



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

JUL 25 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

**ISSUANCE OF DEFICIENCY REPORT (DR) YM-96-D-076 RESULTING FROM
OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT OQA-SA-96-018 OF CERTIFIED
BALANCE SERVICE, INC. (SCPB: N/A)**

Enclosed is DR YM-96-D-076 generated as a result of Supplier Audit OQA-SA-96-018.

Please identify the corrective action to be taken and implemented to correct the deficiency. A DR Continuation Page has been provided. Send the original of your response to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. Response to the DR is due 20 working days from the date of this letter. Any extension to the due date must be requested in writing, with appropriate justification, prior to that date.

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-2276

Enclosures:

1. DR YM-96-D-076
2. PR/DR Continuation Page

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PDR WASTE
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Robert W. Craig

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JUL 25 1996

cc w/encls:

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 encls:

W. L. Belke, NRC, Las Vegas, NV
R. L. Maudlin, YMQAD/QATSS, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV
D. G. Horton, OQA, NV

310014

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

THIS IS A RED STAMP

☐ Performance Report

☒ Deficiency Report

NO. YM-96-D-076

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QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

Certified Balance Service, Inc.'s Quality Assurance
Manual, August 10, 1995

2 Related Report No.

OQA-SA-96-018

3 Responsible Organization:

U.S. Geological Survey (USGS)/Certified Balance
Service, Inc.

4 Discussed With:

C. Warren Hunsberger

5 Requirement/Measurement Criteria:

Certified Balance Service, Inc.'s Quality Assurance (QA) Manual, Section 4.1, states in part: "Suppliers listed in the Certified Balance Service, Inc. Approved Suppliers List must be used for all quality affecting procurements."

Certified Balance Service, Inc.'s QA Manual, Section 4.2.1, states in part: "Procurement documents for calibration services shall request the following information for each calibration performed: (a) Identification of the supplier, (b) Identification of the equipment being calibrated, (c) Identification of calibration standard(s) used,...., (d) Calibration procedure or method used...., (e) Calibration date, (f) Identification of the person performing the calibration, (g) Records of actual calibration data values...."

(Continued on Page 3)

6 Description of Condition:

Contrary to the above:

- A. No objective evidence in the form of an Approved Suppliers List could be provided.
- B. To date, Certified Balance Service, Inc. has not generated any procurement documents for the services provided by the Colorado Department of Agriculture for the calibration of Certified Balance Service, Inc.'s standards. Subsequently, there was no objective evidence that procurement documents included the required information such as identification of the supplier, identification of the equipment being calibrated, etc.

(Continued on Pages 3 & 4)

7 Initiator

Richard L. Maudlin

Date 7/23/96

9 Is condition an isolated occurrence?

☐ Yes

☐ No

☒ Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

1. Investigate and determine the cause of the noted conditions.

(Continued on Page 4)

11 QA Review:

QAR *[Signature]* for R.L.M. Date 7/23/96

12 Response Due Date

20 Working Days From Issuance

13 Affected Organization QA manager Issuance Approval: (QAR for PR)

Printed Name RESPERNCE

Signature

[Signature]

Date 7-25-96

22 Corrective Action Verified

QAR

Date

23 Closure Approved by: (N/A for PR)

AOQAM

Date

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

16 Root Cause Determination: (Not required for PR)

Required

☐ Yes

☐ No

17 Action to Preclude Recurrence: (Not required for PR)

Required

☐ Yes

☐ No

18 Corrective Action Completion Date:

19 Response by:

☐ Initial

☐ Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

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5 Requirement/Measurement Criteria: (Continued)

Certified Balance Service, Inc.'s QA Manual, Section 4.2.1, states in part: "The QA Director....shall verify that the procurement documents contain provisions for requiring subcontractors to implement appropriate QA Programs...."

Certified Balance Service, Inc.'s QA Manual, Section 4.2.3, states in part: "Selection of contractors/vendors shall be based on an evaluation of their capability to provide items, services, in accordance with the requirements of procurement documents."

Certified Balance Service, Inc.'s QA Manual, Section 4.2.5, states in part: "The acceptability of purchased, quality affecting.... services shall be documented upon receipt by a signature from the QA Director."

Certified Balance Service, Inc.'s QA Manual, Section 7.2.2, states in part: "Calibration standard shall have equal or greater accuracy than the equipment being calibrated."

Certified Balance Service, Inc.'s QA Manual, Section 7.2.9, states in part: "Equipment calibration documentation shall include the following information:....Results....of the calibration and statement of acceptability. The documentation of "as-found" and "as-left" data....Identification of the procedure (including revision level) used in performing the calibration."

USGS's Purchase Order 1434-CR-SA-00698 requires that the calibration documentation include a reference to the USGS purchase order and a statement of accuracy of the standards.

Certified Balance Service, Inc.'s QA Manual, Section 9.2.3, states in part: "To facilitate retrievability and aid in the prevention of loss or deterioration, required records shall be on file in two different locations. The cabinet in at least one facility shall bear the Underwriters' Laboratories label certifying two hour fire protection."

6 Description of Condition: (Continued)

- C. Since no procurement documents have been generated, there is no evidence that procurement documents were reviewed and approved for the purchase of the services of the Colorado Department of Agriculture.
- D. There was no documented evidence of vendor evaluation for the selection and use of the Colorado Department of Agriculture.
- E. In the absence of a procurement document, there was no documented evidence of acceptability of the services provided to Certified Balance Service, Inc. by the Colorado Department of Agriculture.

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6 Description of Condition: (Continued)

- F. The accuracy of the Certified Balance Service, Inc.'s standards (K-1), used to perform the calibration of USGS Scales R200D, Serial #37060137; 1712, Serial #3502098; AT261, Serial #K59633; and 2462, Serial #2709142, was less than that of the equipment being calibrated. Example: The accuracy of the standards was to four decimal places and the accuracy of the scales being calibrated was to six decimal places.
- G. Certifications provided by the Colorado Department of Agriculture for the calibration of the Certified Balance Service, Inc.'s standards (CBS-k-14, CBS-k-25, and CBS-k-26) did not include the "As-Found Condition" and did not reference the procedure and revision level used in performing the calibration.
- H. The calibration documentation provided to USGS for the calibration of the R200D balance did not include reference to the USGS purchase order number and a statement of accuracy that the standards used were equal to or greater than that of the device being calibrated.
- I. QA records are not being stored in two different locations and there was no cabinet maintained by Certified Balance Service, Inc. with a two hour fire rating. Records as defined by Certified Balance Service, Inc. include: Personnel qualifications and indoctrination records, Verified data sheets, CBS Purchase Orders, Technical Procedures, Calibration Records, and Deficiency Reports.

10 Recommended Action: (Not required for PR) (Continued)

- 2. Identify and document the impact on quality of the calibrations performed based on standards with a lesser accuracy.
- 3. Evaluate and document the impact on quality in the absence of Certified Balance Service, Inc.'s procurement documents being issued to the Colorado Department of Agriculture.
- 4. Implement remedial actions on documentation deficiencies and the issue of the lack of dual storage of QA records.
- 5. Identify what measures are going to be taken to prevent recurrence of the identified conditions.

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