



Department of Energy

Washington, DC 20585

QA: L

AUG 27 1997

L. D. Foust, Technical Project Officer
for Yucca Mountain Site
Characterization Project
TRW Environmental Safety Systems, Inc.
1180 Town Center Drive, M/S 423
Las Vegas, NV 89134

EVALUATION OF RESPONSES TO DEFICIENCY REPORTS (DR) YM-97-D-044 THROUGH YM-97-D-046 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-019 OF TERRACON WESTERN CONSULTANTS

The OQA staff has completed its review of your responses, dated July 31, 1997, to DRs YM-97-D-044 through YM-97-D-046. The responses to DRs YM-97-D-044 and YM-97-D-045 have been determined to be satisfactory. Verification of completion of the corrective action on these two DRs will be performed after the effective date provided (September 1, 1997).

The review of DR YM-97-D-046 is unacceptable based on the following review comments:

- 1. Your response in Block 15, Extent of Condition: Recommended Action 1, states in part: "Terracon has submitted a revised Quality System Manual (QSM). It has been forwarded to OQA for review in accordance with Administrative Procedure 7.4Q..."
2. Your response in Block 15, Extent of Condition: Recommended Action 2, states in part: "The only procurement activity..."

NH33/1
WM-11
102.7

9709050049 970827
PDR WASTE
WM-11

PDR

040065



Printed with soy ink on recycled paper



ACCIDENTAL WASTE FROM PAPER

AUG 27 1997

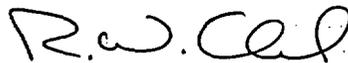
impact of the QARD requirements not covered on work performed by Terracon” Your response to this DR does not include the results of any re-review of the Terracon QSM revision that was required to be implemented on the work performed. Without this re-review, it cannot be determined that “Procurement” is the only QARD requirement not covered in Terracon’s QSM. Block 15, Extent of Condition: Recommended Action 1, states in part: “Terracon has submitted a revised Quality System Manual (QSM) . . . has been forwarded to OQA for review” This action is acceptable for preventing recurrence, but not for determining impact on work already performed.

3. Your response in Block 17, Action to Preclude Recurrence: Recommended Action 3, states in part: “Personnel currently involved with procurement activities are aware of the need to assure future procurements include all technical and quality requirements, necessary to meet the QARD” Please identify what actions were taken since the issue of this DR, to make them aware of this condition.

An amended response to DR YM-97-D-046 is required to be submitted to this office within ten working days of this letter. Please send the original of your amended response to Deborah G. Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, NV 89036-0307.

Any extension to these dates must be requested in writing, with appropriate justification, prior to the respective due date. Please send a copy of extension requests to Deborah Sult.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Lester W. Wagner at (702) 794-1304.



for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2163

Enclosure:
DRs YM-97-D-044 through
YM-97-D-046

L. D. Foust

-3-

AUG 27 1997

cc w/encl:

T. A. Wood, DOE/HQ (RW-55) FORS
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
D. S. Haas, M&O, Las Vegas, NV
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
L. W. Wagner, OQA/QATSS, Las Vegas, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV

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

8 Performance Report
 Deficiency Report

NO. YM-97-D-044

PAGE 1 OF 2

QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

Quality Systems Manual, Revised 1/4/97

2 Related Report No.

OQA-SA-97-019

3 Responsible Organization:

Terracon Western Consultants, Inc.

4 Discussed With:

R. Ludwig, W. Sturm

5 Requirement/Measurement Criteria:

Quality System Manual, Section II, B.1 states, "Each position within the company has a written job description in the company policy manual...All personnel are placed according to experience, education/training, certification, and performance."

6 Description of Condition:

Contrary to the above stated requirement, it was determined that a Level I Technician was performing duties outside the scope of his Position Description, i.e., performing compressive strength and shear tests rather than assisting a Level II Technician in the performance of these tests. It should be noted that this individual had been trained to the implementing standards and was qualified to perform the tests in question; however, his Position Description had not been modified to indicate that, in addition to the Level I tasks, he was also qualified to perform additional activities normally associated with a Level II Technician. Additionally, training records for another Level I Technician could not be located, although a checklist from a recently completed (02/19/97) Internal Quality System Review indicated that training/evaluation records were reviewed and updated as necessary.

