



Department of Energy
Washington, DC 20585

QA: L

NOV 12 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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF 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 verified the corrective action to DR YM-97-D-051 and determined the results to be satisfactory. As a result, the DR is considered closed.

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

R.W. Cal
for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0296

Enclosure:
DR YM-97-D-051

cc w/encl:
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RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

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 Deficiency Report
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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
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3 Responsible Organization: Sandia National Laboratories (SNL)/ ARI Industries, Inc.	4 Discussed With: John Mulvey, Ken Hogue, Richard Guy
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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 evaluted 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 <i>M. Smith</i> Date <u>05/28/97</u>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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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 <i>M. Smith</i> Date <u>05/28/97</u>	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA Manager Issuance Approval: (QAR for PR) Printed Name D. G. Horton	Signature <i>D. G. Horton</i> Date <u>6/3/97</u>
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22 Corrective Action Verified: QAR <i>M. Smith</i> Date <u>11/03/97</u>	23 Closure Approved by: (N/A for PR) AQOAM <i>R.W. Cal</i> Date <u>11/7/97</u>
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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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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 *505 848 0643*

20 Response Accepted

QAR *[Signature]*

Date

07/16/97

21 Response Accepted (N/A for PR)

QAR *[Signature]*

Date *7/21/97*

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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.

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8 Corrective Action Request
 Stop Work Order

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CA: 1

CAR/SWO CONTINUATION PAGE

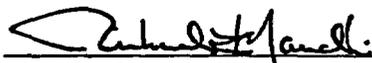
Verification of Corrective Action and Closure of Deficiency Report (DR) YM-97-D-051

On October 23, 1997, a follow-up verification at the ARI Industries, Inc. (ARI) facility in Addition, Illinois, was performed to verify implementation of corrective action to DR YM-97-D-051. The results of the follow-up verification indicate satisfactory implementation of corrective action as follows:

- A. A review of calibration documentation dated May 23, 1997, for the recalibration of the standards used by ARI to calibrate the Sandia National Laboratories (SNL) thermocouples was reviewed. The results of the recalibration indicated that the standards were in calibration. The physical secondary and working standards (02-TC-11-011, 03-RTD-11-003 and 03-RTD-11-001) were observed to be properly identified in accordance with ARI procedures.
- B. Reviewed calibration documentation related to the random sample of 20 thermocouples that were retested after recalibration of the standards referenced in item A above. The results revealed that the SNL thermocouples were in calibration.
- C. The ARI calibration procedure 2A-04, Revision 0, dated July 11, 1997, was reviewed and found to address requirements for Data Reporting. A sample of the completed SNL thermocouple calibration documentation (dated May 5, 1997, and May 12, 1997) was reviewed and found to reference the calibration procedures used and the revision level. Also, reviewed the Individual Training Sheet for the training of the calibration inspector dated July 18, 1997, to the revised calibration procedure 2A-04, Revision 0.

Since ARI's procedures do not require inclusion of the reference to the calibration/method used and the revision level, future procurements need to specify this requirement along with other Yucca Mountain Project unique requirements that are not necessarily accepted practices. It was pointed out by ARI representatives that they are working towards compliance with ANSI NCSL Z-540-1-1994 and, as such, will be including this requirement for reference to procedures used in calibrations in upcoming revisions to their procedures.

Based on the response provided on June 27, 1997, and the above verification results, this DR is considered closed.



Richard L. Maudlin

11-03-97

Date