



Department of Energy
 Office of Civilian Radioactive Waste Management
 Yucca Mountain Site Characterization Office
 P.O. Box 98608
 Las Vegas, NV 89193-8608

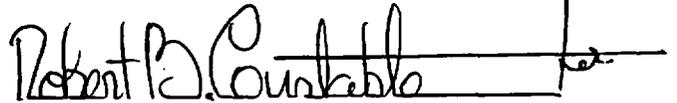
AUG 15 1996

Robert W. Craig
 Technical Project Officer
 for Yucca Mountain
 Site Characterization Project
 U.S. Geological Survey
 1261 Town Center Drive
 Building 4, Room 423, M/S 423
 Las Vegas, NV 89134

**EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT (DR)
 YM-95-D-009 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA)
 SUPPLIER AUDIT OQA-SA-95-002 OF U.S. GEOLOGICAL SURVEY**

The YMQAD staff has evaluated the amended response to DR YM-95-D-009. The amended response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to that date. Please send a copy of extension requests to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

If you have any questions, please contact either Robert B. Constable at (702) 794-5580 or Richard L. Maudlin at (702) 794-1302.



Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-2409

Enclosure:
 DR YM-95-D-009

cc w/encl:
 J. G. Spraul, NRC, Washington, DC
 S. W. Zimmerman, NWPO, Carson City, NV
 T. H. Chaney, USGS, Denver, CO
 Records Processing Center

cc w/o encl:
 W. L. Belke, NRC, Las Vegas, NV
 R. L. Maudlin, YMQAD/QATSS, Las Vegas, NV
 D. G. Sult, YMQAD/QATSS, Las Vegas, NV
 D. Horton, OQA, NV

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9608200205 960815
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recip: J. G. Spraul

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8 Performance Report
 Deficiency Report
 NO. YMQAD-95-D-000
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
 USGS P.O. 1434-CR-95-SA-01372 / Beta Analytic Inc. QA Manual, Rev. 0

2 Related Report No.
 Supplier Audit Report OQA-SA-95-002

3 Responsible Organization:
 USGS

4 Discussed With:
 Tom. Chaney/Darden Hood

5 Requirement/Measurement Criteria:
 USGS P.O. 1434-CR-95-SA-01372, YMP-USGS QA Requirements for Analytical Services, states in part: "Procurement - Describe the approach used to incorporate quality assurance requirements into procurements for quality-affecting materials or services (ensure that quality assurance requirements applicable to sub-tier suppliers are included in all sub-tier supplier issued procurement documents). Describe verification practices used to ensure that received materials or services satisfy the procurement requirements".

Beta Analytic Inc., QA Manual, Revision 0, Section 4.0, Subsection 4.2 states in part: "Signed delivery tickets, invoices, certificates of analysis and/or internal testing results are maintained as quality records of acceptance of quality affecting products or services".

6 Description of Condition:
 Contrary to the above:

(A) Beta Analytic has no program for the qualification and pass down of applicable QA program requirements to its sub-tier suppliers. Presently, Beta Analytic is using Lawrence Livermore National Laboratory (LLNL) for the performance of Accelerator Mass Spectrometry (AMS) testing of geologic samples, however, Beta Analytic has no contract with LLNL for this service.

(B) Beta is purchasing the chemical Benzine which is used in the preparation of samples, however, there is no documented acceptance of the test performed by Beta Analytic of the Benzine upon receipt.

7 Initiator
 R.L. Maudlin *R.L. Maudlin* Date 08/29/95

9 QA Review
 QAR *R.L. Maudlin* Date 08/29/95

10 Response Due Date
 20 Working Days from Issuance

11 QA Issuance Approval
 QAR (PRI)/AOQAM (DR) *R.L. Maudlin* Date 8.30.95

12 Remedial Actions:

*SEE ATTACHED CONTINUATION PAGE, NOTING
 RESPONSE DATED 10/12/95*

13 Remedial Action Response By:
see continuation page dated
 Date 10/12/95

14 Remedial Action Due Date
 Date 12/15/95

15 Remedial Action Response Acceptance

16 PR Verification/Closure

Enclosure

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8
DR NO. YMQAD-95-D-09
PAGE 2 OF 2
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DEFICIENCY REPORT

17 Recommended Actions:

(A) Develop a program for the qualification of suppliers providing quality affecting items and/or services. Identify the method to be used in passing down of quality requirements to sub-tier suppliers. Generate a contract/purchase order for the use of sub-tier suppliers. Upon development of the qualification program for sub-tiers, implement the program for the labs being used to provide quality affecting services.

(B) Upon receipt of chemicals used in quality affecting activities, perform necessary tests and document those tests as required by your QA Manual.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response by:

See continuation page dated 10/12/95
Date 10/12/95

22 Corrective Action Completion Due Date:

12/15/95

23 Response Accepted

QAR Date

24 Response Accepted

AQOAM Date

25 Amended Response Accepted 8/12/96
16. Hudson
Date 8/12/96

25 Amended Response Accepted
AQOAM: [Signature] Date: 8-15-96

QAR [Signature] Date: 1/2/96

27 Corrective Actions Verified

28 Closure Approved by:

ORIGINAL
This is a RED Stamp

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

Performance Report
 Deficiency Report

NO. YMQAD-95-DC09

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PR/DR CONTINUATION PAGE

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- Response
 Amended/Supplemental Response
 Extension Request
 Notification of Completion of Actions
 Void Request

Block 12. Remedial Actions:

- (A) QC Plan results from LLNL will be made available to the YMP-USGS and/or the YMQAD for performance verification.
(B) Beta Analytic Inc. will develop a documented acceptance test record for quality affecting materials purchased by a subtier supplier that are not commercial grade off-the-shelf items.

Block 18. Investigative Actions:

- (A) The acceptance of work between LLNL and Beta Analytic Inc. utilizes a quality control (QC) approach, i.e., use of reference standards, known age international standards, backgrounds, and blinds. This approach, approved by the YMQAD, (ref. CAR-95-041) along with a long history of LLNL providing satisfactory results, knowledge of their personnel and procedures, effectively verifies the integrity of results obtained.
(B) None required.

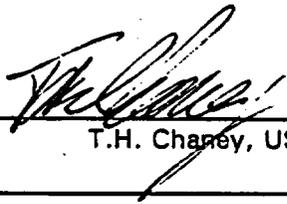
Block 19: Root Cause Determination:

- (A) USGS P.O. 1434-CR-95-SA-01372 was initiated prior to YMQAD approval of the QC Plan approach and therefore, the subtier procurement requirements of YMP-USGS-QMP-4.01 were not properly identified.
(B) The requirement to document acceptance test results was effective 1/1/95 and training to this requirement was ineffective.

Block 20: Action to Preclude Recurrence:

- (A) Beta Analytic Inc. QA Manual Section 4.0 Procurement and Receipt Control will be amended to document the use of QC Plans for subtier analytical service suppliers and, future YMP-USGS procurement documents issued to Beta Analytic Inc. will correctly recognize the QC Plan approach for the use of subtier suppliers of analytical services for Beta Analytic Inc.
(B) Beta Analytic Inc. QA Manager will ensure that the newly developed acceptance test record is completed as required.

