Department of Energy
Yucca Mountain Site Characterization
Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3

APR 07 1992

Michael D. Voegele
Technical Project Officer
for Yucca Mountain
Site Characterization Project
Science Applications International Corporation
The Valley Bank Center, Suite 407
101 Convention Center Drive
Las Vegas, NV 89109

EVALUATION OF AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-92-020 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-92-08

The YMQAD staff has evaluated the amended response to CAR YM-92-020. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing with appropriate justification prior to the date. Please send a copy of extension requests to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Mario R. Diaz at 794-7974.

Robert B Constable f.o.r.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2793

Enclosure:
CAR YM-92-020

cc w/encl:
K. R. Hooks, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
D. K. Chandler, SAIC, Las Vegas, NV, 517/T-04
J. R. Gonzales, SAIC, Las Vegas, NV, 517/T-28

cc w/o encl:
J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-12

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NH03
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Add K. R. Hooks Ltr Encl 1 1

YMP-5

9204160198 920407
PDR WASTE
WM-11 PDR

ORIGINAL
THIS IS A RED STAMP

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

8 CAR NO.: YM-92-020
DATE: 2/5/92
SHEET: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document	2 Related Report No.
T&MSS QAPD, Revision 4	Audit 92-08

3 Responsible Organization	4 Discussed With
SAIC	D. Sorensen/G. Donaldson

5 Requirement:

T&MSS QAPD, Revision 4, Section 12, Paragraph 12.2.B states in part, "Calibration standards shall have accuracy greater than the equipment being calibrated."

T&MSS Standard Practice Procedure SP 1.28, Revision 5, Page 27, Section 1100, states in part, "The (Calibration) Certificate shall contain the following:

a. SAIC Purchase Order number.

c. Name of person responsible for performing the calibration.

j. If the item to be calibrated has a multiple range of operations, the certificate shall show at least five points of calibration... (con't)

6 Adverse Condition:

Several requirements to be recorded on the Certificate of Calibration of various M&TE are missing.

Most of the calibration certificates do not contain the accuracy of the Standard(s) used for the calibration. Without this information, it is not possible to verify and attest that this accuracy is greater than the equipment that was calibrated.

Additionally, the Certificates of Calibration for the following M&TE ID numbers did not contain the information required by items a, c, j, n , and p of Section 5 above.

09064*, 01578, 03353, 17919, 17948

* The certificate for this instrument contained 4 sheets of paper. Only three were traceable to the instrument.

9 Does a significant condition adverse to quality exist? Yes___ No X If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes___ No X ; if Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 working days from issuance

12 Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

13 Recommended Actions:

7 Initiator M. Diaz 1/30/92 Date 2-5-92	14 Issuance Approved by: QADD Date 2/5/92
15 Response Accepted QAR Date	16 Response Accepted QADD Date
17 Amended Response Accepted QAR Date 3-31-92	18 Amended Response Accepted QADD for Date 4/6/92.
19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date

REV. 08/91

ENCLOSURE

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CORRECTIVE ACTION REQUEST (Continuation Page)

5 Requirements (continued)

n. Procedure/instruction with revision, used to perform the calibration.

p. Statement that the item calibrated is within the specified accuracy in all operating ranges."

6 Adverse Condition (continued)

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CORRECTIVE ACTION REQUEST (Continuation Page)

CORRECTIVE ACTION RESPONSE TO CAR YM-92-020
3/11/92

1. Remedial Action

The following describes actions taken to correct specific deficiencies noted.

Part I. Accuracy of the Calibrating Device

ICN 1 to Revision 5 of SP 1.28 was issued on January 27, 1992 to require the vendor to submit to T&MSS the accuracy of the calibrating device. For each quality affecting calibration previously performed, the accuracy of the calibrating device will be compared to the accuracy of the equipment being calibrated to assure that the calibrating device has a greater accuracy.

James Harper and Dennis Sorensen of T&MSS are assigned the responsibility for completion of these actions. The completion date is May 29, 1992.

Part II. Certifications of Calibration

For each of the specific five M&TE items identified in part 6 of the CAR, the applicable certificate was evaluated by the T&MSS technical and QA inspection personnel against the information requirements. In some cases the alleged missing information was present on the certificate. In no case was all five items of information missing on all five cited certificates of calibration. Where information was actually missing, the information was located or actions are under way to made the certificate complete, e.g., the calibration service vendor will be requested to supply required information.

Three of the five devices cited on the CAR are non-quality affecting and, thus, no actions are required.

Concerning the requirements, in some cases items j. and k. do not apply, i.e., item j. applies only when an instrument has multiple ranges of operation and k. is applicable only if the instrument is digital.

The information that follows is the current status of the completeness and corrective action for the five specific M&TE certificates of calibration identified by item ID numbers:

Ltr L 92-1673 - 3/16/92

CORRECTIVE ACTION REQUEST (Continuation Page)

ID Number	Completeness/Corrective Action
09064	All information was present except for the procedure and revision number and multiple calibration points. The purchase number information (PO 39-920013-94) was provided on associated vendor documentation directly traceable to the certificate of calibration. The vendor will not be requested to supply information because this instrument was reclassified as QA/NA. Therefore no corrective action is required.
01578	All information was present except for the (PO) Number. It is our contention that "Rated Accuracy" is equivalent to "Accuracy". The PO information (PO 39-920399-94) is now provided. This instrument was reclassified as QA/NA. Therefore no corrective action is required.
03353	All information is present except for procedure and revision. The certificate illustrates that item is accurate to the degree required by ANSI N323-1978. The PO did not require five points of calibration. This instrument was reclassified as QA/NA. Therefore there is no deficiency. No additional information is required.
17919	All information is provided either directly or indirectly by reference to MIL-STD-45662A. This instrument is a single range instrument; therefore, item j is not required. No corrective action is required.
17948	All information is presented except for the statement of accuracy statement and the vendor procedure and revision number used to perform the calibration; however the procedure was furnished as part of the records package supplied with the certificate. No action is required except that vendor will be required to state that the item calibrated has the required accuracy.

