



Department of Energy
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**EVALUATION OF RESPONSES TO CORRECTIVE ACTION REQUESTS (CAR) YM-92-064 AND
YM-92-065 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD)
AUDIT YMP-92-21 OF LAWRENCE LIVERMORE NATIONAL LABORATORY**

The YMQAD staff has evaluated the responses to CARs YM-92-064 and YM-92-065. The responses have been determined to be unsatisfactory based on the following:

YM-92-064 - As part of the Investigative Action, all instruments listed on the Master Status List within the last year will be reviewed to assure that there is documentary evidence of calibration. However, the finding identified an instrument without certificate of calibration since March 16, 1989. Adequate review of all instruments listed on the Master Status List since that date is required.

YM-92-065 - As part of the Investigative Action, the response based its acceptance on corrective action of CAR YM-92-064; therefore, this response cannot be accepted per the above explanation.

Amended responses are required to be submitted to this office within ten working days of the date of this letter. Send the original of your responses to YMQAD, Attention: Nita Brogan. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Mario R. Diaz at (702) 794-7974.

R. E. Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-285

Enclosure:
CAR YM-92-064 and YM-92-065

9210150091 921007
PDR WASTE
WM-11 PDR

YMP-5

ADD: Ken Hooks *ltr. Encl.*

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WM-11
NH03*

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

6 CAR NO.: YM-92-064
DATE: 8/21/92
SHEET: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document 033-YMP-QP-12.0		2 Related Report No. Audit 92-21	
3 Responsible Organization LLNL		4 Discussed With R. Hamati	
5 Requirement: 033-YMP-QP 12.0, Rev 2, CN 12.0-2-1 para 12.0.4 states in part "The Calibration Coordinator will enter M&TE on the Master Status Listing upon receipt of the required calibration records. The calibration certificate will provide a record of: as found, as left, unique M&TE identifier. The accuracy of standards used for calibration will be equal to or better than the instrumentation calibrated". 033-YMP-R-12, Rev 0, Para 2.6 states in part "calibration records identify, the calibration procedure (including revision) utilized to perform the calibration".			
6 Adverse Condition: Measuring and Test Equipment (M&TE) have been entered in the Master Status List without documented evidence of the calibration record. Additionally some M&TE calibration records do not contain information detailed in item 5 above. Examples are: o Omega/Type J Thermocouple ID# 8261-40-2 in shown as Master Status list dated Sept 23, 1991 as being calibrated on March 16, 1989. however, the pertinent certificate of calibration is missing from the QA Records package. o Stout Test Weights ID# 4935825, Stout Multimeter ID# 5067303, Stout Power Meter/Head ID# 4913045. Their certificates do not contain information described in item 5 above.			
9 Does a significant condition adverse to quality exist? Yes <u> </u> No <u>X</u> If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; 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: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
13 Recommended Actions: 1. For the conditions noted in block 6, assure calibration package contains required documentation and that calibration records reflect all required information. 2. Take action to: determine extent of condition, take action to preclude recurrence, and identify root cause.			
7 Initiator M. R. Diaz <i>Mario Diaz</i> Date <u>8-14-92</u>		14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>8/25/92</u>	
15 Response Accepted QAR Date		16 Response Accepted QADD Date	
17 Amended Response Accepted QAR Date		18 Amended Response Accepted QADD Date	
19 Corrective Actions Verified QAR Date		20 Closure Approved by: QADD Date	

ENCLOSURE

REV. 08/91

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CAR NO. YM-92-064
Date: 9/18/92
Page: 1 OF 2
QA

CORRECTIVE ACTION REQUEST (continuation sheet)

1. Corrective Action Response For CAR # YM-92-064

A. Remedial Action

Copies of required calibration records for the instruments identified during the audit and during the investigative action will be requested from the calibration source(s) and placed in appropriate records packages. Such documentation will include all required information.

B. Investigative Action

Investigation has already been conducted of the incident involving the Omega/Type J thermocouple calibration. It was found that this instrument was only used for non-quality affecting applications and had been calibrated as required on March 1989 and April 1991 (calibration sticker located on instrument). However, calibration records (other than sticker on instrument) were not located in records packages.

All instruments listed on the Master Status List within the last year will be reviewed to assure that there is documentary evidence of calibration.

An additional sample of instrument calibration records for instruments listed on the master list within the last year will be examined to determine the extent of the problem of incomplete information.

C. Root Cause Determination

The cause of the subject problem will be determined after completion of investigative and remedial action. Unnecessary procedure requirements and unclear direction will be identified as applicable.

D. Corrective Action to Preclude Recurrence

The QP requirements for calibration will be reviewed and revised as necessary to assure that 1) Only appropriate requirements for calibration certification are stated, 2) A distinction is made between requirements for quality affecting and non-quality affecting instruments, and 3) Requirements for instrument calibration and calibration documentation are clear.

