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

SUPPLIER AUDIT REPORT

OF

KEITHLEY INSTRUMENTS, INC.

CLEVELAND, OHIO

REPORT NUMBER OQA-SA-97-023
MAY 21-22, 1997

Prepared by: _____ **Date:** 06/03/97
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Approved by: _____ **Date:** 6/6/97
Donald G. Horton
Director
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1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Keithley Instruments, Inc. (Keithley) revealed unsatisfactory conditions resulting in the issuance of one Deficiency Report (DR) to the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) for action which relates to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. The DR addresses deficiencies as follows: (1) There was no objective evidence of training of calibration personnel to the procedures they are required to implement; (2) Keithley purchase requisitions issued for calibration of equipment to Fluke Manufacturing without evidence of vendor survey forms on file; (3) Metrology department procedures are not under document control system; and (4) Deficiencies issued by Keithley in 1995 have not been resolve in a timely manner.

It should be noted that Keithley performs calibrations of instruments in two different departments. If a piece of Measuring and Test Equipment (M&TE) is purchased with an associated calibration, that calibration is performed in the manufacturing department. If a piece of M&TE is returned to Keithley for calibration, that M&TE is calibrated by the service and repair department. In instances the same calibration procedure(s) may be used; however, there could be instances where a different calibration procedure(s) is used by the service and repair department than was used by the manufacturing department. This may be due to the fact that the manufacturing department utilized an automated process for performing the calibrations, where the service and repair department implemented a manual process for calibration of the same model of M&TE. During this audit, both the manufacturing and service and repair departments were evaluated.

The unsatisfactory conditions identified during the audit were discussed with the Quality Manager of Keithley, who agreed to work with CRWMS M&O in the resolution of the unsatisfactory conditions.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of Keithley's quality program. This was accomplished by determining if Keithley's program implements the applicable portions of the OCRWM Quality Assurance Requirements and Description (QARD); satisfies the applicable QA requirements specified in the CRWMS M&O purchase order number A02168JM7C; and satisfactorily implements Keithley's Quality Assurance Manual, QSIP-100, Revision A, as accepted by the CRWMS M&O, for the 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; Measuring and Test Equipment; Corrective Action; QA Records; and Audits.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance (OQA)

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

W. H. Pelster, Quality Manager, Keithley Instruments, Inc.
Laurie Mateja, Senior Human Relations Specialist, Keithley Instruments, Inc.
Sally Zartman, Document Control Supervisor, Keithley Instruments, Inc.
Sandy Decman, Document Clerk, Keithley Instruments, Inc.

5.0 SUMMARY OF AUDIT RESULTS

Keithley's Quality Manual, QSIP-100, Revision A, and associated implementing procedures address the applicable elements of the OCRWM QARD and CRWMS M&O purchase order for the intended scope of work. Effective implementation of the applicable elements of the QARD by Keithley is considered satisfactory, with the exception of those unsatisfactory conditions described in Section 6.0 of this report, "Deficiencies/ Recommendations." One condition adverse to quality was resolved during the audit and related to the Certificate of Calibration addressing all of the requirements of the PO. This item is detailed in Section 6.0 of this report.

The details of the audit, along with the objective evidence reviewed, are contained within the audit checklist, which is available from the OQA's supplier evaluation files.

6.0 DEFICIENCIES/RECOMMENDATIONS/DEFICIENCIES CORRECTED DURING THE AUDIT

The unsatisfactory conditions have been documented on the respective corrective action document and submitted to the CRWMS M&O for action and resolution. There were no recommendations.

DEFICIENCIES

DR No. YM-97-D052

(A) The Keithley Quality Manual, Section 8, requires that the supervisor and the employee identify and plan training needs, schedule training and record the training in the persons training log; (B) QS-101, Section 14.0(A-2 & 3), requires all potential subcontractors be requested to complete a survey form listing their response to specific requirements, return this form and an evaluation to be performed by Keithley to determine if the response is acceptable; (C) The Keithley Quality Manual, Section 1.3, requires procedures and work

instructions used to support our quality system and product quality to be under full documentation change and revision control; and (D) Section 7.1 addresses a corrective action system that will quickly handle a specific customer problem in addition to investigating underlying causes of potential process or product problems.

Contrary to the above requirements: (A) There is no objective evidence to establish that personnel performing calibration have been trained to the task specific procedures required to perform their functions; (B) Keithley purchase requisitions PR P139793 and P147420 were issued to Fluke Service Center in Carrollton, Texas, however there was no documented evidence that a survey form had been sent to this facility and returned for review; (C) Calibration procedures prepared and issued by the Metrology Department are not under the documentation change and revision control system. Examples of procedures found not to be under the documentation and revision control system are: QA-1000C, QA-1004B, QA-1006B, and QA-1012B; and (D) Audit deficiency documents issued in January 1995 have not been resolved and closed to date. No documented justification exists to support why these deficiencies have not been processed in a timely manner. Examples include: NCM 401, NCM 402, NCM 403, and NCM 404.

DEFICIENCIES CORRECTED DURING THE AUDIT

The CRWMS M&O PO A02168JM7C requires that the Certificate of Calibration include information such as the subcontract number, calibration procedure revision, and a statement of traceability to the National Institute of Standards and Technology. Contrary to this requirement, the Certificate of Calibration provided by Keithley for the calibration of Keithley Model 2001, serial number 644379, did not include this information. Prior to completion of the audit, Keithley management issued an update to the Certificate of Calibration addressing the missing information.