Submitted by: _____


T.H. Chaney, USGS QA Manger

Date: October 12, 1995

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 Performance Report
 Deficiency Report

NO. YMQAD-95-D009

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PR/DR CONTINUATION PAGE

EVALUATION OF INITIAL RESPONSE DATED 10/12/95

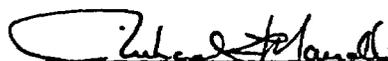
Upon a review of the response to DR YMQAD-95-D009, it was found not to resolve the noted condition.

Your response indicates that USGS wants to allow Beta Analytic Inc. to implement the requirements of QMP 4.01, Option 4 which provides for utilizing a QC Plan to accept LLNL's work.

USGS-QMP-4.01, Rev. 7, Section 2.0 states in part: "This procedure applies to all YMP-USGS personnel, extended staff, and suppliers working directly to the YMP-USGS QA Program". As of this date, Beta Analytic is not considered augmented staff and does not work directly to the USGS QA Program. Beta Analytic has its own QA Program and implementing procedures which address the requirements of the USGS Purchase Orders.

Secondly, QMP 4.01, Attachment 4, Option 5 states in part: "This option is normally used for limited scope samples analysis of such a unique nature that the desired supplier does not work to a documented QA Program that meets QARD requirements". Again, Beta Analytic has a documented QA Program which USGS has approved as meeting the applicable portions of the QARD.

It is apparent that the requirements of QMP 4.01 as stated in your response can not be applied to Beta Analytic for use on its sub-tier suppliers. Please reevaluate your response based on the above and amend your response to address measures for the control of Beta Analytic Inc. sub-tier suppliers.



Richard L. Maudlin

10/31/95

Date

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

- Performance Report
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Amended Response

This amended response and request for extension until February 29, 1996 is submitted for the following:

- The YMP-USGS is looking into alternate sources for the services provided by Beta.
- The YMP-USGS QA Office is awaiting receipt of LLNL's analytic procedure(s), used in the performance of accelerator mass spectrometry (AMS), for Beta.
- Upon receipt of procedures(s) from LLNL, they will be reviewed as part of further investigative actions necessary to determine impact on the quality of the work previously provided by LLNL to Beta.

Block 12. Remedial Actions:

- (A) Alternate sources of C-14 analysis are being looked into. The USGS has requested copies of the LLNL procedures used for the performance of AMS testing for Beta.
- (B) - Same as initial response of October 12, 1995. -

Block 18. Block 18. Investigative Actions:

- (A) The USGS does not have any open procurement documents with Beta. Further investigative actions pending receipt and review of LLNL procedure(s).
- (B) - Same as initial response of October 12, 1995. -

Block 19 Root Cause Determination:

- (A) Lack of clear communications between USGS, Beta and sub-tier suppliers lead to the deficiency.
- (B) - Same as initial response of October 12, 1995. -

Block 20. Action to Preclude Recurrence:

- (A) There are no pending procurement documents planned for Beta.
- (B) - Same as initial response of October 12, 1995. -

Submitted by: Martha H. Mustard
for T. H. Chaney, Quality Assurance Manager, YMP

12-8-95
Date

12/8/95 Chaney to Spence

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

Performance Report
 Deficiency Report

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AMENDED RESPONSE - YMQAD-95-D009

The following information revises and replaces the 12/8/95 response.

Block 12: Remedial Actions (revised):

(A) Based upon discussions among R. Maudlin (YMQAD), B. Parks (USGS ESIP) and T. Chaney (USGS QA) held March 28, 1996 in Lakewood, Colorado, Beta Analytic, Inc. has been asked to revise certain sections of their Quality Assurance Plan to conform to QARD requirements. The attached letter with 1996 QA Plan from Darden Hood (Beta Analytic, Inc.) to Pete Rodriguez (USGS) dated April 29, 1996 documents Beta's collaborative relationship with Lawrence Livermore National Laboratory (LLNL) for the accelerator mass spectrometry (AMS) services provided by LLNL.

(B) -Same as initial response of 10/12/95 -

Block 14: Remedial Action Due Date:

Actions complete with this response.

Block 18: Investigative Actions (revised):

(A) YMQAD (through R. Maudlin) and the USGS worked with Beta Analytic, Inc. to determine the extent of revisions needed to the Beta QA Plan. The attached letter and QA Plan described the revisions Beta Analytic, Inc. has made in response to the deficiencies noted by this report.

(B) -Same as initial response of 10/12/95 -

Block 19: Root Cause Determination (revised):

(A) The USGS contract with Beta Analytic, Inc. relied upon a Beta Analytic, Inc. QC plan which was not an approved YMQAD method for accepting subtier suppliers. Therefore Beta Analytic, Inc. was not required to describe their collaborative relationship with LLNL.

(B) -Same as initial response of 10/12/95 -

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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Block 20: Actions to Preclude Recurrence (revised):

(A) Remedial actions will preclude recurrence of deficiency with Beta Analytic, Inc., while YMQAD-96-C004 will address any other actions as a result of review of USGS procurements for analytical services.

(B) -Same as initial response of 10/12/95 -

Block 22 Corrective Action Completion Due Date:

Actions complete with this response.

Block 13/21 Response by:

Robert W. Craig *5-8-96*
for Robert W. Craig, Chief, Yucca Mountain Project Branch Date

QUALITY ASSURANCE MANUAL

Beta Analytic, Inc.

January 1, 1996

BETA ANALYTIC, INC.

Section: Policy Statement
Revision: 1
Page 1 of 1
Effective Date: January 1, 1996**QUALITY ASSURANCE POLICY STATEMENT**Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

~~Beta Analytic has analyzed over 80,000 radiocarbon samples in 15 years and has a reputation for providing accurate results within its promised delivery schedules. It has been providing radiocarbon dates to the scientific community since 1979 (to over 3400 scientists) and has been active in AMS dating since 1984 in collaboration with ETH (Eidgenössische Technische Hochschule) University in Zürich, Lawrence Livermore National Laboratory (CAMS) and Oxford University.~~

January 1, 1996; the above was changed to the following: (Darden Hood) Rev.1

[Beta Analytic has analyzed over 90,000 radiocarbon samples in 16 years and has a reputation for providing accurate results within its promised delivery schedules. It has been providing radiocarbon dates to the scientific community since 1979 (to over 4000 scientists) and has been active in AMS dating since 1984 in collaboration with ETH (Eidgenössische Technische Hochschule) University in Zürich, Lawrence Livermore National Laboratory (CAMS), Oxford University, and the New Zealand Institute of Geological and Nuclear Sciences.]

It is the only laboratory where direct conversion from the radiometric technique (large samples) to the AMS technique (small samples) is performed without delay in delivery of results. Prior to its inception as an S corporation in the State of Florida in 1979, standard delivery for radiocarbon dates was 1 year. Beta Analytic's promised delivery schedule of 30 days revolutionized the application of the technique and resulted in the practical application of radiocarbon dates by the geological and archaeological research community.

