



Department of Energy

Washington, DC 20585

QA: L

JUL 21 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 RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-051 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-022 OF ARI INDUSTRIES, INC.

The OQA staff has evaluated the response to DR YM-97-D-051. 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 Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Richard L. Maudlin at (702) 794-1302.

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1948

Enclosure:
DR YM-97-D-051

cc w/encl:

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WASHINGTON, D.C.**

8 ☐ Performance Report
☒ Deficiency Report

NO. YM-97-D-051

PAGE 1 OF 3
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

ARI Industries, Inc., Quality Assurance (QA) Manual, Rev. 01/08/97

2 Related Report No.

OQA-97-SA-022

3 Responsible Organization:

Sandia National Laboratories (SNL)/
ARI Industries, Inc.

4 Discussed With:

John Mulvey, Ken Hogue, Richard Guy

5 Requirement/Measurement Criteria:

ARI Industries, Inc. QA Manual, Section QM-11, Revision: Orig, states in part: "To assure the reliability of measurement and test results, all equipment used to demonstrate product conformance shall be controlled, adjusted, maintained, and calibrated. Key Elements:Traceability of calibrations to Nationally recognized standards...."

ARI Industries, Inc. QSP-11, Revision: Orig, Section F(2) states in part: "Traceability of measuring and test results to the equipment used, will be maintained."

6 Description of Condition:

Contrary to the above:

- A. Standards (working thermocouple standard and PRT working standards) used to perform calibrations of SNL Thermocouples could not be traced from the ARI Industries calibration standards to documentation demonstrating traceability to National Institute of Standards and Technology (NIST). Examples of SNL thermocouple calibrations evaluated include LESF-HD-83-WH-1-TC, LESF-HD-84-WH-2-TC and LESF-HD-127-WH-47-TC.

Continued on Page 3

7 Initiator

[Signature]

Date 05/28/97

9 Is condition an isolated occurrence?

☐ Yes ☒ No ☐ Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

- A. Determine the impact on quality due to the lack of documented traceability of calibrations documented to date. Identify all SNL thermocouples impacted by this lack of traceability.
- B. Identify the cause of the problem and actions necessary to prevent recurrence.

Continued on Page 3

11 QA Review:

QAR

[Signature]

Date 05/28/97

12 Response Due Date

20 working days from issuance

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

Printed Name D. G. Horton

Signature *[Signature]*

Date 6/3/97

22 Corrective Action Verified

QAR

Date

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

AQAM

Date

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☐ Performance Report
☒ Deficiency Report

NO. YM-97-D-051

PAGE 3 OF 3
QA: L

PR/DR CONTINUATION PAGE

6. Description of Condition: (Continued)

- B. Calibration data sheets documenting the calibrations of SNL thermocouples did not provide traceability to the unique standard used to perform the calibration and did not reference the procedure(s) used to perform the calibrations.

10. Recommended Action: (Continued)

- C. Evaluate the quality system procedures in place for traceability and make sure that necessary detail is provided to assure that traceability from the standard or item under calibration is fully traceable through a unique identification from the item to NIST or an acceptable alternate. Also, provide procedures which assure that during calibrations, the personnel performing the calibrations documents the unique standard(s) used on the data sheets and that the procedure and revision number used to perform the calibrations is documented.

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PR/DR NO. YM-97-0-051
PAGE ____ OF ____
QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See attached PR/DR continuation page

15 Extent of Condition: (Not required for PR)

See attached PR/DR continuation page

16 Root Cause Determination: (Not required for PR)

Required: ☐ Yes ☒ No

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

Required: ☐ Yes ☒ No

18 Corrective Action Completion Due Date:

8/1/97

19 Response by:

F. Joseph L. Schelling

Date *6/27/97*

Phone *505 818 0643*

20 Response Accepted

QAR

[Signature]

Date

6/16/97

21 Response Accepted (N/A for PR)

QAR

[Signature]

Date *7/21/97*

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NO. YM-97-D-051
PAGE _____ OF _____
QA: L

PR/DR CONTINUATION PAGE

Remedial Action (Block #14):

Prior to the shipment of any thermocouples to Sandia, the three working standards were re-calibrated and a verification check was performed on a random sample of 20 thermocouples (10 percent of sample size) at 50 and 450 degrees, Celsius. All test results were within the required temperature tolerances (see attached data sheet). Additionally, no data has been recorded using these thermocouples and they are not expected to be used until December. In the interim, the location of all the thermocouples are identified and the indeterminate status of the thermocouples has been noted in the scientific notebook, pending closure of this DR.

Extent of Condition (Block #15):

A review of ARI Industries, Inc. calibration process was conducted to determine the extent of impact of the cited condition adverse to quality. A discussion with Ken Hoge of ARI was also conducted to review the current calibration process and to discuss the corrective actions needed to address the DR. The process currently in place for calibration is as follows: ARI calibrates a primary thermocouple (ARI S/N 01-TS-002, NIST test #253123) and a primary SPRT (ARI S/N 100-PRT-11-001, NIST test #256928) that are NIST traceable. These two devices are then used to calibrate a set of working standards that are then used to perform the actual calibrations. The primary thermocouple was used to calibrate the working thermocouple standard (ARI S/N 02-TC-11-001) while the primary SPRT was used to calibrate the working Resistance Temperature Detectors (RTD) (ARI S/N 03-RTD-11-001 and ARI S/N 03-RTD-11-003). Once the working standards were calibrated they were used to calibrate the Sandia thermocouples at 50, 250, 450, and 700 degrees Celsius as required in SNL contract AU-5498.

As discussed in the DR (YM-97-D-051), the working standards were not properly identified in accordance with ARI Industries QA manual with the full ARI S/N, which could potentially lead to a loss of traceability to NIST. This was caused by an inadequate procedure and lack of training to the staff. Upon completing the calibration, the technician then finished completing the documentation. At that point, the technician would document the full serial number of the standards used, relying on his memory, notes, and familiarity with the process to know which standard was used for which calibration. It would be more appropriate, however, to fully identify the standards used at the time the measurement is actually being performed to minimize any possibility of confused the different standards, and the procedure will be revised to make this clear.

In the future, the working thermocouples will be appropriately identified with the full ASI unique serial number. The ARI procedure used to control calibrations for SNL will be revised accordingly, prior to the calibration of any additional SNL thermocouples (expected completion of 8/1/97) and to require that the data sheets used to document the calibration be completed during the calibration. This documentation will include the identification of the unique thermocouple used and the procedure and revision number used to perform the calibration. Training to this new procedure will be conducted and documented.