

Department of Energy

Washington, DC 20585

OCT 1 7 1997

QA: L

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

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) LVMO-98-C-001 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-031 OF SLOPE INDICATOR COMPANY (SINCO)

Enclosed is CAR LVMO-98-C-001 generated as a result of OQA Supplier Audit OQA-SA-97-031.

Based on the results of the audit and the issuance of Corrective Action Request LVMO-98-C-001, a restriction has been placed on the Qualified Suppliers List to prohibit the use of SINCO until resolution and closure of this CAR.

Please provide a response to this deficiency that meets the applicable requirements of Administrative Procedure 16.2Q, Corrective Action and Stop Work. Send the original of your response to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307. Response to the CAR is due 20 working days from the date of this letter. Any extension to due date must be requested in writing, with appropriate justification, prior to the due date.

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

OQA:JB-0080

Enclosure: CAR LVMO-98-C-001

Donald G. Horton, Director Office of Quality Assurance

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cc w/encl:

- L. H. Barrett, DOE/HQ (RW-1) FORS
- T. A. Wood, DOE/HQ (RW-55) FORS
- J. O. Thoma, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- B. R. Justice, M&O, Las Vegas, NV
- R. A. Morgan, M&O, Las Vegas, NV
- J. A. Canepa, M&O/LANL, Los Alamos, NM
- L. R. Hayes, M&O, Las Vegas, NV
- F. J. Schelling, M&O/SNL, Albuquerque, NM, M/S 1325
- S. A. Orell, M&O/SNL, Las Vegas, NV
- J. F. Graff, OQA/SNL, Albuquerque, NM, M/S 1325

cc w/o encl:

- W. L. Belke, NRC, Las Vegas, NV
- R. L. Maudlin, OQA/QATSS, Las Vegas, NV
- D. G. Sult, OQA/QATSS, Las Vegas, NV
- J. R. Dyer, DOE/YMSCO, Las Vegas, NV
- R. W. Clark, DOE/OQA, Las Vegas, NV

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

CAR NO. <u>LVMO-98-</u>	C-001
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CORRECTIVE ACTION REQUEST				
1 Controlling Document: 2 Related Re			oort No.	
			97-031	
SINCO Quality Assurance (QA) Manual dated July 1983		•		
3 Responsible Organization:	3 Responsible Organization: 4 Discussed With:			
Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) / Sandia National Laboratories (SNL) / Slope Indicator Company (SINCO)	Randy Lohman, SINCO; Brad Boisen, SINCO; Karen Smith, SINCO; James Graff, OQA/SNL; Joe Schelling, SNL.			
5 Requirement:			,	
OCRWM QARD, Section 4.0, Subsection 4.2.1, states in part: "Procurement documents issued by each Affected Organization shall include the following provisions (C1) a requirement for the supplier to have a documented Quality Assurance (QA) Program that implements the applicable Quality Assurance Requirements and Description, (QARD) requirements prior to the initiation of work"				
OCRWM QARD, Section 5.0, Subsection 5.2.2 (D), states in part: "Implementing procedures shall include the following information (D) Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished."				
(Continued on page 3)	·			
6 Description of Condition:				
A. The Sandia National Laboratories (SNL) Purchase Order (PO) AU-5501, dated 06/23/97, issued to SINCO for the calibration of the Goodman Jack, Serial No. 8715, did not include quality assurance requirements.				
B. SNL Procurement Procedure QAIP 4-1, Revision 8, does not describe the process for inclusion of quality requirements into SNL POs and how these requirements are verified.				
C. As a result of the lack of QA requirements being specified in the SNL PO AU-5501, the audit of SINCO revealed that SINCO did not implement an effective quality program for SNL PO AU-5501. Examples to support the lack of implementation are as follows:				
(Continued on pages 3 & 4)				
7 Initiator tubul Handle	9 Does a Stop Work condition exist?			
Richard L. Maudlin Date /06/97	Yes No X; If Yes, Attack			
10 Recommended Actions:				
A. Take immediate action to determine how many SNL POs have been issued to suppliers without inclusion of quality requirements. Evaluate the process being implemented by the SNL purchasing group to determine what controls are in place to assure that technical and quality requirements contained within the SNL purchase requisition are included in the SNL purchasing document issued to suppliers.				
(Continued on page 4)				
11 QA Review:	12 Response Due Date:			
Date 106/97	20 Working Days From Issua	nce		
13 Affected Organization QA Manager Issuance Approval: Printed Name D 6 Hoctor Signature Date James Blaylink for 10/15/97				

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CORI	RECTIVE ACTION REQUEST RESPONSE	
14 Remedial Actions:		
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15 Extent of Condition and Impact:		
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16 Root Cause Determination prepared in acc 17 Action to Preclude Recurrence:	ordance with AP-16.4Q is attached.	
17 Action to Precide Recurrence:		
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18 Corrective Action Completion Due Date:	19 Response by:	
	Date	Phone
20 Response Accepted	21 Response Accepted	
QAR Date	DOQA	Date

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⁶ ☑ Corrective Action Request			
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5 Requirement: (Continued)

SINCO QA Manual, Section 1.2, states in part: "Quality Assurance activities are governed by procedures contained in Slope Indicator Company's QA Manual."