In 15 years, Beta Analytic has grown to be the largest source of radiocarbon dates (archaeological and geological) in the world. It has done this by providing accurate results in a timely fashion at a reasonable cost. No other laboratory has proven itself equal in consistently and dependably supplying radiocarbon dates within a timely fashion.

The directors and staff scientists have over 100 years of combined experience in radiocarbon dating. Radiocarbon dating at Beta Analytic is not a division within a larger institution. It is the sole purpose of the company with scientists who have devoted themselves to service rather than internal research. This, combined with the policy of excess-capacity with regards to equipment, personnel and suppliers has resulted in Beta Analytic never passing its fixed promised delivery schedules.

Presently, open contracts exist with the USGS, National Park Service, Corp of Engineers, US Forest Service, Smithsonian Institution and major universities. Analyses are regularly performed for researchers in the US, Canada, Sweden, Norway, England, Ireland, Japan, Thailand, Malaysia, Pakistan, Switzerland, Australia, Argentina, Chile, Columbia, Bolivia, Italy, Taiwan, Mexico, "USSR" and China.

BETA ANALYTIC, INC.

Section: Policy Statement

Revision: 1

Page 2 of 1

Effective Date: January 1, 1996

Beta Analytic presently has a capacity far beyond the needs of any individual submitter or research project. Beta Analytic places its obligation towards meeting its promised delivery schedules second only to providing accurate results. Its collaboration with the worlds leading AMS dating facilities provides for constant intercalibration and consistent quality of results.

To fulfill the commitment and requirements imposed by the U.S. Geologic Survey (USGS) - Yucca Mountain Project, Beta Management is directing all employees that support this work to comply with the requirements of this Quality Assurance (QA) Manual.

BETA ANALYTIC, INC.

Section: Table of Contents
 Revision: 2
 Page 1 of 1
 Effective Date: April 28, 1996

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Approved: Darden G. Hood Date: January 1, 1996
 Co-director and President, Beta Analytic Inc.

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4.0	Procurement and Receipt Control	2
5.0	Technical Procedures	0
6.0	Document Control	2
7.0	Identification and Control of Samples	0
8.0	Calibration	1
9.0	Deficiency Reporting	1
10.0	Records	1
11.0	Audits	1

ATTACHMENTS

- 2.1 Personnel Indroctrination and Qualification Form
- 5.1 SEM Photomicrograph of filimentous graphite
- 7.1 Example date report

August 24, 1995; the following was added. (Darden Hood) Rev.1

[4.1 Quality Assurance document from Isotech, Inc.]

PART B TECHNICAL PROCEDURES

January 1, 1996; the following was added. (Darden Hood) Rev. 2

PART C IMPLEMENTING PROCEDURES

BETA ANALYTIC, INC.

Section: 1.0

Revision: 0

Page 1 of 1

Effective Date: January 1, 1995

1.0 QA PROGRAM

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

1.1 General

This QA Plan establishes the QA program requirements for quality affecting activities performed by Beta Analytic, Inc. for the USGS, Yucca Mountain Project.

Quality affecting activities are defined as any function or task associated with the analysis of geological and archaeological materials submitted for Carbon 14 dating by either the radiometric or AMS (accelerator mass spectrometry) dating methods.

1.2 Scope

The requirements in this QA Manual apply to radiocarbon dating of geological and archaeological carbon bearing materials.

BETA ANALYTIC INC.

RADIOCARBON DATING SERVICES

Dr. MURRY A. TAMERS
Mr. DARDEN G. HOOD
Directors

RONALD E. HATFIELD
Laboratory Manager

CHRISTOPHER PATRICK
TERESA A. ZILKO-MILLER
Associate Managers

Mr. Pete Rodriguez
U.S.G.S.
755 Parfett
Lakewood, Co 80215

April 29, 1996

Dear Pete:

I have enclosed a copy of the the 1996 QA plan and hard-copies of specific section changes implemented to address DOE deficiencies.

Beta Analytic agrees to the following with regards to providing it's services to the Yucca Mountain USGS research team.

1. As negotiated and quoted on existing contracts, we agree to provide a quality assurance report along with dating reports. This report will be provided for AMS radiocarbon dating analyses provided through our joint collaboration with Lawrence Livermore National Laboratory. It will contain the results, and my interpretation, of the the QA pertinent reference standards measured along with the Yucca Mountain USGS research samples.

2. When we send the samples (as graphite) to Lawrence Livermore National Laboratory, we include a list of the samples and standards in the box. We refer to this list as the "task list". We will include a copy of this list along with the results when they are reported.

3. In the event Lawrence Livermore becomes incapable of making the measurements, we will contact the Yucca Mountain USGS Contracts Office before proceeding with measurements at one of our other collaborating AMS facilities.

4. Since all technicians and working colleagues are subordinant to the direction of Dr. Murry Tamers, Mr. Darden Hood, Mr. Ronald Hatfield, Mr. Christopher Patrick, and Ms. Teresa Zilko-Miller (the Beta Analytic officers and managers listed on the company letterhead), these persons take responsibility for the reported results (as based on the C14 content measurements). This specifically addresses DOE deficiency number YMQAD-95-P-005.

9 per 5/7/96

If you have any questions, please do not hesitate to contact me. If this documentation is sufficient to "close this file", please send me written notification to that effect.

Sincerely,



Darden Hood
President

4985 S.W. 74 COURT. MIAMI, FL 33155 U.S.A.

TELEPHONE: 305-667-5167 / FAX: 305-663-0964 / INTERNET: beta@analytic.win.net

WWW HOME PAGE: <http://www.win.net/~analytic/>

3.0 SOFTWARE AND DATA MANAGEMENT

Approved: _____ Darden G. Hood Date: January 1, 1996
 Co-director and President, Beta Analytic Inc.

3.1 General

This section establishes the requirements and responsibilities for the management of the software used and data produced.

3.2 Requirements

3.2.1 Software

The analytical software used at Beta Analytic is internally designed. All programs incorporate multiple cross checks and are run in a compiled mode to avoiding alteration or tampering.

January 1, 1996; the following was added to the above: (Darden Hood) Rev. 1

[Calculation of results is based on the conventions stated and agreed upon in the Journal *Radiocarbon*, Vol. 19, No. 3, 1977, P. 355-363. The age equation is $8033 \times \ln$ (reference standard C14 activity/measured sample activity). Precision is calculated using Gaussian statistics.]

3.2.2 Data

All data is reviewed and verified by a qualified person prior to reporting. Logistical and analytical accuracy is verified by a quality assurance manager prior to reporting.

3.3 Records

~~Hard-copy printouts are attached to each analyzed sample.~~

January 1, 1996; the above was modified to: (Darden Hood) Rev. 1

Hard-copy printouts are attached to each analyzed sample. The hardcopies supply the data necessary to permit independent reproducibility by another qualified individual.

IMPLEMENTING PROCEDURES

BETA ANALYTIC, INC.