Training will be conducted for affected project personnel after completion of the QP review and, as required, revision.

lta dtd 9/21/92 - LLYMP9209132

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CAR NO. YM-92-064
Date: 9/18/92
Page: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (continuation sheet)

2. Responsible individual and commitment date

- A. Affected TALs
- B. Wolfe/Hamati
- C. Wolfe/TALs
- D. Wolfe/Clarke

Commitment Date: 12/1/92

for: W. C. Clarke

3. Response Approved by: William G. Halsey Date: 9/18/92
TPO

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WASHINGTON, D.C.**

8 CAR NO.: YM-92-065
DATE: 8/21/92
SHEET: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document 033-YMP-QP-12.0		2 Related Report No. Audit 92-21	
3 Responsible Organization LLNL		4 Discussed With R. Hamati	
5 Requirement: 033-YMP-QP-12.0, Rev 2, CN 12:0-2-1, Para 12.0.4 states in part "Calibration frequency will be established consistent with the manufacturer's or designer's recommendations".			
6 Adverse Condition: Several M&TE were not calibrated as required by the manufacturer's or designer's recommendations. Examples are: <ul style="list-style-type: none"> o Omega/Type J Thermocouple ID# 8261-40-2 was due for calibration on March 16, 1990. However, several waivers were issued extending the due date until March 16, 1991 based on the instrument being used in an ongoing experiment but requiring to be recalibrated at the end of the experiment. The instrument was used until Feb 22, 1991 and no recalibration has been performed yet. o Thermocouple IDs 3979271, 3979325 and 4004538 has a due date for calibration of Nov 25, 1990. They were used until Jan 9, 1992 without being recalibrated since the above due date. 			
9 Does a significant condition adverse to quality exist? Yes <u> </u> No <u>X</u> If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; 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: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
13 Recommended Actions: 1. Perform the necessary calibration on the instruments reference in block 6. If any of the instruments are found out of calibration, note all uses of the instrument since last calibrations and require work to be redone using instruments that are in calibration. 2. Take action to determine: Extent of condition, action to preclude			
7 Initiator M. R. Diaz <i>Mario Diaz</i> Date <u>8-14-92</u>		14 Issuance Approved by: QADD <i>R. Hamati</i> Date <u>8/25/92</u>	
15 Response Accepted QAR Date		16 Response Accepted QADD Date	
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19 Corrective Actions Verified QAR Date		20 Closure Approved by: QADD Date	

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8 CAR NO.: YM-92-065
DATE: 8/21/92
SHEET: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

13 Recommended Action(s) (continued)
recurrence and root cause.

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. YM-92-065
Date: 9/18/92
Page: 1 OF 2
QA

CORRECTIVE ACTION REQUEST (continuation sheet)

1. Corrective Action Response For CAR # YM-92-065

A. Remedial Action

For instruments used on quality affecting activities only, as found during the investigative action: Determine the calibration frequency required by the experiment designer (Task Leader) if not in accordance with the manufacturer's recommendations. Calibrate those found to be used beyond their calibration frequency. Assess the adequacy of the actual calibrations performed to support the experiments when instrument calibration is found not to be in accordance with manufacturer's or experiment designer's requirements. Assess impact (if any) on the performance of quality affecting experiments. If it is determined that any instruments are 1) out of calibration during a quality affecting experiment, 2) their accuracy can not be determined, and 3) the out of calibration condition significantly impacts the experimental results, reports, publications, and data will be revised, if any. Experiments will not be repeated unless data is required for licensing and other experiments do not provide needed data validation.

B. Investigative Action

Investigation has already been conducted of the incident involving the Omega/Type J thermocouple 8261-40-2 calibration. It was found that this instrument was only used for non-quality affecting applications and had been calibrated as required on March 1989 and April 1991 (calibration sticker located on instrument). However, calibration records (other than sticker on instrument) were not located in records packages. See YM-92-64 for corrective action concerning calibration records.

Additional Investigation will be conducted as to the use of the Thermocouples 3979271, 3979325, and 4004538 to determine if they were used at all, were used on quality affecting or non quality affecting applications, and actual calibration dates.

All instruments that appear on the Master Status List within the last year will be reviewed for calibration frequency in the same manner.

C. Root Cause Determination

To be determined based on the investigative action.

See dtd 9/21/92 - LLYMP9209132

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CAR NO. YM-92-065
Date: 9/18/92
Page: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (continuation sheet)

D. Corrective Action to Preclude Recurrence

To be determined based on the investigative action.

The QP requirements for calibration will be reviewed and revised as necessary to assure that 1) A distinction is made between requirements for quality affecting and non-quality affecting instruments, and 2) the requirements for specifying calibration frequency and accuracy are clearly stated to indicate the following:

- Calibration requirements (accuracy, precision, sensitivity) are determined during the design of a scientific investigation.
- Calibration requirements are driven by the purpose of the scientific investigation.
- Calibration requirements are documented in the applicable activity plan.

Training will be conducted of affected project personnel after completion of the QP review and, as required, revision.

2. Responsible individual and commitment date

- A. Affected TALs
- B. Wolfe/Hamati
- C. Wolfe/TALs
- D. Wolfe/Clarke

Commitment Date: 12/1/92

For: *W. C. Clarke*

3. Response Approved by: *William C. Halsey* Date: 9/18/92
TPO

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Willis L. Clarke

-2-

cc w/encl:

~~K. R. Hooks~~, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
J. A. Blink, LLNL, Las Vegas, NV
D. W. Wolfe, LLNL, Livermore, CA
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