



Department of Energy

Washington, DC 20585

QA: L

OCT 06 1997

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 12, Room 1249, M/S 423
Las Vegas, NV 89134

VERIFICATION OF CORRECTIVE ACTION OF DEFICIENCY REPORT
(DR) YM-96-D-076 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA)
SUPPLIER AUDIT OQA-SA-96-018 OF CERTIFIED BALANCE SERVICE, INC.

The OQA staff has verified the corrective action to DR YM-96-D-076 and determined the results to be unsatisfactory because of reasons stated in the enclosed DR.

Your response, indicating the appropriate corrective action completion date, is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Richard L. Maudlin at (702) 794-1302.

James Blaylock
Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0011

Enclosure:
DR YM-96-D-076

- cc w/encl:
- J. O. Thoma, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- R. W. Henderson, M&O, Las Vegas, NV
- B. R. Justice, Jr., M&O, Las Vegas, NV
- R. A. Morgan, M&O, Las Vegas, NV
- T. H. Chaney, USGS, Denver, CO
- D. J. Sinks, OQA/USGS, Denver, CO
- A. M. Whiteside, OQA/USGS, Denver, CO

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



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THIS IS A RED STAMP
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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
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3 Responsible Organization: U.S. Geological Survey (USGS)/Certified Balance Service, Inc.	4 Discussed With: C. Warren Hunsberger
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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 for <u>Richard L. Maudlin</u> Date <u>7/23/96</u>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown; Must be Yes if PR
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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 <u>[Signature]</u> for R.L.M. Date <u>7/23/96</u>	12 Response Due Date 20 Working Days From Issuance
--	---

13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name <u>RESPENCE</u> Signature <u>[Signature]</u> Date <u>7-25-96</u>
--

22 Corrective Action Verified QAR <u>[Signature]</u> Date <u>09/29/97</u>	23 Closure Approved by: (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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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SEE ATTACHED

15 Extent of Condition: (Not required for PR)

SEE ATTACHED

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:

10/4/96

19 Response by:

Initial *Wayne R. ...* 8/23/96 303 236-0516
 Amended Date Phone X 302

20 Response Accepted

QAR Date

21 Response Accepted (N/A for PR)

AOQAM Date

The actions being taken for each deficiency identified are described below and numbered to correspond with the DR Block 6 Description of Condition:

- A) None required. The current CBS QA Manual, Revision 1, dated 7/15/96 (which was in effect prior to this audit and made available to the auditor) reflects that CBS has only one supplier, State of Colorado Department of Agriculture (CDA), who is on the OCRWM QSL. The use of suppliers not on the QSL will require the concurrence of the customer, USGS. The current CBS QA Manual does not require an Approved Suppliers List.
- B) and C) None required. CBS has had a verbal working agreement with CDA for almost 20 years wherein CDA calibrates CBS weights, and in exchange, CBS services CDA balances. The service that is to be performed and the results that are to be supplied are well understood by both parties. CDA is approved by NIST and is on the OCRWM QSL and provides exactly the same service to USGS as is provided to CBS. CDA uses one of two methods (specific to the particular range of weights being calibrated) and there are no options or deviations from those procedures.
- D) The CBS QA Manual will be revised to reflect that no evaluation of a supplier is required when the supplier is approved by the customer. (CDA is on the OCRWM QSL). Expected Completion Date is 10/04/96.
- E) No remedial action. In the past the certification documentation received from CBS was reviewed and found acceptable; however, the documentation of review by CBS had not been accomplished. In the future, CBS will document reviews of supplier documentation according to the current CBS QA Manual.
- F) No remedial action. Discussions with Chuck Hunsberger of CBS and with the metrology staff at the GB Tech/NASA standards lab subsequent to the issuance of this deficiency indicate that there may have been some misinterpretation of the accuracy issue. Standard industry practice followed for reporting the weight of mass standards is to include an error band called "uncertainty". This figure takes into account all the cumulative errors that may actually occur or that may be anticipated to occur when attempting to determine an "actual" or "absolute" weight. In fact, results of weight determinations are given as "apparent" mass. This is the best that can be humanly done to state the weight of an object and includes an unknown amount of error that will be introduced into a measurement.