Section: Table of Contents

Revision: 0

Page 3 of 1

Effective Date: January 1, 1996

January 1, 1996; the following section was added. (Darden Hood) Rev.1

Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

PART C IMPLEMENTING PROCEDURES

These procedures are proprietary and are maintained seperately from the QA manual and associated technical procedures. Implementing procedures each have a unique identifier, including revision designation. They are reviewed, approved, and maintained by a QA manager. They are available for review at Beta Analytic.

Ver
P-008

BETA ANALYTIC, INC.

Section: Table of Contents
 Revision: 2
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 Effective Date: April 28, 1996

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 Co-director and President, Beta Analytic Inc.

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8.0	Calibration	1
9.0	Deficiency Reporting	1
10.0	Records	1
11.0	Audits	1

ATTACHMENTS

- 2.1 Personnel Indroctrination and Qualification Form
- 5.1 SEM Photomicrograph of filamentous graphite
- 7.1 Example date report

August 24, 1995; the following was added. (Darden Hood) Rev. 1

[4.1 Quality Assurance document from Isotech, Inc.]

PART B TECHNICAL PROCEDURES

January 1, 1996; the following was added. (Darden Hood) Rev. 2

PART C IMPLEMENTING PROCEDURES

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1
P-208*

6.0 DOCUMENT CONTROL

Approved: Darden G. Hood Date: April 28, 1996
Co-director and President, Beta Analytic Inc.

6.1 General

This section establishes the responsibilities for document preparation, review, approval and distribution of this QA Plan and associated technical procedures, including changes thereto.

6.2 Requirements

The quality assurance managers are responsible for preparing, reviewing, approving, distributing and maintaining documents; including changes.

6.3 Records

~~Master copies of all quality affecting documents are maintained and edited as changes are implemented.~~

~~August 17, 1995, the above was changed to: (Darden Hood) Rev. 1~~

~~6.3.1 The QA manual, including the QA Program and Technical Procedures~~

~~A master copy of the QA program is presently kept both in the computer and in hard-copy. Amendments to the program are recorded in either the hard-copy or the computer version, depending on the magnitude of the change. Routine changes to the documents are made by setting apart the old text (one line through it, quotes, parentheses, spacing, etc.) and insertion of the new text. Annually, all amendments are reviewed and verified and a revision number is given to the program.~~

~~April 28, 1996, the following was added: (Darden Hood) Rev. 2~~

~~6.3.2 Implementing procedures~~

~~These procedures are proprietary and are maintained separately from the QA manual and associated technical procedures. Implementing procedures each have a unique identifier, including revision designation. They are reviewed, approved, maintained by a QA manager and are listed in the QA manual table of contents.~~

Low P-008

BETA ANALYTIC, INC.

Section: 11.0

Revision: 1

Page 1 of 1

Effective Date: January 1, 1996

11.0 AUDITS

Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

11.1 General

This section establishes requirements for internal laboratory QA audits to verify compliance with, and to determine the effectiveness of, the QA Program.

11.2 Requirements

~~Internal audits shall be scheduled, planned and performed by the YMP USGS QA Office.~~

January 1, 1996; the following was changed to: (Darden Hood) Rev. 1

~~Audits shall be scheduled, planned, and performed by the Office of Quality Assurance Yucca Mountain Project Quality Assurance Division.~~

11.3 Records

Quality Assurance records generated from the implementation of this section shall be maintained by the USGS QA Office.

12/95
P-012

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Approved: _____ Darden G. Hood _____ Date: January 1, 1996
 Co-director & President, Beta Analytic

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11.0	Final Reports	0
12.0	Updating the Chart	0
13.0	AMS Procedures	0
14.0	SEM Procedures	0

→ for P-010

4.0 PROCUREMENT AND RECEIPT CONTROL

Approved: Darden G. Hood Date: January 1, 1996
 Co-director and President, Beta Analytic Inc.

4.1 General

Beta Analytic has a long standing relationship with its suppliers. Established accounts with suppliers of known, tested materials provides for efficient purchase of needed supplies as demand requires. Consumable products are acknowledged as acceptable by the signing of the invoice or delivery ticket. Quality affecting materials are inspected prior to use.

4.2 Records

~~Signed delivery tickets, invoices, certificates of analysis and/or internal testing results are maintained as records of acceptance of quality affecting products and services.~~

August 24, 1995, the above was changed to the following; (Darden Hood) Rev. 1

Signed delivery tickets, invoices, certificates of analysis and/or internal testing results serve as records of acceptance of quality affecting products and services.

4.3 Performance tests on quality affecting products.

Quality affecting chemicals are tested for integrity prior to use.

April 28, 1996, the following was added; (Darden Hood) Rev. 2

4.4 Procurement of AMS radiocarbon dates

a. AMS measurements are performed at Lawrence Livermore National Laboratory. In the event an alternative AMS facility is needed to provide results, the USGS contract office will be contacted for authorization, prior to AMS measurement.

b. The "task list" sent along with the samples to Lawrence Livermore National Laboratory will be included in the mailed copy of the date report.

*for
 2-20-96
 2-22-96*

BETA ANALYTIC, INC.

Section: 2.0

Revision: 2

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Effective Date: January 1, 1996

2.0 ORGANIZATION

Approved: Darden G. Hood Date: January 1, 1996
 Co-director and President, Beta Analytic Inc.

2.1 General

This section establishes the responsibilities of Beta Analytic, Inc. ~~General Manager & Laboratory Head (Rev. 2) January 1, 1996; this was changed to~~ ["President"] associated with the implementation of this QA Program and the qualification and training of Beta personnel performing quality affecting activities.

2.2 Requirements

2.2.1 Organizational Structure

~~The organizational structure of Beta Analytic, Inc. consists of the General Manager & Laboratory Head and three key individuals; the laboratory manager and two associate managers. These four managers are responsible for the implementation of this QA Program. They have analyzed more samples than anybody else in the world. The QA/QC for materials analyzed under their supervision is unsurpassed. They are each Quality Assurance Managers. Their responsibilities include the following:~~

~~August 24, 1995, the above was changed to: (Darden Hood Rev. 1~~

~~The organizational structure of Beta Analytic, Inc. consists of the General Manager & Laboratory Head and three key individuals; the laboratory manager and two associate managers. These four managers are responsible for the implementation of this QA Program. They have analyzed more samples than anybody else in the world. The QA/QC for materials analyzed under their supervision is unsurpassed. They are each Quality Assurance Managers. They themselves are not solely responsible for the quality of results. All staff members consistently, and routinely cross-check each other. Every sample/sample data is generally viewed by as many as 8 to 10 people. At no time is one sample viewed/reviewed by only one person. Directly, the responsibilities of the managers include the following:~~

- a. ~~approving and interpreting this QA Program, including implementing procedures;~~
- b. ~~providing indoctrination and training of personnel;~~

- c. identifying quality problems; initiating, recommending, and providing solutions to quality problems; and verifying solutions to quality problems;
- d. verifying the proper establishment and execution of this QA Program;
- e. assuring that unsatisfactory conditions are properly controlled, including stopping work that does not meet the requirements outlined herein.