SINCO QA Manual, Section 2.2.2, states in part: "The QC Manager (QAM) is appointed by, and reports directly to, the President." Section 2.3 states: "The formal quality assurance organization is depicted below"

SINCO QA Manual, Section 2.2.3, states in part: "The Quality Assurance Review Committee (QARC) consists of key Quality Assurance personnel selected by the President"

SINCO QA Manual, Sections 3.4.1 (B1a) and 3.4.1 (B1b), state in part: "The QAM is responsible for issuing copies of the Quality Assurance Manual to appropriate Slope Indicator employees. All copies of the QA Manual are numbered for accountability. The QAM maintains a record of all manual holders."

SINCO QA Manual, Section 3.4.2 (B3), states in part: "Control and handling of technical procedures . . . are governed by specific procedures contained in the Quality Control Manual."

SINCO QA Manual, Section 3.5.4 (B1), states in part: "Measuring and test equipment is regularly calibrated."

SINCO QA Manual, Sections 3.5.5 (B), 3.5.6 (B2), and 3.5.6 (B6), state in part: "A nonconformance will arise automatically from the failure to correct a deficiency within the schedule prescribed in an audit . . . or review. The individual identifying the nonconformance in conjunction with a specific item, tags the item 'non-conforming' or 'Out of Calibration/Out of Service' and notifies the appropriate Line Manager and QAM. The QAM is responsible for documenting all nonconformances and corrective actions in a Corrective Action Status Log."

SINCO QA Manual, Section 3.5.5 (B1), states in part: "For internal and Presidential audits, audit checklists are prepared by the QAM The auditor . . . shall prepare an audit report that documents findings, deficiencies, nonconformances

6 Description of Condition: (Continued)

- 1. There is no QA Manager position in the current organizational structure, dated 09/96, as defined in the SINCO QA Manual dated July 1983. The organizational chart currently in the QA Manual is not up to date.
- 2. A Quality Assurance Review Committee as appointed by the President does not exist.
- 3. There are no procedures to describe requirements for the training and qualification of personnel. Presently, all training is primarily focused on health and safety and is informal. Any training provided is not being documented.
- 4. There are no procedures which describe requirements for the selection, qualification, and procurement of subtier supplier calibration services. SINCO is using 2 subtier suppliers for the calibration of the standards used to calibrate the Goodman Jack being used by SNL. A review of one SINCO procurement document (1274T dated 05/08/96), issued for the calibration of standards used for SNL calibration, did not provide evidence of the inclusion of technical and QA requirements.
- 5. The Quality Control Manual which is to contain procedures on the control and handling of technical procedures for calibration does not exist.

Exhibit AP-16.2Q3

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- 6. There is no documented evidence to support control and issue of the SINCO QA Manual and supporting implementing procedures.
- 7. SINCO standards (Lufkin Micrometer, Serial #1914, Starret Dial Indicator, Serial #11410, and Mitutoyo Dial Indicator, Serial #017441) used to calibrate the Goodman Jack for SNL under SNL PO AU-5501 were past due for calibration when used on July 8, 1997. Calibration of all three standards were due for recalibration on 05/10/97, however, were not recalibrated until 08/22/97 and 08/27/97.
- 8. Nonconformances are not being formally documented. Deficiencies are discussed verbally and corrected. Subsequently, no Nonconformance Status Log has been generated.
- There is no documented evidence that internal audits are being performed and documented in reports as required.

10 Recommended Actions: (Continued)

- B. Evaluate the SNL procedure for procurement and revise accordingly to include a detailed description of the process in the preparation, review, and approval of POs and what measures are taken to assure the inclusion of accepted technical and quality requirements.
- C. Take immediate action to determine the impact on the previous calibrations performed by SINCO in the absence of implementation of an approved quality program.
- D. Take immediate action to evaluate the impact on the calibration of the Goodman Jack using standards which were past due for recalibration.
- E Take immediate action to either bring SINCO into compliance with an approved quality program or have the unit calibrated by other approved suppliers.
- F. Take immediate action to place a restriction on the use of SINCO until all of the above conditions have been satisfactorily resolved and a follow-up verification has been performed on SINCO to determine satisfactory compliance with its accepted QA program.
- G. Re-evaluate the acceptability of SINCO's QA Manual to determine compliance with the applicable requirements of the OCRWM QARD for the intended scope of work.
- H. CRWMS M&O and SNL identify all previous procurements related to quality affecting work with SINCO and perform an evaluation to determine what impact the above deficiencies had on that work.
- 1. CRWMS M&O and SNL provide a detailed root cause in accordance with AP 16.4Q analysis as to why the conditions adverse to quality as noted in Block 6 occurred.

Exhibit AP-16.2Q4

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