Department of Energy

Washington, DC 20585

QA: L

APR 08 1998

D. R. Wilkins, 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) LVMO-98-D-038 RESULTING FROM THE OFFICE OF QUALITY ASSURANCE (OQA) AUDIT OQA-SA-98-005 OF GEOKON, INC.

The OQA staff has evaluated the response to DR LVMO-98-D-038. The response has been determined satisfactory with the understanding that Geokon Position Descriptions are not guidelines, but are the basis for accepted minimum requirements for the qualification of calibration technicians. All Geokon personnel performing calibrations for the Yucca Mountain Site Characterization Project will be expected to have documentation on file which supports the minimum requirements as stated in the Geokon Position Descriptions.

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 request to Deborah G. Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

Please be reminded that all future responses are to be signed by the responsible individual, who has the management responsibility for the process or activity that is the subject of corrective action, in accordance with the February 27, 1998, Robert W. Clark letter.

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

R.W. Clark

for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1382

Enclosure:
DR LVMO-98-D-038

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cc w/encl:
T. A. Wood, DOE/HQ (RW-55) FORS
S. L. Wastler, NRC, Rockville, MD
S. W. Zimmerman, NWPO, Carson City, NV
R. L. Strickler, M&O, Vienna, VA
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV
F. J. Schelling, M&O/SNL, Albuquerque, NM, M/S 1325
S. A. Orrell, M&O/SNL, Las Vegas, NV
J. J. Danneels, 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
R. W. Clark, DOE/OQA, Las Vegas, NV

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

8 ☐ Performance Report
☑ Deficiency Report

NO. LVMO-98-D-038

PAGE 1 OF 3

QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
Geokon Quality Assurance (QA) Manual, Revision 08/07/97

2 Related Report No.
OQA-SA-98-005

3 Responsible Organization:
CRWMS M&O/Geokon, Inc.

4 Discussed With:
Marty Gibson

5 Requirement/Measurement Criteria:

A. QA Manual, Section 1.1, states in part, "All employees are required to read and understand Geokon's Quality Policy and Manual."

B. QA Manual, Section 15.0, states in part, "It is the company's policy to hire and/or to ensure that all personnel are suitably educated, professionally qualified or experienced, or suitably skilled or experienced to fulfill responsibilities of the position that they occupy or are hired for."

Continued on Page 3

6 Description of Condition:

A. No objective evidence could be provided to support that Geokon's employees have read and understand the Geokon Quality Policy and Manual.

B. No objective evidence could be provided to reflect that personnel performing the calibrations of ambient/low temperature MPBXs and SPBXs are qualified to fulfill the responsibilities and position they occupy.

Continued on Page 3

7 Initiator Richard L. Maudlin Date 02/04/98

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

10 Recommended Actions: (Not required for PR)

A. Take the necessary action to have all Geokon personnel read and understand the Geokon Quality Policy and Manual. Document this training. As an alternative, consider development of a training class which summarizes the QA program and indoctrinate all personnel. Document this training. Revise the QA Manual accordingly.

B. Take immediate action to train and qualify personnel, if not presently qualified, to perform calibrations of the MPBX and SPBX. Assure that documented qualifications satisfy minimum requirement as defined in the Position Description for the assigned position that the individual occupies.

Continued on Page 3

11 QA Review: Richard L. Maudlin
QAR Richard L. Maudlin Date 02/04/98

12 Response Due Date
20 days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)
Printed Name Catherine Hampton Signature Catherine Hampton Date 2/11/98

22 Corrective Actions Verified
QAR Date

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

Exhibit AP-16.1Q.1

ENCLOSURE Rev. 06/02/97

PR/DR NO. LVMO-98-D-038
PAGE 2 OF 4
FJS 3/6/98 QA: L

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

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See continuation page

15 Extent of Condition: (Not required for PR)

See 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:	19 Response by:
4/30/98	F.J. Schelling Date 3/6/98 Phone (505) 848-0693

20 Response Accepted	21 Response Accepted (N/A for PR)
QAR Date	DOQA Date

Exhibit AP-16.10.2 Rev. 06/02/97

3/10/98 Schelling to Horton

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PR/DR CONTINUATION PAGE

5 Requirement/Measurement Criteria: (Continued)

C. Quality Assurance Operating Procedure (QAOP) 430, Revision A, Section 6.2.10, states in part: "The document owner will assign a sequential DCR number from the DCR Logbook using the next available number, utilizing the last two digits of the calendar year .... "

D. QA Manual, Section 10.0, states in part, "The company operates a program that controls, calibrates, and maintains M&TE which can effect product quality, in compliance with the United States of America, Department of Defense, MIL-STD-45662A." MIL-STD-45662A, Section 5.9, Records, states in part, "... The records shall include an individual record of calibration or other means of control for each item of M&TE and measurement standard, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration procedures used, calibration results, and calibration actions taken."

