



Department of Energy

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WBS #1.2.9.3
"QA"

JUL 24 1989

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U.S. Geological Survey
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CLOSURE OF AUDIT FINDING SHEETS (AFSs) 86-2A-5 AND 86-2A-22 RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE AUDIT 86-2A

AFSs 86-2A-5 and 86-2A-22 have been closed based on satisfactory verification of completed corrective actions. Copies of the AFSs are enclosed for your files.

If you have any questions, please contact Wendell B. Mansel of my staff at 794-7945, or Daniel A. Klimas of Science Applications International Corporation at 794-7881.

Edwin L. Wilmot, Acting Director
Quality Assurance Division
Yucca Mountain Project Office

YMP:WBM-5049

Enclosure:
AFSs 86-2A-5 and 86-2A-22

cc w/encl:
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Dwight Shelor, HQ (RW-3) FORS
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WMPO AUDIT FINDING SHEET (AFS)

N-QA-024
6/85

(To be used for all AFSs with added sheets as required)

QMP-12.01 para 3
through 9 & SOP-02-
page 37 & 38 - of 7
para 12.1.4

Audit Finding No. 862a-5

Audited Checklist Reference

Audited Organization USGS - Denver

Organization Unit Rock Properties
Measurements Lab

Activity Control of M & TE

Response Assigned To W. W. Dudley, Jr.

Reported By (Auditor) S. Singer

Requirement (Cite) Chapter 12 Control of Measuring and Test Equipment Section 1, 2. SCOPE OF COMPLIANCE. This procedure applies to all USGS instruments that require calibration

in support of the NNWSI Project. It applies to all NNWSI-USGS personnel and their (cont'

Finding A review of the Rock Properties Measurement Lab revealed lack of compliance/imple
mentation in the following areas: (1) the QA Calibration Form is not being completed for
each instrument requiring calibration and is not being sent to the USGS QA Office prior
to the instrument's use. (2) The USGS QA Office is not entering this information (cont'

Approved By LA S. Singer 4/8/86

Response Due Date 30 days after
Receipt of
Report

Approved By WMPO/NV James Blyskal 4/10/86

Date

Response (To be completed by audited organization) After investigation and review of the
nine specific problem areas, the following remedial actions were taken: 1) A calibra-
tion form has been completed for each affected instrument in the Rock Properties
Measurement Lab. The USGS QA Manager has copies. (continued)

Implementation Date Approx 11/01 Submitted By W. W. Dudley, Jr. Date 5/11/86

To be completed by lead auditor (LA) and reviewed by WMPO/NV

Corrective Action Response
 Satisfactory Unsatisfactory

Reviewed by LA/Date S. Singer 10/30/86

Reviewed by WMPO/NV/Date James Blyskal 10/30/86

Corrective Action Implementation
 Satisfactory Unsatisfactory

Reviewed by LA/Date Dan Klimas 6/23/89

Reviewed by WMPO/NV/Date James Blyskal 6/26/89

Reaudit Date _____

Remarks See Attached documentation

Audit Finding Closed LA Concurrence/Date Dan Klimas 6/23/89

Reference and Number(s) for unsatisfactory reaudit _____

USGS Audit Findings Response (continued)

The cause of the lack of proper control of M&TE in the Rock Properties Measurement Lab is a result of:

1. Inadequate training of Lab personnel for implementing quality requirements;
2. Relative newness of implementing the Quality Program; and
3. Procedural inconsistencies and inadequacies.

Preventive measures which will be taken include:

1. Completion of a formal QA Indoctrination and Training Program for all USGS Participants prior to the lifting of the stop work order. This program will also establish the basic framework for ongoing indoctrination for new employees.
2. The Stop Work Order has emphasized the necessity of establishing and implementing quality requirements. Based on the training noted in item 1 above, combined with the overall QA awareness since the Stop Work Order, we anticipate project personnel will be cognizant of pertinent requirements and their responsibilities for implementing these requirements.
3. Procedural problems have been resolved by revision to the USGS NNWSI QA Program Plan (QAPP) and the implementing Quality Management Procedures. The QA Manual was approved by USGS Management and submitted to WMPO on July 16, 1986 for review and approval.

