



**Department of Energy**

Washington, DC 20585

FEB 04 1997

QA: L

R. W. Craig, Technical Project Officer  
for Yucca Mountain Site  
Characterization Project  
U.S. Geological Survey  
1261 Town Center Drive  
Building 4, Room 423, M/S 423  
Las Vegas, NV 89134

**EVALUATION OF SUPPLEMENTAL RESPONSE TO DEFICIENCY REPORT (DR)  
YM-96-D-058 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER  
AUDIT OQA-SA-96-016 OF SETRA SYSTEMS, INC.**

The OQA staff has evaluated the supplemental response to DR YM-96-D-058. The supplemental 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 that date. Please send a copy of extension requests to Deborah Sult, OQA/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

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-0820

Enclosure:  
DR YM-96-D-058

cc w/encl:  
J. O. Thoma, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
T. H. Chaney, USGS, Denver, CO  
Records Processing Center

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

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RADIOACTIVE WASTE MANAGEMENT  
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Setra Systems, Inc. QA Manual, Rev. 1/18/93; M&TE Calibration System, Rev. 12/4/93; QARD/RW-0333P, Revision 5		2 Related Report No. OQA-SA-96-016	
3 Responsible Organization: Setra Systems / U.S. Geological Survey		4 Discussed With: Gene Zinoni	
5 Requirement/Measurement Criteria: A. QA Manual, Section 6.3, states in part: "Personnel performing operations that required certification by the government...., or customer shall be properly trained according to Setra Systems departmental procedures and manuals." B. QA Manual, Section 4.2.1, states in part: "Subcontracts and purchase orders shall include or supply quality requirements." C. M&TE Calibration System Manual, Section 10.0, states in part: "Upon return of the equipment, the Quality Assurance Department will review the information and initial and date the Certificate or report if acceptable." D. QARD, Section 5.0, Subsection 5.2.2 states in part: "Implementing documents shall include the following... Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished."			
6 Description of Condition: Contrary to the above: A. There was no documented evidence of personnel qualification and training for the two individuals performing USGS calibrations. B. Setra Systems P.O. 4992 to DH Instruments did not include quality requirements (i.e., reference to having a calibration program which meets MIL-STD-45662A). C. There was no objective evidence that the QA department had reviewed supplier calibration documentation for acceptance. D. There is no formal procedural process for the review of incoming P.O.s/contracts to assure that all customer QA requirements are addressed by Setra Systems (i.e., USGS P.O. 1434-CR-SA-00156 was received by Setra Systems with customer special QA requirements; however, these requirements were not included on any Setra documentation.			
7 Initiator Richard L. Maudlin Date 5/07/96		9 QA Review QAR [Signature] Date 5/07/96	
10 Response Due Date 20 Working Days From Issuance		11 QA Issuance Approval QAR (PR)/AOQAM (DR) Date	
12 Remedial Actions			
13 Remedial Actions Response By N/A Date		14 Remedial Action Due Date N/A Date	
15 Remedial Action Response Acceptance QAR N/A Date		16 PR Verification /Closure QAR N/A Date	

ENCLOSURE

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**17 Recommended Actions:**

- A. Develop procedures and a system for documenting personnel training and qualification. Implement requirements.
- B. Determine the impact of QA requirements not being incorporated into the PO for DH Instruments. Reinstruct personnel responsible for the preparation and review of POs about assuring incorporation of appropriate QA requirements.
- C. Review all affected supplier calibration documentation and evaluate for affect on quality. Take the necessary action to review all applicable supplier calibration documentation and document acceptance. Reinstruct personnel on the requirements to perform this review.
- D. Develop a procedural process for the review of POs for special customer requirements (i.e., QA program requirements). Take the necessary action to review previous USGS POs for any and all quality requirements. Determine impact of any actions taken relative to implementation of USGS QA requirements.

**18 Investigative Actions:**

**SEE ATTACHED**

**19 Root Cause Determination**

N/A

**20 Action to Preclude Recurrence:**

Setra's QA Manual will be revised.

