

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

**SUPPLIER AUDIT REPORT**

**OF**

**BETA ANALYTIC INC.**

**MIAMI, FLORIDA**

**REPORT NUMBER OQA-SA-95-002  
AUGUST 16 THROUGH 17, 1995**

Prepared by:  Date: 08/28/95  
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Approved by:  Date: 9/1/95  
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## 1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Beta Analytic Inc. revealed unsatisfactory conditions resulting in the issuance of six Performance Reports and one Deficiency Report to the United States Geological Survey (USGS), for issuance to Beta Analytic Inc. for action, related to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Detailed 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 unsatisfactory. Beta Analytic Inc. has established a series of multiple cross-checks throughout the entire preparation and testing process, except for the Accelerator Mass Spectrometry (AMS) analysis which is performed by other laboratories not under the direct control of Beta Analytic Inc. These cross checks continually review and evaluate the accuracy of previous operations. With the exception of Procurement, the unsatisfactory conditions found are considered remedial in nature and do not impact the results of the tests performed by Beta Analytic Inc.

The unsatisfactory conditions identified during the audit were discussed with Beta Analytic Inc. management who agreed to resolve the unsatisfactory conditions prior to and/or upon receipt of the reported conditions adverse to quality by the USGS. It is recommended that Beta Analytic Inc.'s services be limited to C12/C14 age dating by the use of Liquid Scintillation Counters or limited to preparation of samples for AMS testing only. When the corrective action related to the procurement issue documented in Deficiency Report (DR) YMQAD-95-D-009 has been accepted and verified, then Beta can be used for AMS testing services.

## 2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of Beta Analytic Inc.'s quality program. This was accomplished by determining if the Beta Analytic's program satisfies the QA requirements specified in the USGS procurement document 1434-CR-95-SA-01372, Beta Analytic Inc.'s Quality Assurance Manual, Revision 1, dated January 1, 1995, as approved by the USGS on May 26, 1995, and the OCRWM Quality Assurance and Requirements Description (QARD) for the scope of work. The QA program elements determined to be applicable are: Organization, QA Program, Procurement Control, Implementing Procedures, Document Control, Measuring and Test Equipment, Nonconformances, Corrective Action, QA Records, Audits, and Sample Control.

## 3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD)

Robert B. Constable, Audit Team Member, OQA, YMQAD

#### 4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

M.A. Tamers, Dr., Co-Chairman, Beta Analytic Inc.  
D.G. Hood, General Manager, Beta Analytic Inc.  
R.E. Hatfield, Laboratory Manager, Beta Analytic Inc.  
C. Patrick, Counter Manager, Beta Analytic Inc.  
T.A. Zilko-Miller, AMS Manager, Beta Analytic Inc.

#### 5.0 SUMMARY OF SURVEY RESULTS

Beta Analytic Inc.'s QA Program Manual, dated January 1, 1995, addresses the applicable elements of the USGS procurement document No. 1434-CR-95-SA-01372 and the applicable elements of the OCRWM QARD for the intended scope of work. Procedures were in place and implementation was considered to effectively produce the desired results except for those areas deemed unsatisfactory and noted in Section 6.0 of this report. The area of most concern was related to the evaluation and pass down of QA requirements to sub-tier suppliers. Specifics of the unsatisfactory conditions are described in Section 6.0 of this report "Deficiencies/Recommendations." In addition, it should be noted that Beta Analytic Inc. has implementing procedures which describe the step by step process of performing work supported by the QA Manual, however, these procedure are considered by Beta Analytic Inc. as proprietary and were not submitted as part of the QA Program documentation submitted to USGS for review. These procedures are available for review during audits and surveillances by OCRWM OQA, but may not be removed from the facility.

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

#### 6.0 DEFICIENCIES/RECOMMENDATIONS

The unsatisfactory conditions have been documented on the respective corrective action document and submitted to USGS for resolution. 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

1. DR No. YMQAD-95-D-009 - (A) Beta has no program for the qualification and pass down of applicable QA program requirements to its sub-tier suppliers. Presently, Beta Analytic Inc. is using Lawrence Livermore National Laboratory (LLNL) for performance of AMS testing of geologic samples, however, Beta has no contract with LLNL for this service. Work is done on the honor system. (B) Beta is purchasing the chemical Benzine which is used in the preparation

of samples, however, there is no documented acceptance of the Benzine by Beta upon receipt and after testing.

2. PR No. YMQAD-95-P-007 - There is no software documentation in the form of a users guide/manual for the Carbon Age Dating Calculation Software titled "RCCALC", Version 1a, which describes the formulas in the calculation, how the program works, and a description of how it is to be used. In addition, the program has a set of imbedded cross checks to prevent input error, however there is no documentation to explain how this set of cross checks works.
3. PR No. YMQAD-95-P-008 - Implementing procedures maintained by Beta do not have any unique identifier and revision designation, and there is no documented approval of these procedures. These procedures are proprietary and are maintained separate from the QA Manual and associated technical procedure.
4. PR No. YMQAD-95-P-009 - (A) AMS test report from LLNL, dated 08/11/95, for samples submitted under USGS PO Number 143-CR-95-SA-01372 did not address some identifiable portion of the submitters number, and (B) Test documentation submitted to USGS for USGS PO Number 143-CR-95-SA-01372 does not include the identification of the persons performing the analysis.
5. PR No. YMQAD-95-P-010 - (1) There are no detailed procedures for the calibration of the Liquid Scintillation Counters and (2) Calibration documentation does not reflect the ID of the procedure used.
6. PR No. YMQAD-95-P-011 - Records are filed by Vendor Name in metal file cabinets, however, there is no protection against damage by moisture, fire, or infestation.
7. PR No. YMQAD-95-P-012 - USGS does not perform audits as of July 1995. Beta does not have an internal audit program.

## RECOMMENDATIONS

1. Since Beta Analytic Inc. has no internal assessment of the QA Program it is recommended that top level management (i.e.: a management level above that of the General Manager) perform an internal assessment of the Beta Analytic Inc's total QA Program at least once a year. The value to Beta Analytic Inc. in implementing such assessment would be to: (1) assure continued satisfactory implementation and effectiveness of the present QA Program and (2) provide for input for improvement based on a complete assessment of all processes, procedures and their interfaces.