2.2.2 Personnel Qualification and Training

Due to the unique laboratory procedures and protocols employed, the quality assurance managers do not consider previous experience in the training and indoctrination of personnel. All new personnel start at an entry-level position. Each person is required to keep a notebook of all procedures associated with their responsibilities. A quality assurance manager reviews the notebook and documents approval prior to releasing personnel from their direct supervision.

2.3 Records

Quality Assurance records generated from the implementation of this section include:

1. Completed Beta Personnel Qualification Form, Attachment 2.1.
2. Maintaining a training notebook.

3.0 SOFTWARE AND DATA MANAGEMENT

Approved: _____ Darden G. Hood Date: January 1, 1996
 Co-director and President, Beta Analytic Inc.

3.1 General

This section establishes the requirements and responsibilities for the management of the software used and data produced.

3.2 Requirements

3.2.1 Software

The analytical software used at Beta Analytic is internally designed. All programs incorporate multiple cross checks and are run in a compiled mode to avoiding alteration or tampering.

January 1, 1996; the following was added to the above: (Darden Hood) Rev. 1

[Calculation of results is based on the conventions stated and agreed upon in the Journal *Radiocarbon*, Vol. 19, No. 3, 1977, P. 355-363. The age equation is $8033 \times \ln(\text{reference standard C14 activity/measured sample activity})$. Precision is calculated using Gaussian statistics.]

3.2.2 Data

All data is reviewed and verified by a qualified person prior to reporting. Logistical and analytical accuracy is verified by a quality assurance manager prior to reporting.

3.3 Records

~~Hard copy printouts are attached to each analyzed sample.~~

January 1, 1996; the above was modified to: (Darden Hood) Rev. 1

Hard-copy printouts are attached to each analyzed sample. The hardcopies supply the data necessary to permit independent reproducibility by another qualified individual.

4.0 PROCUREMENT AND RECEIPT CONTROL

Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

4.1 General

Beta Analytic has a long standing relationship with its suppliers. Established accounts with suppliers of known, tested materials provides for efficient purchase of needed supplies as demand requires. Consumable products are acknowledged as acceptable by the signing of the invoice or delivery ticket. Quality affecting materials are inspected prior to use.

4.2 Records

~~Signed delivery tickets, invoices, certificates of analysis and/or internal testing results are maintained as records of acceptance of quality affecting products and services.~~

August 24, 1995, the above was changed to the following; (Darden Hood) Rev. 1

~~Signed delivery tickets, invoices, certificates of analysis and/or internal testing results serve as records of acceptance of quality affecting products and services.~~

4.3 Performance tests on quality affecting products:

~~Quality affecting chemicals are tested for integrity prior to use.~~

April 28, 1996, the following was added; (Darden Hood) Rev. 2

4.4 Procurement of AMS radiocarbon dates:

a. AMS measurements are performed at Lawrence Livermore National Laboratory. In the event an alternative AMS facility is needed to provide results, the USGS contract office will be contacted for authorization, prior to AMS measurement.

b. The "task list" sent along with the samples to Lawrence Livermore National Laboratory will be included in the mailed copy of the date report.

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Effective Date: January 1, 1995

5.0 TECHNICAL PROCEDURES

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

5.1 General

This section establishes the requirements for the development of technical procedures.

5.2 Requirements

All work shall be performed in accordance with this QA Plan and approved technical procedures.

5.3 Records

A master copy is maintained and updated with revisions as they are implemented.

6.0 DOCUMENT CONTROL

Approved: Darden G. Hood Date: April 28, 1996
Co-director and President, Beta Analytic Inc.

6.1 General

This section establishes the responsibilities for document preparation, review, approval and distribution of this QA Plan and associated technical procedures, including changes thereto.

6.2 Requirements

The quality assurance managers are responsible for preparing, reviewing, approving, distributing and maintaining documents; including changes.

6.3 Records

~~Master copies of all quality affecting documents are maintained and edited as changes are implemented.~~

August 17, 1995, the above was changed to: (Darden Hood) Rev. 1

6.3.1 The QA manual; including the QA Program and Technical Procedures

A master copy of the QA program is presently kept both in the computer and in hard-copy. Amendments to the program are recorded in either the hard-copy or the computer version, depending on the magnitude of the change. Routine changes to the documents are made by setting apart the old text (one line through it, quotes, parentheses, spacing, etc.) and insertion of the new text. Annually, all amendments are reviewed and verified and a revision number is given to the program.

April 28, 1996, the following was added: (Darden Hood) Rev. 2

6.3.2 Implementing procedures

These procedures are proprietary and are maintained separately from the QA manual and associated technical procedures. Implementing procedures each have a unique identifier, including revision designation. They are reviewed, approved, maintained by a QA manager and are listed in the QA manual table of contents.

7.0 IDENTIFICATION AND CONTROL OF SAMPLES

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

7.1 General

This section establishes the requirements for identification, control, and traceability of samples.

7.2 Requirements

7.2.1 Sample Identification

A unique laboratory number is placed directly on each individual sample (and sub sample) using indelible ink. This number, along with the submitter's name, submitter's number, and material type are used to collectively identify the sample.

7.2.2 Sample Tracking

Samples are tracked from collection through final using a chart of individual sample progress and sample data sheets.

7.2.3 Sample Traceability

The laboratory number, plus some identifiable portion of the submitter number is written on all documentation associated with the samples.

7.2.4 Nonconforming Samples

Nonconforming samples are those that contain inconsistencies between submittal documents and sample containers. Handling methods are discussed in technical procedures.

7.3 Records

Records include all correspondence, sample data sheets, written log sheets, the laboratory tracking chart and computer records.

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Effective Date: January 1, 1995

8.0 CALIBRATION

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

8.1 General

This section establishes requirements for the calibration and control of liquid scintillation counters (LSC) used for the measurement of C14 content.

8.2 Requirements

8.2.1 Calibration Standards

Calibration is to NBS Oxalic acid. High sensitivity secondary internal standards are calibrated to Oxalic acid and used to maintain instrument calibration. Internal standards are directly traceable to the oxalic acid.

8.2.2 Accuracy

LSC's must show reproducibility within 1% to qualify for analysis of unknown materials. Once calibrated, reference standard variation of less than 1% and daily instrument stability changes of less than 1 to 3% are required to remain on-line.

8.2.3 Calibration Schedule

A calibration shall be performed whenever the accuracy of equipment is suspect and at quarterly intervals.

8.2.4 Controlled environment

Calibration is dependent on temperature control. The LSC's are maintained in a temperature controlled room with backup environmental equipment.

8.2.5 Procedures

Calibrations are performed in accordance with documented procedures discussed in technical procedures.

8.2.6 Identification

LSC's are primarily identified by number and secondarily by a color code.

8.2.7 Calibration Status and Tracking

Computer and written files are maintained to track and schedule routine calibrations and calibration results.

8.2.8 LSC Calibration Documentation

Counter calibration documentation includes all necessary data to uniquely identify and attach the appropriate calibration to the appropriate instrument.

