



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 21, 2000

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT
REPORT NO. OAR-01-02, "OBSERVATION AUDIT OF OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION,
AUDIT NO. OQA-SA-01-006"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (OAR) No. OAR-01-02, of the U.S. Department of Energy's (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) supplier audit of Beta Analytic Inc. (BAI). The audit, OQA-SA-01-006, was conducted on November 16-17, 2000, at BAI's facility in Miami, Florida.

The scope of the audit evaluated the effectiveness of the BAI Quality Assurance Program for Yucca Mountain Project Activities, as delineated in U.S. Geological Survey Purchase Order 99CRSA1014 and associated implementing procedures. BAI prepares USGS samples for the Accelerated Mass Spectrometry (AMS) analysis for the purpose of Carbon-14 age dating of the samples. The AMS is performed by LLNL Center for Accelerator Mass Spectrometry which is on the OCRWM approved suppliers list.

The NRC observers concluded that Audit No. OQA-SA-01-006 was effective in determining the level of compliance of BAI activities associated with the Yucca Mountain Project. Within the areas evaluated, the DOE audit team identified a minor potential deficiency which was corrected and verified prior to the writing of the DOE audit report.

The NRC staff determined that this DOE audit was effective in conducting the audit. The NRC staff also agrees with the audit team conclusions, findings, and recommendations, as presented at the audit exit. The NRC observers generated no audit observer inquiries during this audit.

NM5507
WMH

J. Carlson

- 2 -

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at 301-415-6684.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. William Reamer', with a long horizontal flourish extending to the right.

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-01-02, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. OQA-SA-01-006"

cc See attached list.

Letter to J. Carlson from C. W. Reamer dated: December 21, 2000

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
S. Hanauer, DOE/Wash, DC
C. Einberg, DOE/Wash, DC
J. Carlson, DOE/Wash, DC
N. Slater, DOE/Wash, DC
A. Gil, DOE/Las Vegas, NV
R. Dyer, YMPO
S. Brocoum, YMPO
R. Clark, YMPO
C. Hanlon, YMPO
T. Gunter, YMPO
G. Dials, M&O
J. Bailey, M&O
D. Wilkins, M&O
M. Voegele, M&O
S. Echols, Winston & Strawn
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
D. Bechtel, Clark County, NV
E. von Tiesenhausen, Clark County, NV
A. Kalt, Churchill County, NV
G. McCorkell, Esmeralda County, NV
L. Fiorenzi, Eureka County, NV
A. Remus, Inyo County, CA
B. Duke, Lander County, NV
J. Pitts, Lincoln County, NV
J. Wallis, Mineral County, NV
L. Bradshaw, Nye County, NV
M. Murphy, Nye County, NV
J. McKnight, Nye County, NV
B. Ott, White Pine County, NV
D. Weigel, GAO
W. Barnard, NWTRB
R. Holden, NCAI
A. Collins, NIEC
R. Arnold, Pahrump County, NV
J. Lyznicky, AMA
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
J. Curtiss, Winston & Strawn

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. OAR-01-02
OBSERVATION AUDIT OF THE
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE DIVISION
AUDIT NO. OQA-SA-01-006


12/18/00
Ted Carter
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management


12/18/00
Bruce Mabrito
Center for Nuclear Waste
Regulatory Analyses

Reviewed and Approved by:


12/21/00
N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

Enclosure

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management, observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) supplier audit of Beta Analytic Inc. (BAI). Audit No. OQA-SA-01-006, was conducted on November 16-17, 2000, at the facility in Miami, Florida.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the BAI Quality Assurance Program, by reviewing documentation and interviewing BAI staff supporting BAI work activity.

The NRC staff objective was to gain confidence that BAI and OQA are properly implementing the applicable provisions contained in the Quality Assurance Requirements and Description and the requirements contained in Subpart G, "Quality Assurance," to Part 60, of Title 10 of the U.S. Code of Federal Regulations (10 CFR Part 60).

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit No. OQA-SA-01-006 was useful, effective, and conducted in a professional manner. Audit team members were independent of the activities they audited and appeared to be knowledgeable in the quality assurance (QA) and technical disciplines within the scope of the audit. The audit team members' qualifications were previously reviewed and the members were found to be qualified earlier in their respective disciplines.