WMPO Audit Finding No. 862a-5 cont'd Req. cont'd

contractors. 4. RESPONSIBILITIES. 4.1 The

Principal Investigator (PI) is responsible for ensuring that USGS-controlled instruments requiring calibration meet the requirements of this procedure.

5. PROCEDURE. 5.1 A QA Calibration Form (Attachment 1) shall be completed by the PI or a delegate for each instrument requiring calibration and sent to the USGS QA Office prior to the instrument's use. 5.2 The USGS QA Office shall

enter the information into a calibration system, and provide the originating PI a copy of the information. 5.5 The PI is responsible for ensuring that the

calibration status of instruments are displayed at some readily accessible location. To comply, a sticker shall be affixed to each instrument denoting the calibration status according to one of the following three categories:

1. Showing equipment identification, date calibrated, date recalibration is due, procedure number and calibrator.
2. Indicating the equipment identification, "OPERATOR TO CALIBRATE", and the procedure number.
3. Showing the equipment identification and "NO CALIBRATION REQUIRED".

5.6 Nonconformance reports shall be prepared in accordance with NNWSI-USGS-QMP-15.01 for instruments that are used after the recalibration due date or displays no calibration status sticker.

6. QA REQUIREMENTS. 6.1 Personnel performing equipment calibration shall be certified to have the qualifications necessary to perform the required cali-

bration. These qualifications shall be based on training and experience and documented according to procedure NNWSI-USGS-QMP-2.03. 6.2 Calibration

standards used for calibration of instruments shall be traceable to the National Bureau of Standards (NBS) or other known standards; this includes primary and working standards. If NBS standards do not exist, the reference standard used shall be supported by certificates, reports, or data sheets attesting to the

WMPO Audit Finding No. 862a-5 cont'd

Req. cont'd

date, accuracy, and conditions under which the results were obtained. If reference standards are used, they will be stored and handled in such a way as to maintain the required accuracy and characteristics of the standard.

6.3 The method and interval of calibration for each item shall be defined, based on the type of equipment stability, characteristics, required accuracy, intended use, the manufacturer's recommendations, and other conditions that affect measurement control. Instruments that are out of calibration shall be tagged or segregated and shall not be used until they have been recalibrated. If any instrument is found to be out of calibration consistently, then it shall be repaired or replaced. A calibration shall be performed when the accuracy of the instrument is suspect. 8. RECORDS MANAGEMENT. The calibration forms and any other documents associated with this procedure which are Quality Level I or II documents shall be processed as an official NNWSI QA record.

USGS Audit Findings Response (continued)

- 2) The USGS QA Office is presently reviewing the QA calibration forms and initiating the necessary actions to incorporate the information into the calibration system. This system is under development, and while it now will track Calibration data, it is expected to become fully operational by the end of this fiscal year.
- 3) Calibration status stickers have now been affixed to all appropriate instruments in the Laboratory.
- 4) Nonconformance Report No. USGS NCR 86-01 documented the lack of calibration stickers. Hold tags were attached as required. The disposition and verification shall be in accordance with QMP-15.01, R1.
- 5) Certifications for personnel performing calibrations are being completed as required by QMP-2.03. The originals are sent to the USGS QA Manager who forwards the certifications to the USGS Records Processing Center as required by QMP-17.01.
- 6) All calibration standards are now: a) traceable to NBS standards, b) traceable to other known standards, or c) substantiated by reports or data sheets as recorded by the PI.
- (7) Technical procedure NWM-USGS-GPP-10 is under review to determine adequacy regarding identification of the "method and interval of calibration." If necessary, based on results of this review, the technical procedure will be revised to incorporate these requirements.
- 8) There were no specific instruments identified as "out-of-calibration", therefore tagging or segregation is not required.
- 9) QMP-12.01 requires these completed calibration forms to be submitted as part of the QA records in compliance with QMP-17.01. The calibration forms are considered backup data which QMP-17.01 requires processing as part of the data package that is to be submitted following the completion of the report concerning the work.

