



QA: QA

Lori McCaig, QA Manager  
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Sunnyvale, CA 94086

**BECHTEL SAIC COMPANY, LLC (BSC) QUALITY ASSURANCE (QA) SUPPLIER  
SURVEY REPORT BSC-SFE-02-003 OF CHARLES EVANS AND ASSOCIATES.**

Enclosed is the Supplier Survey Report BSC-SFE-02-003 of Charles Evans and Associates that was performed on January 17-18, 2002, in Sunnyvale, California, to evaluate the implementation and effectiveness of Charles Evans and Associates' Quality Assurance Program.

The survey revealed that Charles Evans and Associates' Quality Assurance Program and their implementation contains conditions adverse to quality that require resolution to meet the QA requirements that are imposed on suppliers of analytical services for the Yucca Mountain Site Characterization Project. The conditions adverse to quality are addressed in section 5.0 of the enclosed survey report as recommendations in the following QA program areas: Procurement Document Control, Control of Purchased Items and Services, Control of Measuring and Test Equipment, Corrective Action, Audits, Software, and Sample Control.

Once BSC has received documentation resolving the recommendations, a determination will be made whether to perform a follow-up evaluation or surveillance. Upon successful resolution of the recommendations, Charles Evans and Associates will be placed on the Office of Civilian Radioactive Waste Management Qualified Supplier List.

This survey is considered complete and closed as of the date of this letter.

If you have any questions, please contact either Richard L. Maudlin at (702) 295-2961 or Daniel A. Klimas at (702) 295-2665.

A handwritten signature in black ink that reads "D. T. Krisha".

Donald T. Krisha, Manager  
Quality Assurance

2/22/02  
Date Signed

RLM:bw-0220021553

Handwritten initials in the bottom right corner, possibly "RLM" or similar, written in black ink.

February 22, 2002

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cc: w/encl:

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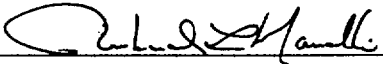
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BECHTEL SAIC COMPANY, LLC (BSC)  
QUALITY ASSURANCE


SUPPLIER SURVEY REPORT  
OF  
CHARLES EVANS AND ASSOCIATES  
SUNNYVALE, CA

REPORT NUMBER BSC-SFE-02-003

JANUARY 17-18, 2002

Prepared by:   
Richard L. Maudlin  
Survey Team Leader  
BSC Quality Assurance

Date: 02-13-02

Approved by:   
Donald T. Krishna, Manager  
BSC Quality Assurance

Date: 2/22/02

## **1.0 SURVEY SUMMARY**

BSC conducted a supplier survey of Charles Evans and Associates on January 17-18, 2002 at the Sunnyvale, CA facility. Charles Evans and Associates provides surface chemistry characterization analytical services. The survey revealed that Charles Evans and Associates' Quality Assurance (QA) Program and their implementation contains conditions adverse to quality that require resolution to meet the QA requirements that are imposed on suppliers of analytical services for the Yucca Mountain Site Characterization Project. The conditions adverse to quality are addressed in Section 5.0 of the enclosed survey report as recommendations in the following QA program areas: Procurement Document Control, Control of Purchased Items and Services, Control of Measuring and Test Equipment, Corrective Action, Audits, Software, and Sample Control.

The recommendations must be resolved before BSC Quality Assurance can make a determination to place Charles Evans and Associates on the Office of Civilian Radioactive Waste Management (OCRWM) Qualified Supplier List (QSL). Upon resolution of these recommendations, a decision will be made to perform a follow-up evaluation before placing them on the QSL.

## **2.0 SCOPE**

The supplier survey was conducted to evaluate the implementation and effectiveness of Charles Evans and Associates' Quality Assurance Program as delineated in their Quality Manual dated 08/24/01 and associated implementing procedures. 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; Corrective Action; QA Records; Audits; Software; and Sample Control.

The details of the survey, along with the objective evidence reviewed are contained within the survey checklist, which is available from the BSC Records Processing Center.

## **3.0 SURVEY TEAM MEMBERS**

Richard L Maudlin, Survey Team Leader, BSC QA  
Charles C. Warren, Survey Team Member, BSC QA  
Tiangan Lian, Observer, BSC/LLNL  
Steve Mahler, Observer, BSC/LLNL

#### 4.0 PERSONNEL CONTACTED DURING THE AUDIT

Lori McCaig, Quality Manager, Charles Evans and Associates  
Pat Lindley, Senior Manager, Charles Evans and Associates  
Greg Serossman, Specialist, Charles Evans and Associates  
Chuck Hitzman, Facilities/Instrument Maintenance, Charles Evans and Associates  
Westly Nieveen, Scientific Fellow, Charles Evans and Associates  
Edie Bishop, Sample Receiving, Charles Evans and Associates  
John Moskito, Staff Scientist, Charles Evans and Associates

#### 5.0 SURVEY RECOMMENDATIONS

The following recommendations must be resolved prior to BSC placing Charles Evans and Associates on the OCRWM QSL.