7 Initiator

Michael Malone

Date 05/12/97

9 Is condition an isolated occurrence?

Yes

No

Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

1. Perform investigative action to determine the extent of deficiency and impact, if any, on the work performed.
2. Identify remedial action necessary to correct the deficiency.
3. Based on the results of the investigation, perform root cause determination, or provide justification if not required.
4. Determine and implement actions to prevent recurrence.

11 QA Review:

QAR *Michael Malone*

Date 5/14/97

12 Response Due Date

20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name Donald G. Horton

Signature *Donald G. Horton*

Date 5/29/97

22 Corrective Action Verified

QAR

Date

23 Closure Approved by: (N/A for PR)

AOQAM

Date

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

PR/DR NO. YM-97-D-044
PAGE 2 OF 2
QA:L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

Condition 1 A note-to-file explanation of the position description has been placed in the training file of Miguel Ambrosio. In addition, his ACI Concrete Strength Testing Certification has been received and placed in his file.

Condition 2 All Training Records have been returned to the appropriate file and files have been relocated in an administrative office.

15 Extent of Condition: (Not required for PR)

Condition 1 Item 1 - Level I Technician - Miguel Ambrosio
Item 2 - The position descriptions detailed in the Quality System Manual, Section 2, Appendix B are generic corporate descriptions utilized throughout all Terracon Offices. The requirements for various levels are guidelines to encourage employees to become skilled in performing numerous test procedures. Mr. Ambrosio has completed training and certification for some of the procedures required for Level II Status (Including Compressive Strength and Splitting Tensile Strength Testing). (CONTINUED)

16 Root Cause Determination: (Not required for PR)

Required Yes No

Condition 1&2 A root cause determination is not required in that the training records reviewed were acceptable for national accreditation which is the intent of the Quality System Manual.

17 Action to Preclude Recurrence: (Not required for PR)

Required Yes No

Condition 1 A policy statement will be added to the QSM Section 2, Appendix J.

Condition 2 Training Records will be updated to a current status as technicians increase their efficiency and assume duties in addition to those detailed in their position descriptions. Training records will be maintained in a more-controlled location.

18 Corrective Action Completion Due Date:

9/01/97

19 Response by: Ronald R. Ludwig

Initial

Amended

Date 7/31/97 Phone 597-9393

20 Response Accepted

QAR

Date 8/11/97

21 Response Accepted (N/A for PR):

AOQAM

Date 8/26/97

Exhibit AP-16.10.2

AUGUST 1/97 LV.EA.BRT. 08/97-008

CONTINUATION SHEET

YM-97-D-044

Item 15 (cont'd) Condition 1 Item 2

But has not completed training for all of the Level II Requirements.

Condition 1 Item 3

Other position descriptions in the Quality System Manual, Section 2, Appendix B are also generic corporate descriptions. It would not be unusual for employees to be documentably competent at specific tasks yet fail to satisfy all of the requirements for a level promotion.

Condition 2 Item 1

The Second Level I Technician was Eleazar Ambrosio.

Condition 2 Item 2

Training files for some personnel were misfiled at the time of the audit and have subsequently been located and stored in a more controlled location. Eleazar is assigned to the Soil and Aggregate Testing Laboratory and does not perform concrete tests as required by this purchase order. No training records had been generated for his file and to date no certifications have been achieved.

AMERICAN CONCRETE INSTITUTE

This is to certify that

Miguel M. Ambrosio

*has demonstrated knowledge and ability by passing
written and performance examinations covering:*

ASTM Standards: C 617 C 1231 C 39 C 78

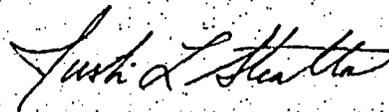
and is hereby recognized as an

ACI Concrete Strength Testing Technician

Exam Date: 04/26/1997

Expires: 04/26/2003

Examiner:



2481

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

8 Performance Report
 Deficiency Report
NO. YM-97-D-045
PAGE 1 OF 2
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
Terracon's Quality Systems Manual (QSM), Revised 1/4/96