The audit team concluded that the BAI QA program had been satisfactorily implemented in the areas evaluated. The NRC staff determined that this audit was effective. The NRC staff also agrees with the audit team conclusions and recommendations.

3.0 AUDIT PARTICIPANTS

3.1 NRC Observers

Ted Carter	Team Leader	NRC
Bruce Mabrito	Team Member	Center for Nuclear Waste Regulatory Analyses)

3.2 OQA Audit Team

Richard Maudlin	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
F. Harvey Dove, Ph.D., P.H.	Technical Specialist	OQA/QATSS

3.3 Observer

Bruce Parks	Observer	U.S. Geological Survey (USGS), Denver, CO
-------------	----------	--

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of BAI was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on the NRC Manual Chapter 2410, dated July 12, 2000.

4.1 Scope of the Audit

The scope of the audit was to evaluate the effectiveness of the BAI QA program, Revision QA_5.00, dated January 2000, and associated implementing procedures as delineated in USGS Purchase Order 99CRSA1014 . BAI prepares USGS samples for the Accelerated Mass Spectrometry (AMS) analysis for the purpose of Carbon-14 age dating of the samples. The AMS is performed by LLNL Center for Accelerator Mass Spectrometry which is on the OCRWM approved suppliers list.

4.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team demonstrated a sound knowledge of the applicable M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate the pertinent BAI activities associated with the past and on-going activities and implementation of the QA Program.

The DOE audit team and NRC observers caucused at the end of each day of auditing. Also, meetings of the audit team and BAI management (with the NRC observers always present) were held to discuss the audit status and preliminary findings.

A USGS staff member was present during most of the audit to observe and assist in information transfer and to respond to questions pertaining to the USGS Purchase Order to BAI.

4.3 Audit Team Qualification and Independence

The qualifications of the DOE audit team leader and the OQA audit team member had been reviewed earlier and were then found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by an NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education, and experience records for the two DOE audit team members were previously reviewed and found acceptable. NRC observers had previously reviewed the technical specialist's qualifications and found that the technical specialist had sufficient technical education, training, and experience.

4.4 Examination of QA Programmatic Elements

The NRC staff observed that each of the audit team members reviewed appropriate documentation and interviewed key BAI personnel to determine their understanding of implementing procedures and processes. Training, education, and experience records were reviewed to assure BAI personnel met

the requirements of their individual position descriptions. Objective evidence was provided and reviewed by the auditor and it was determined that all personnel were in compliance.

4.5 Examination of Technical and Programmatic Activities

After an introductory BAI explanation of the general processes used to determine radiocarbon dating information, the DOE auditors used their checklists as a tool to determine if the QA program was being effectively implemented. In addition to specific questions from the prepared programmatic and technical checklists, the auditors used acceptable sampling techniques to determine if traceability of prepared radiocarbon dating specimens was adequate.

Various "Beta numbers" were identified as discrete tasks specifically for the USGS and those were traced back through the BAI documentation chain. These included USGS water samples and other samples submitted in Fiscal Year (FY) 2000, which were traced from initial receipt through to final age determination. Specifically, the DOE audit team tracked 15 water samples that were prepared for the Yucca Mountain program during the FY and found the documentation complete, including the sampling bags, labels, forms, and paperwork. No inconsistencies were noted by the audit team and this was concurred in by the NRC observers.

The BAI management explained that the calibration of radiocarbon dating of samples is accomplished by regular and periodic "round robin" testing at eight Accelerated Mass Spectrometric laboratories worldwide. The DOE audit team and NRC observers were shown documentation to explain how the round robin radiocarbon (or ^{14}C) consortium system functions and how it maintains an age dating calibration control on the labs performing such work.

Preparation of radiocarbon samples in the BAI laboratory was observed by the DOE technical specialist and one of the NRC observers. The sample preparation process is now commercialized by BAI and the technicians followed a standard procedure which was developed in a university laboratory setting by 1970. BAI claims to be the largest radiocarbon dating laboratory in the world now, having produced over 120,000 analyses. The BAI technicians answered the DOE audit team technical specialist questions while performing the preparation activities. The DOE technical specialist also checked the qualifications of the BAI technicians and stated they were well qualified for their positions. The NRC observer concluded that the sample-preparation technicians used approved procedures.