1. The Charles Evans and Associates Quality Manual does not provide requirements for procurement documents to include technical and quality requirements as required by Sections 4.0 of the OCRWM Quality Assurance Requirements and Description Document (QARD). A review of one Charles Evans and Associates purchase order, PO 7786, dated 03/14/01, failed to include appropriate technical and quality requirements. In addition, no evidence could be provided to reflect review of the purchase order by the purchasing agent prior to release as required by the Charles Evans and Associates Quality Manual, Section 6, Subsection QM 6.3. It is recommended that Charles Evans and Associates revise their Quality Manual and/or implementing procedures to provide requirements for the inclusion of technical and quality requirements in procurement documents. Additionally, reviews of purchase orders by the purchasing agent should be performed as required by the implementing procedure.
2. The Charles Evans and Associates Quality Manual does not provide requirements for the qualification of suppliers of items and services as required by Section 7.0 of the OCRWM QARD. In addition, no documentation could be provided to support the qualifications of critical suppliers, Simco Electronics and Kenneys Scale and Balance Service. It is recommended that Charles Evans and Associates revise their Quality Manual and/or implementing procedures to provide requirements for the qualification of suppliers of items and services.
3. The Charles Evans and Associates Quality Manual does not provide requirements for the receipt verification/inspection of items and services. No documentation could be provided to support the receipt verification/inspection of the calibration of measuring and test equipment to the requirements of Charles Evans and Associates' purchase order PO 7786. It is recommended that Charles Evans and Associates revise their Quality Manual and/or implementing procedures to provide requirements for the receipt verification/inspection of items and services.

4. The Charles Evans and Associates Quality Manual does not provide requirements for: traceability of Measuring and Test Equipment (M&TE) to National Institute of Standards and Technology (NIST), traceability of calibration documentation to calibration data, and the validity of results of past use when M&TE is found to be out-of-calibration. Also, the Gold and Copper Foil Standards used in the calibration of the XPS, Model 5600, were not uniquely identified, no status indicators were noted, and no documentation could be provided to demonstrate traceability of the standards to NIST. It is recommended that Charles Evans and Associates revise their Quality Manual and/or implementing procedures to provide requirements for traceability of M&TE to NIST, the traceability of calibration documentation to the calibration data, and the validity of results of past use when M&TE is found to be out-of-calibration. Prior to placement on the OCRWM QSL, applicable M&TE to be used to support YMP work must have been calibrated against standards traceable to NIST.
5. During the review of Charles Evans and Associates' internal audit reports, it was noted that conditions adverse to quality were being documented on nonconformances. However, no Corrective Actions Requests, Form 149, were being generated, as required by the Charles Evans and Associates Quality Manual, Section 14, Subsection 14.4.2. It is recommended that Charles Evans and Associates implement or revise their Quality Manual to include the generation of a Corrective Action Request for all deficiencies identified during an audit.
6. No documentation could be provided to support the ISO training for one Charles Evans and Associates auditor as required by Charles Evans and Associates' implementing procedure QP 17-1, Internal Audit Procedures, dated 08/24/01. It is recommended that Charles Evans and Associates locate or regenerate documentation to support the ISO training for all Charles Evans and Associates' auditors.
7. No documented evidence could be provided to reflect the software verification of Multipak, Version V6.1A, used in the analytical XPS Technique, as required by QP 9-3, Qualification of Processes, Instruments, and Software, dated 08/24/01. It is recommended that Charles Evans and Associates either locate the existing documentation, or recreate documentation to support the qualification of Mutipak, Version V6.1A.
8. Historical copies of entries in the Job Chain of Custody Log, at the receipt, are not maintained. Upon completion of the analysis, the logs are allowed to be destroyed. As a result, traceability of the samples received after completion of the analysis cannot be assured. Charles Evans and Associates' procedures do not provide any retention requirements for traceability logs. It is recommended that Charles Evans and Associates establish time limits for the maintenance of Chain of Custody Logs for a period of time consistent with the need to demonstrate control of the samples internal to Charles Evans and Associates, after analysis of the samples is complete.

9. Selected samples for Job Number E2151 were used to determine acceptable traceability through the analytical process. The Sample Tracking Log in the sample return area failed to identify the control of the samples for Job Number E2151. The page in the logbook for these samples was missing. It is recommended that Charles Evans and Associates review and evaluate the effectiveness of the existing internal sample control process and make the necessary changes to assure sample control from receipt through return of the samples to the customer.
10. The unique identification of multiple samples is not logged in at receipt. There is no traceability between the Charles Evans and Associates assigned sample tracking number and the unique customer sample identification for multiple samples. It is recommended that Charles Evans and Associates revise existing sample receipt procedures to require verification of all samples received against customer submittal documentation (i.e. customer purchase order).
11. There are no Charles Evans and Associates implementing procedures in place which require analytical output documentation to include a reference to the unique identification of the equipment used to perform the analysis and reference to the individual who performed the analysis. It is recommended that Charles Evans and Associates revise existing procedures for the analysis of samples to include a reference of the equipment used to perform the analysis and the identification of the person performing the analysis.