WMPO Audit Finding No. 862a-5 cont'd

Finding cont'd

into a calibration system -- to include all affected instruments. (3) The calibration status of instruments is not being displayed at a readily accessible location. Stickers are not affixed to each instrument denoting the calibration status in accordance with Para. 5.5 above. (4) Nonconformance reports have not been written for instruments that display no calibration status sticker. (5) No documented certifications are on file for personnel performing equipment calibrations. (6) Calibration standards used for calibration of instruments are not traceable to the NBS or other known standards. Where NBS standards do not exist, the reference standard is not supported by certificates, reports or data sheets attesting to the date, accuracy and conditions under which the results were obtained. (7) The method and interval of calibration for each item has not been defined, based on the type of equipment stability, characteristics, required accuracy, intended use, manufacturer's recommendations or other conditions that affect measurement controls. (8) Instruments out of calibration are not tagged or segregated. (9) Calibration forms, which are QA Level I or II documents, are not processed as NNWSI QA records.

SPECIFICATION/DRAWING/PROCEDURE REQUIREMENTS:

NNWSI-USGS-QMP-12.01, RO. Para. 5.5: "The PI is responsible for ensuring that the calibration status of instruments are displayed....a sticker shall be affixed to each instrument denoting the calibration status."

Para. 6.1: "Personnel performing equipment calibration shall be certified to have the qualifications necessary to perform the required calibration..."

(Reference WMPO Audit Finding No. 862a-5.)

DEFICIENCY:

The instruments being used lack the required stickers and the personnel performing calibrations in the Rock Properties Measurement Lab lack the required certification, thereby rendering the quality of related work activities and/or results as indeterminate.

DUPLICATE

WMPO AUDIT FINDING SHEET (AFS)

N-QA-024
6/85

(To be used for all AFSs with added sheets as required)

Audit Finding No. 862a-22 Audited Checklist Reference 862a-16.5.1

Audited Organization USGS - Denver

Organization Unit QA Activity NCR, CAR and Audit Procedures

Response Assigned To W. W. Dudley, Jr. Reported By (Auditor) N. Voltura/S. Singer

Requirement (Cite) NNWSI-USGS-QMP-16.01, Rev. 0 Para. 5.1 states in part: ". . .Periodic examination of Nonconformance Reports, Audit Reports, or other documents often reveal the need for a CAR, but a CAR also may be issued as a result of any observation (cont'd)

Finding Contrary to the above, no documentation, USGS CAR, has been generated to identify numerous recurring conditions adverse to quality. There are 29 outstanding/open audit findings identified by LANL for USGS which have not been resolved; many of these identify recurring conditions.

Approved By LA S. Singer 4/8/86 Response Due Date 30 days after Receipt of Report

Approved By WMPO/INV James Blaylock 4/10/86 Date _____

Response (To be completed by audited organization) This deficiency stems from the earlier lack of a management assessment procedure, and the more recent non compliance with the current Management Assessment Procedure QMP-2.01. Open findings extend back to the predecessor of the current QA Office, and an effort is underway to close out these items or to provide the suggested Corrective Action Request. Records show (cont'd)

Implementation Date Approx 11/1/86 Submitted By W. W. Dudley Jr. Date 5/11/86

To be completed by lead auditor (LA) and reviewed by WMPO/INV

Corrective Action Response
 Satisfactory Unsatisfactory

Reviewed by LA/Date S. Singer 10/30/86
 Reviewed by WMPO/INV/Date James Blaylock 10/30/86

Corrective Action Implementation
 Satisfactory Unsatisfactory

Reviewed by LA/Date Dan Haines 6/21/89
 Reviewed by WMPO/INV/Date James Blaylock 6/21/89
 Reaudit Date _____

Remarks Reference USGS NCR's 88-14 thru 20

Audit Finding Closed LA Concurrence/Date Dan Haines 6/21/89

Reference and Number(s) for unsatisfactory reaudit _____

"BEST AVAILABLE COPY"

ENCLOSURE

WMP0 Audit Finding No. 862a-22 cont'd

Req. cont'd

which discloses a ". . . recurring adverse situation or condition."

USGS Audit Findings Response (continued)

there were 29 such open findings at one time and many of these have been resolved to date. The effort to complete this task continues.