<b>21 Response By:</b> A. E. Lykins <i>[Signature]</i> Date <u>7/29/96</u>		<b>22 Corrective Action Completion Due Date</b> September 27, 1996	
<b>23 Response Accepted</b> QAR <u>N/A</u> Date		<b>24 Response Accepted</b> AOQAM <u>N/A</u> Date	
<b>25 Amended Response Accepted</b> QAR <u>[Signature]</u> <u>10/3/96</u> Date <u>09/09/96</u>		<b>26 Amended Response Accepted</b> AOQAM <u>[Signature]</u> Date <u>10/10/96</u>	
<b>27 Corrective Action Verified:</b> QAR Date		<b>28 Closure Approved by</b> AOQAM Date	

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Block 5, Requirement/Measurement Criteria, continued:

- E. QA Manual, Section 5.5.4, states in part: "Measuring standards shall be labeled to indicate the date of the last calibration, by whom it was calibrated, and when the next calibration is due."
- F. QA Manual, Section 6.1, states in part: "Prompt corrective action shall be taken to correct all conditions which cause nonconformances..."
- G. QARD, Section 17.0, Subsection 17.2.11, states in part: "QA records shall be temporarily stored in a container or facility with a fire rating of 1-hour or dual storage shall be provided.
- H. QA Manual, Section 2.2, states in part: "Setra Systems documentation...shall include...periodic review and/or audit of QA systems and procedures." Also Setra M&TE Calibration System Manual, Section 2.0, states in part: "The Quality Manager shall ensure that the calibration system conforms to the objectives described in this manual. This shall be done annually, through an independent audit or an internal audit conducted by the QA Manager or his designee."

Block 6, Description of Condition, continued:

- E. The Deadweight Tester used to calibrate USGS barometers did not have a calibration sticker affixed to the equipment.
- F. Setra Systems, "Calibration Failure Report," for Setra instrument 23911D00 identified corrective action to reduce the calibration interval from 6 months to 3 months for 2 calibrations, and if the calibrations were acceptable, return the calibration to 6 months. Contrary to the stated corrective action, the instrument only received one 3 month calibration and then was returned to a 6 month interval.
- G. Supplier calibration records for standards used by Setra to calibrate USGS barometers is not being temporarily stored in a 1-hour fire rated cabinet or dual storage.
- H. No objective evidence of internal audit reports could be provided to support annual or periodic audits of Setra's system.

Block 17, Recommended Actions, continued:

- E. If placing the calibration sticker on the physical item is not practical, revise the QA Manual and M&TE Calibration System Manual to allow traceability of documentation to the specific item in lieu of labeling item(s).
- F. Sample other Failure Reports to determine if the stated corrective action has been appropriately implemented.
- G. Establish a system for the temporary storage of records which relate to the calibration performed for USGS. The system shall be that QA records are stored in a 1-hour fire rated file cabinet or dual storage. An alternative is that USGS request all QA records to be sent to them for safekeeping.
- H. Acquire copies of previous audit reports of Setra's calibration program. Assure that future audit reports are appropriately maintained to demonstrate evidence of annual/periodic audits as described by the QA program manuals.

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**Response to YMQAD-96-D058**

**Block 18:** In telephone conversations on July 9, and July 24, with the QA Coordinator of Setra Systems, Setra committed to respond to and correct all deficiencies listed in Block 6. For those conditions where objective evidence is required, Setra will provide additional documentation. For the conditions that require a change in process, Setra plans to revise portions of their QA Manual. It is anticipated that this will be a lengthy task; therefore, Setra will not forward a written response to the USGS until the end of August, 1996. The USGS will provide an amended response after the receipt of the Setra response.

In reference to Condition D, the procurement document passed on the requirement that calibrations shall be done to documented procedures. The QARD cited is inappropriate in this case as the reviews were done by USGS.

In reference to Condition G, this is a QARD requirement and not a Setra QA requirement. The calibration documentation that USGS is concerned with is forwarded to USGS when instruments are calibrated. It is the USGS's understanding that the supplier is required to maintain their internal QA records in accordance with their procedures.

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**Amended Response to YMQAD-96-D058**

The Setra QA Manager has an ISO-9000 Gap analysis scheduled for 11/01/96. The results of that analysis will determine the specific changes to be made to the Setra QA Manual and how the deficiencies will be addressed. These determinations will be made and a completion date set by 12/01/96. The USGS will provide an amended response by 12/15/96.