2 Related Report No.
OQA-SA-97-019

3 Responsible Organization:
Terracon Western Consultants, Inc., Las Vegas Lab.

4 Discussed With:
Ron Ludwig, Bill Sturm

5 Requirement/Measurement Criteria:

1. QAM, Section III-A requires that each laboratory maintain a master equipment list for major equipment requiring calibration, verification, and checking.
2. QAM, Section III-B requires that each piece of equipment to be calibrated will have a completed data sheet for each calibration, verification, and check performed.
3. QAM, Section VI-B-2 requires whenever, during calibration or verification and checks, test equipment is found to be beyond acceptable limits, it will be red tagged and removed from service pending repair or disposal/replacement.

6 Description of Condition:

1. The Master Equipment Test List was found not to be current.
2. 1995, 1996 & 1997 calibration records for the Compression Machine Transducers (#1483, #1545, and #1611) and the Cure Room Temperature Chart Recorder #248095 were not available for review.
Note: Faxed copies of the calibration worksheets generated during the January 1997 calibration of the Transducers were obtained for review. These copies were provided by the National Calibration Services' (NCS) individual who performed the calibration.
3. While Terracon does remove equipment from service when it is found to be beyond acceptable limits, there were no "red tags" available for identifying out of acceptable limits equipment.

7 Initiator
Lester W. Wagner / Michael Malone Date 5/14/97

9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

- A. Perform investigative action to determine the extent of deficiencies and impact, if any, on work performed.
- B. Provide remedial actions necessary to correct the identified deficiencies.
- C. Provide indoctrination/orientation in affected areas to minimize the possibility of recurrence.

11 QA Review:
QAR [Signature] Date 5/14/97

12 Response Due Date
20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name Donald G. Horton Signature [Signature] Date 5/19/97

22 Corrective Action Verified
QAR Date

23 Closure Approved by: (N/A for PR)
AOQAM Date

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

PR/DR NO. YM-97-D-045
PAGE 2 OF 2
QA:L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

Condition 1 The Quality System Manual has been revised to present the equipment list as a sample form for a master list maintained in the laboratory supervisors office.

Condition 2 Misfiled calibration records have been located and filed in the correct locations.

Condition 3 Red tags have been purchased to be placed on 'out of calibration' equipment.

15 Extent of Condition: (Not required for PR)

Condition 1 The master equipment list located in the Quality System Manual used by the DOE Audit Team was not current in that the QSM had been last revised in November 1996. The current revised manual contains only a sample form that could be used to list laboratory equipment and this form is located in Section 2 Appendix F of the QSM. The Master Equipment list, filed in the accreditation file located in the laboratory supervisor's office, is in a current status.

Note: The current revised Quality System Manual used by Terracon/Las Vegas for accreditation (CONTINUED)

16 Root Cause Determination: (Not required for PR)

Required Yes No

Condition 1, 2, & 3 A root cause determination is not required for conditions 1, 2, & 3 for reasons detailed in Block 15.

17 Action to Preclude Recurrence: (Not required for PR)

Required Yes No

Condition 1 Reference remedial action (Block 14)

Condition 2 No Action Required

Condition 3 A "Red Tagging" system, as detailed in QSM Section 1, III.D has been implemented.

18 Corrective Action Completion Due Date:

9/01/97

19 Response by: Ronald R. Ludwig

Initial

Amended Date 7/31/97

Phone 597-9393

20 Response Accepted

QAR

Date

8/11/97

21 Response Accepted (N/A for PR):

AOQAM

Date

8/26/97

Exhibit AP-16.1Q.2

August 1, 1997 LV. EA. BRJ. 08/97-008

CONTINUATION SHEET

YM-97-D-045

Item 15 (cont'd) Condition 1

has been submitted to Kiewit/PB for review and approval.

Condition 2

The calibration records for the compression machine transducers were misfiled at the time of the audit and have been located and placed in the accreditation file located in the laboratory supervisors office. The cure room temperature chart recorder #248095 had not been calibrated prior to the DOE audit. The recorder is a relatively new unit and was scheduled for a calibration that occurred on 5/23/98 (Certificate of Calibration Attached).

