMP-12.01, R3 was modified on August 23, 1989 to allow 30 days after calibration for submittal of the form.

Records management deficiencies concerning QA Calibration Forms occurred because QA Calibration Forms had not been reviewed as QA Records for compliance with QMP-17.01. Revision 4 to QMP 12.01 re-classifies these forms as non-QA records, thereby eliminating the need for this review.

BLOCK 17 EFFECTIVE DATE:

Modification 1 to QMP-12.01, R3 was effective August 23, 1989.

Revision 4 to QMP-12.01 is currently scheduled to be effective March 1, 1990.



T.H. Chaney, Acting YMP-USGS Quality Assurance Manager Date

Ltr dtd 2/14/90 - Hayes to Chaney