Submitted by: \_\_\_\_\_

*T. H. Chaney*  
T. H. Chaney, QA Manager - YMP-USGS

Date: \_\_\_\_\_

*9/19/96*

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AMENDED RESPONSE - YMQAD-96-058

SETRA is in the process of evaluating whether or not they want to try for ISO-9000 certification. They expect to complete the evaluation and notify the USGS by Dec.1,1996. The extent of changes to their QA program will depend on whether they decide to go for the ISO-9000 certification. The specifics of how several of the deficiencies identified in the subject DR will be corrected are dependent on what course of action Setra chooses. Listed below are the responses to the specific deficiencies identified in the DR.

A. The intent of the training requirement in the Setra QA manual is to ensure that skills which require an annual recertification are documented. Whether or not this requirement is expanded to include broader training documentation will depend on Setra's decision regarding the ISO certification.

B. The quality requirements to meet Mil Std 45662A were missing from this procurement due to human error and is considered an isolated incident. The service was completed in accordance with the Mil Std requirements even though they were missing from the purchase order. This procurement is closed and there is no need for further action.

C. The best method to implement this step is being evaluated. No procedural changes are necessary. Any actions will be completed in accordance with the schedule above.

D. Setra has agreed to do a review of USGS procurement even though this is a ISO-9000 requirement and not a QARD requirement.

E. This requirement is in conflict with equipment operation manual. There is evidence that the equipment was properly calibrated; it was just not attached to the equipment. How the manual will be changed will be addressed as part of the ISO-9000 revisions described above.

F. This situation occurred because of a data entry error in the computerized calibration tracking system. The equipment is functioning correctly.

G. This is addressed in the results of the QSL Workshop.

H. Two audit reports were missing. One by a customer and one internal. The customer considers their audit reports proprietary and does not release them. They have provided a letter to Setra saying the audit results were satisfactory. Because of a recent move, the internal audit report has not been recovered but is expected to be found as the new office is set up.

Submitted by:   
T. H. Chaney, Quality Assurance Manager - YMP

Date: 9/30/96

**ORIGINAL**

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**1/6/97 SUPPLEMENTAL RESPONSE FOR DEFICIENCY REPORT (DR) YM-96-D-058**

*Deficiency Item A: There was no documented evidence of personnel qualifications and training for the two individuals performing USGS calibrations.*

The calibration process for USGS instruments is a computer based system such that if not followed correctly the instrument will not be calibrated. Training for this process is on-the-job training. Setra will put a memo to file stating the two individuals are qualified and trained to perform the calibrations.

*Deficiency Item B: Addressed in 9/30/96 response.*

*Deficiency Item C: There was no objective evidence that the QA Department had reviewed supplier calibration documentation for acceptance.*

Setra will review all current calibration certificates for dead weight testers to ensure they reflect purchase order requirements.

*Deficiency Item D: There is no formal procedural process for the review of incoming Purchase Orders to assure that customer QA requirements are addressed by Setra Systems.*

Setra Systems has implemented a Customer Service Process to alert Setra to special requirements by its customers that would need to be addressed during the filling of the purchase order.

*Deficiency Item E: Addressed in 9/30/96 response.*

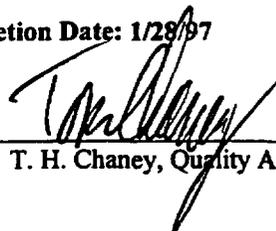
*Deficiency Item F: Addressed in 9/30/96 response.*

*Deficiency Item G: Addressed in 9/30/96 response.*

*Deficiency Item H: No objective evidence of internal audit reports could be provided to support annual or periodic audits of Setra Systems.*

Investigative actions have been unable to produce copies of earlier audit reports. The Setra Systems QA Manager will prepare a listing of the previous audits identifying the audit dates, audit scope, organization conducting the audit, and the audit results.

Action Completion Date: 1/28/97

Submitted by:   
T. H. Chaney, Quality Assurance Manager - YMP

Date: 1/6/97

1/6/97 Chaney to Horton