

U.S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
OFFICE OF QUALITY ASSURANCE

SUPPLIER AUDIT REPORT

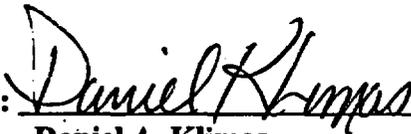
OF

SATEC SYSTEMS, INC.

GROVE CITY, PENNSYLVANIA

REPORT NUMBER OQA-SA-96-013  
MARCH 27-28, 1996

Prepared by:



Date:



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Approved by:



Date:



Donald G. Horton  
Director  
Office of Quality Assurance

## 1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Satec Systems, Inc. revealed unsatisfactory conditions resulting in the issuance of a Deficiency Report (DR) by the Office of Quality Assurance (OQA) for corrective action related to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Implementing technical procedures were in place for the scope of work and implementation was considered to be effective in producing the desired results except in the areas found to be unsatisfactory. The services furnished by Satec Systems, Inc. for this procurement are for use by the Yucca Mountain Project Branch, U.S. Geological Survey (USGS), in connection with the Civilian Radioactive Waste Management Program managed by the U.S. Department of Energy. Satec Systems, Inc. performs the calibration of a Load Frame located at the USGS.

The unsatisfactory conditions identified during the audit were discussed with Satec Systems, Inc.'s management who agreed to correct the unsatisfactory conditions. Corrective actions associated with DR YMQAD-96-D052 will be evaluated by the OQA as appropriate. The unsatisfactory conditions and recommendations are detailed in Section 5.0

## 2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of the Satec Systems, Inc.'s QA program. This was accomplished by determining if the Satec Systems, Inc.'s QA program meets the quality and technical requirements specified in the USGS Purchase Order, Number 1434-CR-96-SA-00070, the Satec Systems, Inc. Quality Assurance Manual, Revision 4, dated November 15, 1995, and the OCRWM Quality Assurance Requirements and Description (QARD) document for the specific scope of work. The QA program elements determined to be applicable are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Control of Measuring and Test Equipment; Nonconformances; Corrective Action; QA Records and Audits.

## 3.0 AUDIT TEAM AND OBSERVERS

Daniel A. Klimas, Audit Team Leader, Yucca Mountain Quality Assurance Division

#### 4.0 PERSONNEL CONTACTED DURING THE AUDIT

David Harris, Service QA Manager, Satec Systems, Inc.  
Joseph Argyros, Service Manager, Satec Systems, Inc.

#### 5.0 SUMMARY OF AUDIT RESULTS

The Satec Systems, Inc. QA Manual, Revision 4, dated November 15, 1995, addresses the applicable elements of the USGS purchase order and the applicable elements of the QARD for the intended scope of work. Technical procedures were in place for the calibration services provided, and implementation was considered to be effective except for those program areas determined to be unsatisfactory. Deficient conditions were identified in the implementation of the following QA program elements: QA Program (training documentation); Document Control; Control of Purchased Items and Services; Calibration; Nonconformances; Corrective Action; QA Records; and Audits. Details of the unsatisfactory conditions and recommendations are described in Section 6.0.

The details of the audit, along with the objective evidence reviewed, are contained in the audit checklist which is available from the OQA's supplier audit quality records file.

#### 6.0 DEFICIENCIES/CORRECTED DURING THE AUDIT/RECOMMENDATIONS

The unsatisfactory conditions have been documented on DR YMQAD-96-D052 for corrective action and resolution. There were no conditions that were corrected during the audit. Recommendations, as applicable, have been provided for your consideration and action as deemed appropriate. The recommendations are offered as suggestions to improve your processes and are not required to be acknowledged unless otherwise stated.

##### DEFICIENCIES

All the identified deficiencies have been documented on DR YMQAD-96-D052.

1. Documentation of the indoctrination training of individuals is inadequate for determining the specific training that was administered; i.e., identifying training to specific procedures or the content of training.
2. The control and distribution of manuals and procedures are not being adequately implemented as some of the manual assignment pages are not being returned as required.

3. The calibration recall system requires that the Service Manager approve the recall list in order to issue purchase orders for equipment requiring calibration. This is not being implemented
4. Calibration equipment that is taken out of use is stored in an area that is segregated from usable equipment but was not tagged "Do Not Use" as required by the QA Manual.
5. A vendor audit that was performed by Satec Systems, Inc. of Rice Lake Weighting Systems identified a deficiency. There was no evidence that this deficiency was corrected, or that a follow-up verification was performed to close out the deficiency, or that the vendor was removed from the Approved Vendors List.
6. The National Standards Testing Laboratory and the Boekeler Instrument Company were not evaluated (audited) on a triennial basis.
7. Vendors are required to complete a quality assurance vendor survey in order to verify conformance to purchase order requirements. The surveys for National Standards Testing Laboratory and Boekeler Instrument Company could not be located.
8. Nonpermanent Quality Assurance records are on file and maintained for the appropriate period of time; however, these records do not meet the storage requirements for one-hour fire rated container, or facility, or dual storage.

#### RECOMMENDATIONS

1. It is recommended that Satec Systems, Inc. develop administrative procedures to support the implementation of their QA program and to provide the level of detail needed to assure documented evidence of the adequacy and implementation of the program. Satec Systems, Inc. has already recognized the need for administrative controls as evidenced by a draft procedure for purchase order review. It is recommended that administrative procedures for document control, internal, and vendor audits, nonconformances, corrective action, and records also be considered.