

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

SUPPLIER AUDIT REPORT

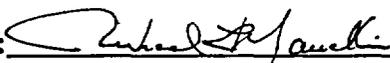
OF

CERTIFIED BALANCE SERVICE, INC.

ENGLEWOOD, COLORADO

REPORT NUMBER OQA-SA-96-018

JULY 17, 1996

Prepared by:  Date: 08/02/96

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Approved by:  Date: 8/4/96

Donald G. Horton
Director
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Enclosure

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Certified Balance Service, Inc. revealed unsatisfactory conditions resulting in the issuance of one Deficiency Report to the U.S. Geological Survey (USGS) for action which relates to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. The Deficiency Report relates to: (1) A lack of implementation of the Certified Balance Service, Inc.'s procurement requirements; (2) Calibration standards did not possess an accuracy equal to or greater than that of the item being calibrated; (3) Certification documentation from the Certified Balance Service, Inc.'s supplier did not include the "As-Found Condition," and reference to the procedure and revision level used to perform the calibration; (4) Certified Balance Service, Inc.'s calibration documentation provided to USGS did not include reference to the USGS purchase order number and a statement of accuracy of the standards used; and (5) QA records were not being stored in two different locations. It should be noted that Certified Balance Service, Inc. issued Revision 1, dated July 15, 1996, of their QA Manual just prior to the audit. A review of the changes produced by this revision was performed to determine any reduction in commitment to the OCRWM Quality Assurance Requirements and Description (QARD) and USGS procurement documents.

The unsatisfactory conditions identified during the audit were discussed with the Director of Certified Balance Service, Inc. who agreed to work with the USGS in resolving the unsatisfactory conditions. Based on the above, impact on the calibrations previously performed by Certified Balance Service, Inc. needs to be evaluated.

The results of the audit warrant a recommendation that use of Certified Balance Service, Inc. be suspended until an evaluation of the impact of the deficiencies on calibrations performed by Certified Balance Service, Inc. have been performed and a determination that Certified Balance Service, Inc. is in full compliance with its QA Manual.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of Certified Balance Service, Inc.'s quality program. This was accomplished by determining if the Certified Balance Service, Inc.'s program satisfies the QA requirements specified in the USGS procurement document 1434-CR-95-SA-00698, implementation of the Certified Balance Service, Inc.'s QA Manual, Revision dated August 10, 1995, as accepted by the USGS, and the OCRWM QARD for the scope of work. The QA program elements determined to be applicable are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Measuring and Test Equipment; Corrective Action; QA Records; and Audits.

3.0 AUDIT TEAM AND OBSERVERS

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

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

C. Warren Hunsberger, President and Director, Certified Balance Service, Inc.
Wayne Rodman, QA Specialist, USGS

5.0 SUMMARY OF AUDIT RESULTS

Certified Balance Service, Inc.'s QA Manual, Revision dated August 10, 1995, addresses the applicable elements of the USGS procurement document 1434-CR-95-SA-00698 and the applicable elements of the OCRWM QARD for the intended scope of work. Implementation of the Certified Balance Service, Inc.'s QA Manual was considered ineffective. Specifics of the unsatisfactory conditions are described in Section 6.0 of this report, "Deficiencies/ Recommendations." One condition adverse to quality was corrected during the audit. This condition related to the documentation for the standards calibrated by the Colorado Department of Agriculture that did not include the due date for recalibration. The documentation was immediately corrected to reflect the due date.

The details of the audit, along with the objective evidence reviewed, are contained within the audit checklist which is available from the OQA's supplier evaluation files.

6.0 DEFICIENCIES/RECOMMENDATIONS

The unsatisfactory conditions have been documented on the respective corrective action document and submitted to USGS for resolution. Recommendations, as applicable, have been provided for USGS/Certified Balance Service, Inc.'s management consideration and action as deemed appropriate. It is requested that USGS/Certified Balance Service, Inc. provide the actions taken in regard to the recommendations discussed in this report.

DEFICIENCIES (DR)

DR YM-96-D-076 - Certified Balance Service, Inc.'s 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." 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 ... The QA Director ... shall verify that the procurement documents contain provisions for requiring subcontractors to implement appropriate QA Programs ...” 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.” 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.” Section 7.2.2 states, in part: “Calibration standard shall have equal or greater accuracy than the equipment being calibrated.” 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 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.”

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.
- 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.
- 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; Certified Balance Service, Inc. Purchase Orders; Technical Procedures; Calibration Records; and Deficiency Reports.

RECOMMENDATIONS

Certified Balance Service, Inc. has been operating to a USGS approved QA Manual, dated August 15, 1995. At the time of this audit Certified Balance Service, Inc. presented a revised QA Manual, Revision 1, dated July 15, 1996. This revised manual was compared to the earlier revision (August 15, 1995) to determine if any of the changes adversely affected Certified Balance Service, Inc.'s commitments to meet the applicable OCRWM QARD requirements that were imposed in the purchase order. Most of the changes were to clarify/correct the language found in the August 15, 1995 version. There were also changes to remove some overcommitments, such as keeping records in a two

hour Underwriters' Laboratories fire rated container and in dual storage. However, there were two areas where the changes removed too much detail.

- A. In Section 5.0, "Technical Procedures," Paragraph 5.2.1, procedure content has been modified to remove some of the information of what a technical procedure must contain. There is no impact on work and no deficiency because no technical procedure has been developed using the revised QA Manual. It is recommended that USGS work with Certified Balance Service, Inc. to get Paragraph 5.2.1 revised to reflect words similar to that found in the OCRWM QARD, Section 5.0, Paragraph 5.2.2.

- B. In Section 7, "Calibration," Paragraph 7.2.8, "Calibration Status and Tracking," was deleted. The audit revealed that Certified Balance Service, Inc. was maintaining a status of Measuring & Test Equipment requiring calibration and tracking when recalibration was due. It is recommended that USGS work with Certified Balance Service, Inc. to get Paragraph 7.2.8 added back into the QA Manual. As a minimum, Paragraph 7.2.8 should reflect words similar to:
"Equipment requiring calibration shall be tracked to ensure that it is calibrated by the calibration due date."

In conclusion, it is recommended that USGS review the Certified Balance Service, Inc. QA Manual, Revision 1, for acceptance for use within the OCRWM program. This review and acceptance process should address getting the proper commitments, such as the examples provided above, within the Certified Balance Service, Inc. QA Manual.