The individual assigned responsibility for assuring completion of these actions is Dennis Sorensen of T&MSS. The anticipated completion date is May 29, 1992.

2. Investigative Action

The following describes actions taken (or, to be taken) to determine the extent of the conditions adverse to quality.

CORRECTIVE ACTION REQUEST (Continuation Page)

Part I. Accuracy of the Calibrating Devise

For all quality affecting M&TE devices, an evaluation of accuracy of the calibrating standards relative to each calibrated device will be made. Additional evaluations will document the acceptability of the M&TE item and the data obtained through usage. NCRs will be prepared to document any case of deficient data (That data obtained from devices that were nonconforming to accuracy requirements).

The individuals assigned responsibility for completion of these actions are Dennis Sorensen and James B. Harper of T&MSS. The anticipated completion date is May 29, 1992.

Part II. Certificates of Calibration

The procurement documents and the certificates of calibration for all devises used and for those devises received where use is anticipated will be reviewed to determine if corrective action is necessary. Supplemental information will be obtained to augment or correct deficient certificates.

The individual assigned responsibility for completion of these actions is Dennis Sorensen of T&MSS. The anticipated completion date is May 29, 1992.

3. Root Cause Determination

Part I Accuracy of Calibrating Device

The controlling procedure for specifying certificate of calibration requirements misstated the accuracy requirement for calibrating standards. It requested the accuracy of the calibrated item.

Part II Certificates of Calibration

The root cause of these deficiencies is lack of attention to detail during the technical and QA review of procurement documents, the receipt inspection process and the process for acceptance of calibration services. During each of these activities, the accountable reviewer should confirm that each required certificate of calibration item has been translated to applicable documentation.

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CORRECTIVE ACTION REQUEST (Continuation Page)

4. Corrective Action to Preclude Recurrence

Part I Accuracy of Calibrating Devices

The controlling procedures, SP 1.28, was modified by ICN 1 to revision 5 to ensure that the instructions are clear with respect to the accuracy requirement for calibrating standards. No further action is required.

Part II Certificates of Calibration

SP 1.28 will be reviewed and modified as appropriate to assure clarity of the applicability and contents of the certificate of calibration. Personnel will be retrained on the procedure. The individuals assigned this action are R.S. Bostian and J.B. Harper. This action will be complete by April 15, 1992.

A checklist is now used by QA personnel during the receipt inspection process to assure that documentation of adherence to calibration requirements is complete. No additional action is required.

Response Approved: _____ Date: 3/17/92
Responsible Manager

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CORRECTIVE ACTION REQUEST (Continuation Page)

CORRECTIVE ACTION RESPONSE TO CAR YM-92-020
3/11/92

Ammended Response
3/26/92

1. Remedial Action

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Part I. Accuracy of the Calibrating Device

ICN 1 to Revision 5 of SP 1.28 was issued on January 27, 1992 to require the vendor to submit to T&MSS the accuracy of the calibrating device. For each quality affecting calibration previously performed, the accuracy of the calibrating device will be compared to the accuracy of the equipment being calibrated to assure that the calibrating device has a greater accuracy.

James Harper and Dennis Sorensen of T&MSS are assigned the responsibility for completion of these actions. The completion date is May 29, 1992.

Part II. Certifications of Calibration

For each of the specific five M&TE items identified in part 6 of the CAR, the applicable certificate was evaluated by the T&MSS technical and QA inspection personnel against the information requirements. In some cases the alleged missing information was present on the certificate. In no case was all five items of information missing on all five cited certificates of calibration. Where information was actually missing, the information was located or actions are under way to make the certificate complete, e.g., the calibration service vendor will be requested to supply required information.

Three of the five devices cited on the CAR are non-quality affecting and, thus, no actions are required. However, these three devices (ID-09064, 01578, and 03353) were used in activities formerly classified as quality affecting. Since these same three devices were downgraded to QA/NA (See Grading Reports RFP1-A, RFP-2, RFP-3 and RFP-4) all resulting data is now designated as Non-Quality and will not be used in a quality affecting application.

Concerning the requirements, in some cases items j. and k. do not apply, i.e., item j. applies only when an instrument has multiple ranges of operation and k. is applicable only if the instrument is digital.

The information that follows is the current status of the completeness and corrective action for the five specific M&TE certificates of calibration

Ltr dtd 3/26/92 - L92-1673

CORRECTIVE ACTION REQUEST (Continuation Page)

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The individuals assigned responsibility for completion of these actions are Dennis Sorensen and James B. Harper of T&MSS. The anticipated completion date is May 29, 1992.

Part II. Certificates of Calibration

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3. Root Cause Determination

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CORRECTIVE ACTION REQUEST (Continuation Page)

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Part II Certificates of Calibration

SP 1.28 will be reviewed and modified as appropriate to assure clarity of the applicability and contents of the certificate of calibration. Personnel will be retrained on the procedure. The individuals assigned this action are R.S. Bostian and J.B. Harper. This action will be complete by May 29, 1992.

A checklist is now used by QA personnel during the receipt inspection process to assure that documentation of adherence to calibration requirements is complete. No additional action is required.

Management Approval D K Chandler DATE 3/27/92