E. QA Manual, Section 14.0, states in part, "The company performs planned and documented Internal QA audits to verify compliance with the QA Program and Quality System ... Normal time periods for a complete program audit are not to exceed one year."

6 Description of Condition: (Continued)

C. To date, Geokon has not instituted a DCR Logbook for tracking changes to documents other than drawings or sketches.

D. QAOP 1100, Revision: Initial, does not address requirements for the contents of Certificates of Calibration or calibration data when documenting internal Geokon calibrations.

E. To date, no documented evidence could be provided to reflect a complete program audit of the Geokon QA Program has been performed.

10 Recommended Actions: (Continued)

C. Take action to develop a DCR Logbook and implement this log in tracking changes to documents other than drawings and sketches. An alternative may be to just use the Engineering Change Notice system for documenting all changes to all documents, including procedures.

D. Revise QAOP 1100 to address content of Certificates of Calibration or calibration data, which consist of MIL-STD-45662A or ANSI/NCSL Z540-1, 1994.

E. Implement your documented audit plan to assure that the entire QA Program is audited in FY98.

PR/DR CONTINUATION PAGE

14 Remedial Action (Continued)

1. A revision to the Geokon Quality Policy and Manual is being processed to replace the "read and understand" requirement with new employee training, which is implemented by QAOP1800. The revised manual is expected to be released by mid-April 1998. A training plan was prepared and all employees hired since June, 1996 were trained to it, as documented by training records.
2. A position description has been developed to establish minimum qualifications for any new hires for this type of work and documentation of calibration personnel being trained and qualified to perform the task is maintained. At the present time, an extensive "hands-on" training program has been completed by the individual calibrating vibrating wire transducers for YMP SPBX and MPBX instrumentation. This individual was hired prior to the establishment of qualifications for new hires, but has considerable experience in performing this work and is considered qualified for the position.
3. QAOP430 is being revised to eliminate the DCR Logbook and document changes using the Engineering Change Notice system. This revision should be completed by mid-April 1998.
4. QAOP1100 has been revised to reflect the calibration documentation requirements and is presently in review for an expected release by mid-April 1998.
5. The documented audit plan is being implemented and is being performed as scheduled. To date, one internal audit has been done and is being closed, and two are scheduled to be performed in February, 1998.

15 Extent of Condition (Continued)

1. The draft Geokon Quality Policy and Manual which contained the "read and understand" requirement has been replaced by one that requires personnel to be aware of and work to the quality program. An implementing document, QAOP 1800, has been released which implements training and includes using the Quality Manual as a guide.
2. The qualification and training status of the four technicians was evaluated, and it has been determined that these individuals are adequately qualified on the basis of their experience and/or education, and trained for their assignments. The qualifications of the individual performing the YMP calibrations, for example, include a Bachelor degree, ten years of related experience, and several years of on-the-job training and experience in calibration. The Job descriptions maintained by the Geokon Human Resources organization are used as a guide for posting openings, but should not be interpreted as minimum standards to perform the work.
3. It was determined that an Engineering Change Notice (ECN) is the standard practice at Geokon for tracking document changes. QAOP 430 is therefore being revised to replace the DCR Log with ECNs.
4. Geokon is in the process of finalizing their implementation of an ANSI Z540 program. With respect to the content of calibration certificates, their intention is to solicit feedback on content requirements from known customers and develop an updated standard certificate for the purposes of efficiency and cost savings.
5. An investigation showed that the lack of internal audits also results from Geokon being in the final stages of implementing the ANSI Z 540 program; audit procedures have been written, audit personnel qualified, and the first program audit is currently in process.

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

8 ☐ Performance Report
☑ Deficiency Report

NO. LVMO-98-D-038

PAGE 1 OF 4

FYS 3/6/98 QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:	2 Related Report No.
Geokon Quality Assurance (QA) Manual, Revision 08/07/97	OQA-SA-98-005

3 Responsible Organization:	4 Discussed With:
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Continued on Page 3

7 Initiator	8 Is condition an isolated occurrence?
Richard L. Maudlin Date 02/04/98	☐ Yes ☐ No ☑ Unknown; Must be Yes if PR

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Continued on Page 3

11 QA Review:	12 Response Due Date
QAR Richard L. Maudlin Date 02/04/98	20 days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)

Printed Name Catherine Hampton Signature Catherine Hampton Date 2/11/98

22 Corrective Actions Verified	23 Closure Approved by: (N/A for PR)
QAR Date	OQA Date

Enclosure

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

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See continuation page

15 Extent of Condition: (Not required for PR)

See 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:	19 Response by:
4/30/98	F.J. Schelly Date 3/6/98 Phone (505) 848-0693

20 Response Accepted	21 Response Accepted (N/A for PR)
DAR [signature] Date 04/07/98	DOQA R.W. Cole Date 4/7/98

PR/DR CONTINUATION PAGE

5 Requirement/Measurement Criteria: (Continued)

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