

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

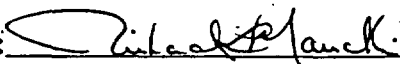
SUPPLIER SURVEY REPORT

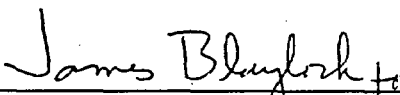
OF

CAL LAB, INC.

GARDEN GROVE, CALIFORNIA

REPORT NUMBER OQA-SFE-97-003
APRIL 7-8, 1997

Prepared by:  Date: 04/17/97
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Approved by:  Date: 4/25/97
Donald G. Horton
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1.0 EXECUTIVE SUMMARY

The supplier survey of Cal Lab, Inc. (CLI) revealed inadequate conditions resulting in several recommendations related to CLI's Quality Assurance (QA) program and program implementation for the Office of Civilian Radioactive Waste Management (OCRWM) activities. At the present time, CRWMS M&O has not issued any procurement documents to CLI. The recommendations relate to: A lack of procedures which describe training and qualification of personnel and audits; implementation of procurement requirements; implementation of document control; and implementation of calibration requirements. It should be noted that CLI is going through a transition from being a Westinghouse calibration laboratory working under Westinghouse Energy Services' corporate QA Program to CLI which is an independent supplier of calibration services. Most of the QA program requirements being implemented by CLI are requirements that were implemented under the Westinghouse QA program.

The recommendations identified during the survey were discussed with the Vice President of Quality, CLI, who agreed to work with the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) in the resolution of the unsatisfactory conditions. It is recommended that an audit of this supplier be performed, if accepted by the CRWMS M&O, as soon as possible after issuance of the initial purchase order.

2.0 SCOPE

The supplier survey was conducted at the request of the CRWMS M&O to evaluate the capability of CLI's facility, personnel, and QA program, including implementation, to determine if CLI's QA program and implementation meets the requirements for the intended scope of work and appropriate OCRWM QA program requirements. The QA program elements determined to be applicable by the CRWMS M&O are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Items and Services; Control of Measuring and Test Equipment; Corrective Action; and Audits.

3.0 Survey TEAM AND OBSERVERS

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

4.0 PERSONNEL CONTACTED DURING FACILITY SURVEY

Greg Parker, Vice President of Quality, CLI
Tony Gruehl, President, CLI

5.0 SUMMARY OF SURVEY RESULTS

CLI's QA program document addresses all of the applicable requirements of the Quality Assurance Requirements and Description (QARD) with the exception of training and qualification of personnel and audits. Implementation was considered marginal or inadequate since, in part, some activities are still being performed using Westinghouse Energy Services' program documentation. The problems identified during this survey are documented as recommendations, since the CRWMS M&O has not issued any procurement documents to this prospective supplier, and are described in Section 6.0; "Recommendations". Acceptance of this supplier is contingent on satisfactory resolution of the recommendations by the CRWMS M&O and CLI. To date, CLI has not initiated any nonconformance reports or requests for corrective action. Subsequently, implementation of corrective action could not be verified.

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

6.0 RECOMMENDATIONS

The recommendations are provided for your consideration should you desire to pursue approval of CLI and have them added to the OCRWM Qualified Suppliers List. The recommendations will require the development of procedures and resolution of the problems noted during the evaluation of program implementation.

1. Develop an organizational chart as required by SOP 1.01 which references Figure 1 for a description of the CLI organizational structure.
2. Prepare, review, and approve a procedure for the indoctrination, training and qualification of personnel as referenced by SOP 1.01.
3. As of the date of the survey, CLI does not have in place a CLI Approved Suppliers List as required by SOP 6.01. CLI is presently still using the Westinghouse Energy Services' corporate Approved Suppliers List. CLI needs to prepare a CLI Approved Suppliers List.
4. CLI is issuing purchase orders under the name of Westinghouse Energy Services. CLI needs to issue all future purchase orders under CLI for calibration services.
5. CLI is required by SOP 5.01 to review and approve implementing procedures prior to issue. Presently, CLI has issued SOPs prior to review and approval, as noted by the issue date on each SOP. CLI needs to address why these procedures were issued prior to approval.

6. SOP 11.01 requires that calibrations performed by CLI be calibrated by qualified personnel. In the review of personnel qualifications, it was noted that one individual's Certificate of Qualification did not contain supporting documentation on training and experience. CLI needs to acquire or develop supporting documentation for this one individual regarding training and experience.
7. COM-001 identifies three classes of reference standards (Level I, II, II); however, the procedure does not identify how these classes will be documented to be able to identify which equipment falls into what class.
8. COM-001 discusses calibration interval, but does not identify how this interval is documented. Calibration interval is being documented on the "Instrument History Record" for each piece of Measuring and Test Equipment (M&TE). CLI needs to identify procedurally where the interval will be documented.
9. COM-001 requires the generation of a recall list every month for CLI's M&TE. No documented evidence could be provided to reflect that these recall lists have been generated on a monthly basis. CLI needs to maintain at least one copy of the recall list (i.e.; last list issued) to demonstrate compliance with the procedure.
10. COM-001 requires that test equipment calibration certificates include a statement of accuracy or measurement uncertainty. This statement is not being included in the calibration certificates. CLI needs to comply with the procedure or revise the procedure to accurately reflect present practices.