Condition 3

At the time of the audit there was no equipment known to be out of calibration. Should a piece of equipment be found to be "out of calibration" the equipment would be either repaired or removed from service and locked in a secured storage area until repaired and recalibrated.



A-CAL ASSOCIATED CALIBRATION, INC.

4343 E. LA PALMA AVE., ANAHEIM, CA 92807 • 714/996-2042 • FAX: 714/996-7881

Certificate of Calibration

TERRACON CONSULTANTS WESTERN INC.
4343 SOUTH POLARIS AVENUE
LAS VEGAS, NV 89103

DATE: 5-23-97
INV.#: 2350
P.O.#: 24010
RECALL: 5-23-98
CAL. INTERVAL: 1 YEAR

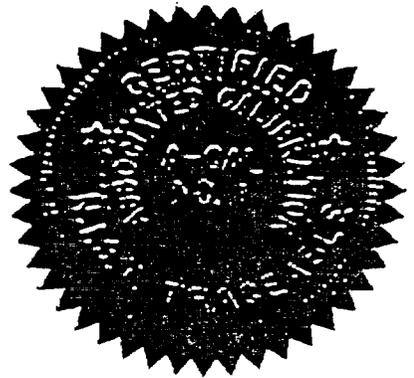
A-CAL/ASSOCIATED CALIBRATION certifies that the instruments listed meet or exceed all appropriate A.S.T.M. (American Society For Testing And Materials), published Military Specifications and Manufacturer Specifications. Preventative maintenance is done at the time of calibration.

A-CAL/ASSOCIATED CALIBRATION maintains "Calibration Systems Requirements" in compliance with MIL-STD-45662A and ISO 9000. The calibration standards accuracies are traceable to the National Institute of Standards and Technology, within limitations of the institute's calibration services, or have been derived from accepted values of National Physical Constants. Compliance is maintained to ISO10012-1 : 1992 (E) ANSI / NCSL Z540-1-1994.

MANUFACTURER:	DICKSON	PROCEDURE USED:	AMS2750 REV.C
INSTRUMENT:	TEMPERATURE CHART RECORDER	RATED ACCURACY:	±2°F SEE REVERSE
MODEL NUMBER:	DT4100FB7P3A	TOLERANCE AS FOUND:	IN <input checked="" type="checkbox"/> OUT <input type="checkbox"/>
SIZE RANGE:	0-100°F	ADJUSTMENTS MADE:	NO <input checked="" type="checkbox"/> YES <input type="checkbox"/>
SERIAL NUMBER:	248095	LOCATION:	CURING ROOM
IDENTIFICATION #:	NONE	TEMPERATURE:	73°F
CONDITION AS FOUND:	GOOD <input type="checkbox"/> FAIR <input checked="" type="checkbox"/> POOR <input type="checkbox"/> DAMAGED <input type="checkbox"/>		

STANDARDS USED:
THERMO ELECTRIC CALIBRATOR:
ID #ACS 099, SN #30980-6-3, Model #MICROMITE PLUS
3115300100, Calib.: 4-4-97, Due: 7-4-97, N.I.S.T.
#255923-256368-253458-256795-254366-251971-810165-810166-
813256-256419-251562-WWVB-256530-731/LA84.

Robert Hazelton
Technical Engineer
Robert Hazelton



THIS IS A RED STAMP

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

8 Performance Report
 Deficiency Report

NO. YM-97-D-046

PAGE 1 OF 2

QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

Kiewit/Parsons Brinckerhoff (Kiewit/PB) Management Control Procedure (MCP)-4.0, Procurement, Revision 15.

2 Related Report No.

OQA-SA-97-019

3 Responsible Organization:

Kiewit/PB

4 Discussed With:

Dave Haas

5 Requirement/Measurement Criteria:

MCP-4.0, Section 3.4.2.D.1. QA Program, states in part, "POs for items and services that are not considered commercial grade shall require the supplier to have a documented QA program that implements applicable QARD requirements or shall require the supplier to conduct some or all of its work under the Kiewit/PB QA program."