8.2.9 Documenting the Use of LSC's

A record is maintained including the date and results of all standards and unknowns measured in each instrument.

8.2.10 Out-of-Calibration LSC's

Counters are considered to be out-of-calibration if either of the following conditions exist:

- a. The calibration due date or interval has passed without recalibration; or
- b. The instrument becomes unstable.

8.2.11 Counters consistently falling out-of-calibration are removed from service, repaired or replaced.

8.3 Records

Written and computer records are maintained for all standard measurements, unknown measurements and instrument performance history.

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TECHNICAL PROCEDURES

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TECHNICAL PROCEDURES

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Co-director and President, Beta Analytic Inc.

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Effective Date: January 1, 1995

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

3.0 CHEMICAL ANALYSIS & PRETREATMENT

3.1 General and Requirements.

Prior to chemical analysis, an associate manager inspects the sample and verifies that both the log-in and cataloging of the sample were performed accurately. Correspondence is scrutinized and prescriptions for chemical analyses are formulated. Any nonconformances halt the analysis of the sample. A "green sheet" is filled out and, if necessary, the submitter is contacted for instructions.

Isolation of the appropriate atoms for measurement determines the accuracy of the measurement. Pretreatments include complete mechanical and physical isolation of the best possible carbon fraction for dating. Physical pretreatments consist of removing anomalous organic components (associated silts/sediments/roots/etc.) in the attempt to isolate a single component which best represents the desired time event (e.g. charcoal in the case of an archaeological hearth feature). Chemical pretreatments consist of exposing the isolated material to the full range of pH. Alkaline and acid solutions (concentrations, exposure times, and temperatures monitored) are individually applied to remove carbonates and secondary organic acids. In special cases, cellulose, collagen, or solvent extractions are applied to complex samples. The pretreatment applied to each sample is listed on the date report along with each result. In depth discussion of those pretreatments are included in a glossary of pretreatment terms included with each date report.

3.2 Records

Pretreatment procedures are recorded and maintained in a master manual. This manual is verified and amended by QA managers as changes are implemented.

Initial calibration of LSCs consists of baseline measurements for background and efficiency. An internal standard, directly traceable to Oxalic acid is repeatedly measured to determine the modern reference value. A highly sensitive "hot" solution is measured before and after each counting period to monitor instrument stability. The counter is taken off line if the variation in this standard is more than 1 to 3 %. The instrument is returned to service if subsequent monitoring, assessment, and/or repair result in reference standard variation of less than 1%.

The scintillator used is butyl-PBD dissolved in toluene, and the cocktail consists of 4 mls sample benzene plus 0.5 mls scintillation solution. If 4 mls of sample benzene are not available, reagent grade (99.999% pure) Thiophene free benzene is added.

Measurement is made on an interval basis of 50 or 100 minutes to allow statistical analysis of the scintillation counter. Prior to removing the sample from the counter, stability is verified and the data is scrutinized for anomalies. If the distribution does not closely follow Gaussian statistics, the sample is transferred and counted in another counter for verification. Counting is performed for periods of 1 to 5 days.

Calculation of the date is performed only after cross-checking all transcribed numbers, synthesis records, cocktail preparation, counting data, and counting analysis. The calculation program contains multiple questions which double and triple cross-check the data entry in a fool-proof fashion. Calculations are based on the Libby half life and follow the conventions of Stuiver and Polach (*Radiocarbon, Volume 3, 1977*).

Published methodology is used in all aspects of analysis. See references.

4.2 Records

Radiometric analysis and counter loading procedures are recorded and maintained in a master manual. This manual is verified and amended by QA managers as changes are implemented.

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Revision: 1

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Effective Date: August 19, 1995

Approved: Darden G. Hood Date: April 19, 1996
Co-director and President, Beta Analytic Inc.

5.0 AMS ANALYSIS OF SMALL QUANTITY SAMPLES

5.1 General and Requirements.

AMS (Accelerator Mass Spectrometry) is a direct counting method used to analyze extremely small samples (as compared to decay counting used in radiometric dating which requires much larger samples). AMS measurements are performed through a collaboration with Accelerator Laboratories. ~~These laboratories presently include ETH (Eidgenössische Technische Hochschule) in Zürich, Switzerland, CAMS (Lawrence Livermore National Laboratory) in Livermore, California, and OxA (Oxford University Accelerator Group) in Oxford, England. By the end of 1995 ANSTO (Australian Nuclear Science & Technology Organization) in New South Wales, Australia, RuG (Centrum voor Isotopen Onderzoek) in Groningen, The Netherlands, and PRIME Lab (Purdue University) are expected to join the consortium.~~

April 19, 1996; the above was modified to the following. (Darden Hood) Rev. 1

[These laboratories presently include ETH (Eidgenössische Technische Hochschule) in Zürich, Switzerland, CAMS (Lawrence Livermore National Laboratory) in Livermore, California, OxA (Oxford University Accelerator Group) in Oxford, England and the New Zealand Institute for Geological and Nuclear Sciences.]

All chemical treatments and target preparation are performed by Beta in our AMS graphitization laboratory. The samples are then sent by express courier to one of the collaborating AMS facilities for measurement. Results are returned via computer link for final calculation, cross-checks and reporting.

The consortium allows for analysis of large numbers of samples with short turn-around times. The Beta Consortium provides the most dependable delivery times in the world. Other laboratories only have one instrument (Accelerator Mass Spectrometer). Beta has up to 6 instruments at one time, eliminating the problem of delay in delivery due to instrument malfunction.

Sample graphitization results in filamentous graphite (See SEM photo in Attachment 5.1). This type of graphite is a loose, fluffy black powder, and is the best material for the accelerator. Good yields, low backgrounds and fewer memory problems (than CO₂) are characteristics of graphite measurement.

C14 content and age measurement is four part process; 1) production of ions from the sample, 2) acceleration of the ionized particles, 3) separation of isotopes by weight, and 4) counting of number of ions present. The sample is ionized by a Cesium (Cs+) ion source. The Cs+ beam bombards the sample, releasing C- ions in a process known as sputtering. The flow of C- ions produced is known as the beam current. This ion flow is channelled and accelerated through the machine,

stripped of electrons to create a positive carbon ion and passed through a magnetic field. The heavier the ion, the less its path will be affected by the magnet (12C ions the most and 14C ions the least). This allows the ions to be separated by mass. Each type of ion beam current is then collected and measured in terms of a current (milliamps) which is compared to the values obtained from reference standards.

