



## Department of Energy

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WBS 1.2.9.3  
QA

FEB 15 1990

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EVALUATION 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) (NN1-1990-1186)

The Project Office QA staff has evaluated your response to SDR 418, Revision 0, and has determined that it is unsatisfactory. This determination is based on the fact that Change Notice, Quality Management Procedure (QMP) 12.01, Mod.01.Ro for YMP-USGS-QMP-12.01, Revision 3, dated August 23, 1989, violates several requirements from QAP/88-9, Revision 2, and Administrative Procedure (AP)-1.7Q, Revision 2, such as:

1. Statement ". . . for periodic equipment with calibration intervals less than two months, a submission of a QA calibration form is only required for activation and again for deactivation . . ." contradicts Section 12, Paragraph 2.3. Every time an item requires calibration, regardless of period of time for calibration, it shall be documented on an appropriate form which shall be handled and kept as a QA record.
2. Statement ". . . all QA calibration forms shall be submitted to the QA office within 30 days from performance of a calibration . . ." contradicts requirements in AP-1.7Q, Revision 2. Work on the calibration form is being done by technical personnel; therefore, document(s) shall be authenticated and sent to the Local Records Center within 10 working days after the date of completion. Additionally, Paragraph 5.1.1.5 of the change indicates that the QA calibration form is completed by the Principal Investigator.
3. Statement ". . . the QA office may make corrections to the record per directions from the applicable technical personnel or the record source . . ." contradicts Section 17, Paragraph 9.1 and AP-1.7Q, Paragraph 5.5.3. The correction shall include the date and initials or signature of the person within the originating organization authorized to make such corrections. In this case the originating organization is the technical personnel and not the QA office.
4. Statement ". . . once the record has passed QA review it is considered to be a complete QA record . . ." contradicts Section 17, Paragraph 1.1. A complete record is a document that will either receive no more entries,

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and is signed and dated by the originator, and as applicable, by personnel authorized to approve the document. Personnel approving the document should be from the same organization that originated the record, not from the QA office.

Additionally, the response to this SDR dated October 10, 1989, fails to address the following items mentioned as examples of deficiencies:

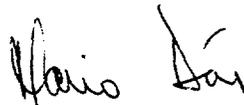
1. The identification of technical procedure and the revision number used during the calibration are missing on some QA calibration records.
2. All Remote Seismic Telemetry Station Calibration forms contain a reproduced or Xerox copy of the signature of the person completing those forms.
3. All QA records provided by the 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.

In Section 16, preventive actions fails to address the fact that all personnel involved with these documents and QA records shall be retrained to ensure that they are aware of the requirements, and the changes to the affected procedures. It also fails to address how this retraining will be accomplished and documented.

The same type of work is being performed by the technical personnel and the QA office personnel. Therefore, in order to preclude recurrence, training of all personnel involved with the calibration records is required and mandated.

An amended response to this SDR is required to be submitted to this office within 10 working days of the date of this letter. Any extension to this date must be requested in writing with appropriate justification prior to the due date. Please send the original of your response to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada, 89109.

Your cooperation and timely response is appreciated. If you have any questions, please contact Robert B. Constable of my staff at 794-7945, or Daniel A. Klimas of SAIC at 794-7881.

*for* 

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

YMP:RBC-2001

Enclosure:  
SDR 418, Revision 0

**YMPO 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 Organization in Block 5	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				
	11 QAE/Lead Auditor/Date <i>AA DePaul</i> 8/28/89	12 Division Manager/Date <i>Sheldedge</i> 8-28-89	13 Project Quality Mgr./Date <i>James Blaylock</i> 8/28/89		
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>J. Willmon</i> / 10/10/89 Quality Assurance Manager, USGS, Yucca Mtn. Project					
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
	21 Remarks				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

**ENCLOSURE**

YMPO STANDARD DEFICIENCY REPORT  
CONTINUATION SHEET

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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.

YMI STANDARD DEFICIENCY REPORT  
CONTINUATION SHEET

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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

Larry R. Hayes

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cc w/encl:

Ralph Stein, HQ (RW-30) FORS  
D. E. Shelor, HQ (RW-3) FORS  
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J. H. Nelson, SAIC, Las Vegas, NV, 517/T-04  
S. W. Zimmerman, NWPO, Carson City, NV  
J. E. Kennedy, NRC, Washington, DC ←←

cc w/o encl:

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