6 Description of Condition:

Kiewit/PB Purchase Order 19801090, Amendment 1, to Terracon, required all work to be performed in accordance with Terracon's Quality Systems Manual. The PO did not contain any requirements for Terracon to work under any portion of the Kiewit/PB QA program. Terracon's Quality Systems Manual, as submitted and approved by Kiewit/PB, does not contain any requirements for control of procurement activities (i.e., procurement documents to include technical and quality requirements, supplier qualification, etc.).

NOTE: The only procurement activity provided by Terracon for the work performed under the Kiewit/PB PO is for calibration services. Procurement of calibration services by Terracon is accomplished via a telecon to the local National Calibration Services Rep who performs the calibration. There are no technical and quality requirements invoked nor any evaluation of the suppliers' capabilities. The calibration supplier did provide a record of calibration with a NIST traceability number listed.

7 Initiator

Lester W. Wagner

Date 5/23/97

9 Is condition an isolated occurrence?

Yes

No

Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

1. Re-review Terracon's QSM in accordance with Kiewit/PB MCP-7.2, "Supplier Quality Evaluation and Approval," to identify and document the applicable QARD requirements not covered by the Terracon QSM.
2. Investigate to determine the impact of the QARD requirements not covered on work performed by Terracon on Kiewit/PB Purchase Order 19801090.
3. Assure future procurements include, as appropriate, technical and quality requirements not covered by the supplier's quality program but necessary to meet the QARD requirements for the type of work being performed.

11 QA Review:

QAR

Date 5/23/97

12 Response Due Date

20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name Donald G. Horton

Signature

Date 5/29/97

22 Corrective Action Verified

QAR

Date

23 Closure Approved by: (N/A for PR)

AOQAM

Date

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

PR/DR NO. YM-97-D046
PAGE 2 OF
QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

Recommended Action 2 - During the audit (as referenced in the Note in Block 6) the calibration services supplier provided a record of calibration with an NIST traceability number listed. Subsequently, the calibration was re-checked. The re-calibration certificates document a) equipment identification, b) the technical standards to which and by which the equipment was calibrated, c) traceability to NIST Standards, and d) that preventative maintenance was done at the time of calibration. This provides documentation of technical and quality requirements comparable to what would have been required if the appropriate wording had been included in the procurement documents. Hence, there was no impact resulting from the identified deficiency and no additional remedial action needs to be taken.

15 Extent of Condition: (Not required for PR)

Recommended Action 1 - Terracon has submitted a revised Quality System Manual (QSM). It has been forwarded to OQA for review per AP-7.4Q (Kiewit/PB's MCP-7.2 was deleted, effective 6/2/97). It will be reviewed for resolution of this deficiency.

Recommended Action 2 - As noted in Block 6, Description of Condition, "The only procurement activity provided by Terracon for the work performed under the Kiewit/PB PO is for calibration services....The calibration supplier did provide a record of calibration with a NIST traceability number listed." (See Remedial Action for impact)

There are currently no other POs with Terracon, nor are any currently planned.

16 Root Cause Determination: (Not required for PR) Required: Yes No

As identified in Block 15 for Recommended Action 2, the calibration services identified in this DR was the only procurement activity Terracon performed under this Kiewit/PB PO. Hence, the scope of the deficiency is limited to the condition identified herein. Furthermore, the cause is sufficiently clear that no root cause determination is required.

17 Action to Preclude Recurrence: (Not required for PR) Required: Yes No

PO 1980-1090 to Terracon has been cancelled. There are currently no other planned procurement activities with Terracon under PO 1980-1090, or any other PO.

Recommended Action 3 - Terracon will revise their QSM to address control of procurement activities. The new Terracon PO for calibration services (with a different vendor) has a reference to Terracon's QSM passing on the requirement that NIST traceability number be provided on the calibration reports.

Recommended Action 3 - Personnel currently involved with procurement activities are aware of the need to assure future procurements include all technical and quality requirements, necessary to meet the QARD requirements, which are not already covered by the supplier's quality program. In addition, an additional restriction will be placed on the QSL (using the AP-7.4Q procedure) preventing additional purchase orders to Terracon until these corrective actions are completed.

18 Corrective Action Completion Due Date:

09/01/97

19 Response by: R. L. Rixford, QAR, K/PB



Date 07/31/97

Phone 297-7570

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR)

DOQA

Date