Chemical analysis is essentially a 3 part process; 1) pretreatment, 2) combustion or acidification to CO₂, and 3) graphitization. Pretreatment has already been discussed. Combustion = C (in sx) + O₂ →heat→ CO₂. "Five-nine" oxygen (99.999% pure) is used in combination with ascarite to ensure that no CO₂ is present in the O₂ used for combustion. Achieving a good vacuum is essential in AMS (remember we are dealing with numbers of atoms). This is achieved with the help of a water vapor purge. Electronic pressure gauges monitor line pressure to millitorrs. Sulfur compounds and water in the sample gas are removed through distillation using various types of slushes at various temperatures. Acidification = CaCO₃ + H₃PO₄ → CO₂. No distillation is necessary since impurities present in the sample (ie. not carbon) remain behind in the acid. Graphitization = CO₂ + 2H₂ → C + H₂O. It is accomplished with the aid of a cobalt catalyst. This Co powder is pretreated in a hydrogen atmosphere prior to the production of graphite. The Co is heated to 600C in H₂. Any C present is converted to methane gas (CH₄) and any water present vaporizes at this high temperature. Both of these contaminants can then be pumped away. The sample CO₂ is then introduced into the evacuated reaction vessel (containing the pretreated Co catalyst), mixed with H₂ gas and the Co reaction site is heated to 600C. Graphite (pure C) forms on the Co and water (H₂O) is produced as a side product and is frozen out with methane slush in a separate freeze tip. The graphite is then loaded into a target and sent to the AMS lab for counting.

Graphite from standards is produced using the same chemical techniques and materials as the samples. These are used to monitor the chemical synthesis at Beta and to calculate the sample age. Standard graphite is produced from NBS Oxalic acid, TIRI wood (4,500 BP), TIRI turbidite (18,300 BP) and splits of radiometrically analyzed materials. The oxalic acid is used to calculate the radiocarbon age. The three known age standards are used to ensure chemical synthesis purity, instrument stability, intercalibration, and as quality control on both laboratories.

Graphite produced from coal (for organic materials) and calcite (for carbonates) is used for background measurements. The source of background for AMS C¹⁴ dating is variable and highly dependant on sample chemistry. The measured activities of these background materials signify the amount of contamination present in our pretreatments, graphitization system, and the accelerator itself. This contamination is assumed to be present in every sample. As long as it remains constant, it is subtracted as background activity from each sample and standard measurement. Typical backgrounds on Beta graphite in the CAMS accelerator are around 49,000 years (as compared to machine background on NBS graphite of 60,000 years).

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Effective Date: August 19, 1995

Published methodology is used in all aspects of AMS analysis. See references.

5.2 Records

AMS analysis procedures are recorded and maintained in a master manual. This manual is verified and amended by QA managers as changes are implemented.

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Effective Date: January 1, 1996

Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

6.0 STABLE ISOTOPE RATIOS (C13/12)

6.1 General and Requirements.

Measurement of C13/C12 ratios is done in collaboration with Isotech, Inc. in Champaign, Illinois. ~~Material pretreatment and combustion is performed at Beta Analytic and the sample gas is then shipped to Isotech for measurement. Results are returned via computer link for final calculation, cross checks and reporting.~~

January 1, 1996; The above was modified to the following. (Darden Hood)
Rev. 1

[Material pretreatment is performed at Beta Analytic. The solid sample, or the sample as CO₂, is then shipped to Isotech for measurement. Results are returned via computer link for final calculation, cross-checks and reporting.]

See Appendix A for QA/QC at Isotec.

6.2 Records

C13/C12 sample preparation procedures are recorded and maintained in a master manual. This manual is verified and amended by QA managers as changes are implemented.

BETA ANALYTIC, INC.

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Effective Date: January 1, 1995

Approved: Darden G. Hood Date: January 1, 1995

Co-director and President, Beta Analytic Inc.

7.0 DATE REPORT/CALENDAR CALIBRATION

7.1 General and Requirements.

A cumulative list of cross-checks is performed on each sample prior to summarizing the sample(s) in a listed date report. The final report contains each sample dating result, along with it's submitter number, our laboratory number, the material type, the pretreatment applied, the analysis method used, and any special comments. The conventions used in the calculations are listed on each report sheet.

Each report package includes a letter, the final dating results, a statement of procedures and final reporting, a pretreatment glossary, calendar calibrations (where applicable), calibration literature, and blank sample data sheets. Invoices are either included with the results or sent separately.

Applicable calendar calibrations are included for organic materials and fresh water carbonates between 0 and 10,000 BP and for marine carbonates between 0 and 8,300 BP. Calibrations are not included if the results are too young, too old, or inappropriate for calibration. The submitter is told to read the calibration explanation sheet before interpreting the results (especially for calcareous materials). Calibration is performed using the internationally accepted calibration data (Stuiver et. al., 1993) and calculated using the method of spline fitting (Talma et. al., 1993).

See Attachment 7.1 for an example date report.

7.2 Records

Date reporting procedures are recorded and maintained in a master manual. This manual is verified and amended by QA managers as changes are implemented.

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Effective Date: January 1, 1995

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

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January 1, 1996; the following section was added. (Darden Hood) Rev.1

Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

PART C IMPLEMENTING PROCEDURES

These procedures are proprietary and are maintained separately from the QA manual and associated technical procedures. Implementing procedures each have a unique identifier, including revision designation. They are reviewed, approved, and maintained by a QA manager. They are available for review at Beta Analytic.

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QUALITY ASSURANCE PLAN

BETA ANALYTIC, INC.

Section: 9.0

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9.0 DEFICIENCY REPORTING

Approved: Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

9.1 General

Deficiencies are defined as materials or measurements deemed unsuitable for C14 age determination. Should the material prove to be unsuitable for analysis, or should results be too subjective for reporting, the submitter is contacted and given options. If a laboratory error occurs, excess material is re-analyzed.

9.2 Records

Samples are placed on hold, using their uniquely defined sample designation numbers. The submitter is contacted and all correspondence is documented on a "green sheet" which is maintained in the submitter's file.

BETA ANALYTIC, INC.

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Revision: 0

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Effective Date: January 1, 1995

10.0 RECORDS

Approved: _____ Darden G. Hood Date: January 1, 1995
Co-director and President, Beta Analytic Inc.

10.1 General

This section establishes the requirements to control the review and retention of records required by this QA Program.

10.2 Requirements

10.2.1 It is the responsibility of the quality assurance managers to ensure required records are complete, legible, and accurate.

10.2.2 Unless otherwise requested, these records shall be maintained for a minimum of 3 years.

10.3 Records

A quality assurance manager reviews and acknowledges the accuracy, legibility and completeness of every analysis performed. This is denoted by the attachment of the initials of the reviewing manager to every analysis tracking sheet.

QUALITY ASSURANCE PLAN

BETA ANALYTIC, INC.

Section: 11.0

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Effective Date: January 1, 1996

11.0 AUDITS

Approved: Darden G. Hood Date: January 1, 1996
Co-director and President, Beta Analytic Inc.

11.1 General

This section establishes requirements for internal laboratory QA audits to verify compliance with, and to determine the effectiveness of, the QA Program.

11.2 Requirements

~~Internal audits shall be scheduled, planned and performed by the YMP USGS QA Office.~~

January 1, 1996; the following was changed to: (Darden Hood) Rev. 1

Audits shall be scheduled, planned, and performed by the Office of Quality Assurance Yucca Mountain Project Quality Assurance Division.

11.3 Records

Quality Assurance records generated from the implementation of this section shall be maintained by the USGS QA Office.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

Performance Report
 Deficiency Report

NO. YMQAD-95-D009

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PR/DR CONTINUATION PAGE

AMENDED RESPONSE - YMQAD-95-D009

The following information revises and replaces the 12/8/95 response.