During the programmatic portion of the audit, the DOE audit team leader checked the current BAI QA Program and the applicable criteria for the tasks being performed. The areas of concentration included: the qualification of personnel; certification and documentation; procurement issues; application of appropriate quality requirements in accordance with the USGS Purchase Order; generated nonconformance reports and related corrective actions; calibration of equipment; electronic and hard copies of records; software used; traceability of samples; and use of scientific notebooks when developing new processes. There were no areas of noncompliance noted by the DOE team leader.

The audit team leader's investigations were watched by an NRC observer and there was agreement in the line of questions and concurrence with the stated results.

The DOE audit team technical specialist reviewed sample tracking sheets for USGS/Yucca Mountain program work, along with those for a national museum. The documentation was readily available, easily presented, and well kept according to the DOE audit team member. The NRC observer agreed with the assessment.

During the first day of the audit, it was mentioned by the DOE audit team leader that the latest version of the BAI proprietary implementing procedures, which are part of the QA manual, had a problem of incorrect headers on some of the manual sections. This item was specifically covered in the second day of the audit. Due to the specific text software program in use at BAI and the age of some of the QA manual sections, making the header changes so that the manual was consistent throughout, was not an easy process. In the post-audit meeting the DOE audit team leader stated that if the BAI QA implementing procedures could be made consistent through manipulation of software within approximately 10 days, he would not carry that over as an open item to audit OQA-SA-01-006. BAI management agreed to this arrangement and the DOE audit team leader confirmed that the corrections were made to the BAI proprietary implementing procedures within the time frame. NRC observers were present to see this method of securing compliance and concurred in its application.

The NRC observers concluded that the methods used by the audit team members provided an adequate approach and was effective in determining the level of compliance of the BAI activities.

4.6 NRC Staff Findings

The NRC staff has determined that OQA Audit No. OQA-SA-01-006 was effective in determining the level of compliance of BAI activities associated with the radiocarbon dating services. The NRC staff agreed with the audit team conclusion that the BAI QA program had been satisfactorily implemented. The NRC staff also determined the following:

- The NRC staff found OQA Audit No. OQA-SA-01-006 thorough, comprehensive, technically detailed, and professional.
- The DOE audit team technical specialist did an acceptable job with the technical portion of the audit. He demonstrated an acceptable level of understanding of the technical methods that were the subject of the audit. The radiocarbon dating services BAI was offering were determined to be traceable and acceptable.
- The NRC observers were allowed to question the BAI technical staff as needed.
- The NRC observers were present when the commitment was made by BAI management to correct the BAI implementing procedure header inconsistency.

4.6.1 Audit Observer Inquiries

There were no audit observer inquiries issued during this audit observation, and there were no previous audit observer inquiries at BAI to be closed.

J. Carlson

- 2 -

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at 301-415-6684.

Sincerely,

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-01-02, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. OQA-SA-01-006"

cc: See attached list.

DISTRIBUTION:

File Center	PUBLIC	ACNW	LSS	CNWRA NMSS r/f	HLWB r/f
SWastler	CGlenn	BMabrito	WBelke	JHolonich	KHooks
JHolonich	ECollins	JGreeves	RLatta		

DOCUMENT NAME: S/DWM/HLWB/thc/OAR-01-02BAI Vendor.wpd

ADAMS Accession # ~~XXXXXXXXXX~~

*SEE PREVIOUS CONCURRENCE

OFC	HLWB <i>THC</i>	TECH ED*	HLWB <i>THC</i>	HLWB <i>THC</i>	HLWB
NAME	TCarter:vlm	EKraus	LCampbell	NKStablein	CWReamer <i>CR</i>
DATE	12/18/00	12/18/00	12/18/00	12/21/00	12/21/00

OFFICIAL RECORD COPY

ACNW: YES NO Delete file after distribution: Yes No

1) This document should/should not be made available to the PUBLIC THC 12/18/00
(Initials) (Date)

2) This document is related to the HLW program It should be placed in the LSS THC 12/18/00
(Initials) (Date)