Block 12: Remedial Actions (revised):

(A) Based upon discussions among R. Maudlin (YMQAD), B. Parks (USGS ESIP) and T. Chaney (USGS QA) held March 28, 1996 in Lakewood, Colorado, Beta Analytic, Inc. has been asked to revise certain sections of their Quality Assurance Plan to conform to QARD requirements. The attached letter with 1996 QA Plan from Darden Hood (Beta Analytic, Inc.) to Pete Rodriguez (USGS) dated April 29, 1996 documents Beta's collaborative relationship with Lawrence Livermore National Laboratory (LLNL) for the accelerator mass spectrometry (AMS) services provided by LLNL.

(B) -Same as initial response of 10/12/95 -

Block 14: Remedial Action Due Date:

Actions complete with this response.

Block 18: Investigative Actions (revised):

(A) YMQAD (through R. Maudlin) and the USGS worked with Beta Analytic, Inc. to determine the extent of revisions needed to the Beta QA Plan. The attached letter and QA Plan described the revisions Beta Analytic, Inc. has made in response to the deficiencies noted by this report.

(B) -Same as initial response of 10/12/95 -

Block 19: Root Cause Determination (revised):

(A) The USGS contracts with Beta Analytic, Inc. relied upon a Beta Analytic, Inc. QC plan which was not an approved YMQAD method for accepting subtier suppliers. Therefore Beta Analytic, Inc. was not required to describe their collaborative relationship with LLNL.

(B) -Same as initial response of 10/12/95 -

5/21/96 Chaney to Spence

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

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PR/DR CONTINUATION PAGE

Block 20: Actions to Preclude Recurrence (revised):

(A) Remedial actions will preclude recurrence of deficiency with Beta Analytic, Inc., while YMQAD-96-C004 will address any other actions as a result of review of USGS procurements for analytical services.

USGS has requested that OQA perform a qualification survey of the LLNL AMS Laboratory. Based on the results of this evaluation, LLNL will be placed on the QSL as a qualified supplier. All procurement documents, both existing and future will contain a statement that Beta Analytic, Inc will use LLNL for all AMS testing in fulfillment of this USGS purchase order. In the event that Beta Analytic, Inc can not use LLNL, no samples will be processed until an alternative method can be established and approved by USGS. Since Beta Analytic, Inc. does not have a program for supplier qualification, USGS will assume the responsibility for qualification of all Beta Analytic, Inc. sub-tier suppliers providing quality affecting services.

Beta Analytic, Inc has documentation which supports the procurement of services from LLNL and is available for review. All future requests for LLNL services or the services of other laboratories will be documented by Beta Analytic, Inc.

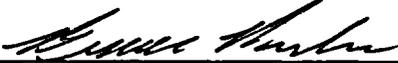
Beta Analytic Inc.'s revised QA Plan assures that only qualified suppliers will be used in the performance of work to USGS purchase orders. LLNL will be used for all AMS measurements. The revised QA Plan states "In the event an alternative AMS facility is needed to provide results, the USGS contract office will be contacted for authorization prior to AMS measurements" (see section 4.4 in Procurement and Receipt Control section of attached Beta Analytic Inc. QA Plan). The USGS thus will be able to ensure that only qualified sub-tier suppliers are used.

(B) -Same as initial response of 10/12/95 -

Block 22 Corrective Action Completion Due Date:

Actions complete with qualification of LLNL by OQA. The anticipated data of completion is July 1, 1996

Block 13/21 Response by:


Robert W. Craig, Chief, Yucca Mountain Project Branch Date 5/16/96

EVALUATION OF RESPONSE TO DR YMQAD-95-D009

The amended response dated May 16, 1996 has been reviewed and found unacceptable in resolving the condition adverse to quality.

The approach to qualify the Lawrence Livermore National Laboratory (LLNL) - Center for Accelerator Mass Spectrometry (AMS) for use by Beta Analytical Inc is acceptable. However, what has not been addressed is the inclusion of QA requirements in Beta procurement documents that LLNL - Center for AMS will work to the QA Program as approved by the USGS.

The QARD, Section 4.0, Subsection 4.2.1(C)(2) states in part: "Procurement documents issuedshall include.... Quality Assurance Requirements including.... A requirement for the supplier to incorporate the appropriate QARD requirements into any sub-tier-issued procurement documents."

Based on the above requirement, re-evaluate your response and indicate the action(s) you have taken with Beta Analytical, Inc to comply with the QARD.


Richard L. Maudlin, QAR

06/03/96
Date

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

- Performance Report
 Deficiency Report

NO. YMQAD-95-D009

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PR/DR CONTINUATION PAGE

AMENDED RESPONSE FOR DEFICIENCY REPORT YMQAD-95-D009

The following provides an update for Item A, Block 20, and amends the 5/16/96 response for Item A, Blocks 20 and 22.

BLOCK 20 Actions to Preclude Recurrence:

Updated Information:

A) The DOE OQA performed a qualification survey of the LLNL AMS Laboratory. Based on the results of this evaluation, one recommendation was made by the auditor that a QA manual and technical procedure be developed for use by LLNL in analyzing USGS-YMPB samples submitted by Beta Analytic, Inc. for AMS dating. The resolution for this recommendation is being completed as part of the actions associated with the YMQAD evaluation of LLNL. LLNL can therefore be placed on the YMP Qualified Suppliers List as a qualified supplier. All procurement documents, both existing and future, will contain a statement that Beta Analytic, Inc. will use LLNL for all AMS testing in fulfillment of the USGS purchase order. In the event that Beta Analytic, Inc. can not use LLNL, no samples will be processed until an alternative method can be established and approved by the USGS. Since Beta Analytic, Inc. does not have a program for supplier qualification, the USGS will assume the responsibility for qualification of all Beta Analytic, Inc. sub-tier suppliers providing quality-affecting services.

Beta Analytic, Inc. revised their QA Plan to assure that only qualified suppliers will be used in the performance of work to USGS purchase orders. LLNL will be used for all AMS measurements. The revised QA Plan states: "In the event an alternative AMS facility is needed to provide results, the USGS contract office will be contacted for authorization prior to AMS measurements" (see section 4.4 in Procurement and Receipt Control section of Beta Analytic Inc. QA Plan-- copy attached to 5/16/96 response). The USGS thus will be able to ensure that only qualified sub-tier suppliers are used.

Amended Information:

A) Beta Analytic, Inc. has documentation available for review which supports the procurement of services from LLNL. All future requests for LLNL services or the services of other laboratories will be documented by Beta Analytic, Inc. This documentation will include the following (or equivalent) terminology: "For the enclosed samples, please follow the current approved QA manual and technical procedure you have developed to support the USGS Yucca Mountain Project work."

BLOCK 21 Response by: Robert W. Craig
for Robert W. Craig, Chief, Yucca Mountain Project Branch

7/31/96
Date

Block 22 Corrective Action Completion Due Date: DR actions completed with this response.