A balance specification relative to accuracy is given as "readability". For example, the most accurate balances found in the Fisher Scientific and Cole-Parmer catalogs list readability as 0.01mg (0.00001g). The effects of repeatability, linearity, and

other error-producing factors which would degrade the readability specification are not included in the manufacturers claimed accuracy. Commonly, the accuracy of a balance is generalized to be the manufacturers claimed readability specification without thought as to other factors. This represents an unknown amount of error in stating the "accuracy" of any balance.

A typical calibration worksheet from the Colorado Department of Agriculture gives apparent mass, tolerance, and uncertainty figures. Certificate No. 9907 shows that for a 1mg weight the apparent mass is 1mg minus 0.0003mg, the tolerance is 0.014mg and the uncertainty is 0.00760mg. Note that contrary to what was understood during the CBS audit, the apparent mass figure indicates to 6 decimal places. The point that Mr. Hunsberger was trying to make is that based on the manufacturers claimed accuracy without regard to accuracy degrading factors, and if all tolerances and uncertainties were applied to the weights, the weight standards could theoretically be less accurate than the balances being calibrated. Whether they are, and by how much, cannot be known with any certainty.

Discussions with Gordon Rattray confirm that he makes no measurements for YMP-USGS work that require accuracy greater than 5mg.

In conclusion, and confirmed by the GB Tech conversation, the standards used can be considered more accurate than the balances being calibrated, the balances are being adequately calibrated in accordance with standard industry practice, and their accuracy far exceeds any YMP-USGS requirements.

- G) The certifications in question were for larger (1kg) weights which are considered non-precision weights. According to Bill Young, Chief Metrologist, CDA, it is their policy (for larger weights) to only give as-found data if a particular weight is found out-of-tolerance. The reason for this policy is that these weights have large acceptable tolerances and changes within those tolerances are expected and not to be used to apply corrections.

The addition of a procedure number to CDA certificates will be addressed according to the resolution of current CDA deficiencies.

- H) The calibration documentation in question will be revised to add the PO number. The requirement for a statement that the standard's accuracy is greater than the equipment being calibrated is being deleted from USGS QMPs and will not be required in future procurement documents. Expected completion date is 10/04/96. Future documentation supplied by CBS will include the PO number typed onto the worksheet.

- I) No remedial action required. The over commitment reflected in the CBS QA Manual, Revision 0, was removed in the current CBS QA Manual.

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EVALUATION OF RESPONSE TO DEFICIENCY REPORT YM-96-D-076

Your response has been received and evaluated. Responses to parts B, C, and F were considered unacceptable in resolving the noted condition as follows.

A. Your response to item A in Block 6 of the DR has been evaluated and found acceptable. A review of the updated CBS QA Manual will be performed to verify deletion of the requirements to maintain an approved suppliers list.

B. Your response to Item B in Block 6 of the DR has been evaluated and found unacceptable. QARD, Revision 5, Section 4.0, Subsection 4.2.1 (C)(1)(2) states in part: "Procurement documents shall include the following provisions Quality Assurance Requirements including: (1) A requirement for the supplier to have a documented Quality Assurance (QA) program that implements applicable Quality Assurance Requirements and Description, (QARD) requirements prior to initiation of work. (2) A requirement for the supplier to incorporate the appropriate QARD requirements into any sub-tier supplier-issued procurement document." The QARD does not allow, as your response indicates, the use of "VERBAL AGREEMENTS" between the purchaser and the supplier. Certified Balance System, Inc. is required by the QARD and your procurement document to have a documented QA program which requires USGS suppliers to pass down those applicable QARD requirements to their sub-tier suppliers. All contractual requirements between Certified Balance System, Inc. (CBS) and the Colorado Department of Agriculture must be documented. Please re-evaluate your response in light of the aforementioned and respond indicating the approach that CBS will use in documenting the quality and technical requirements to be applied to sub-tier suppliers.

C. See response to B.

D. Your response to Item D in Block 6 of the DR has been evaluated and found acceptable. An evaluation of completed corrective action will be performed subsequent to October 04, 1996.

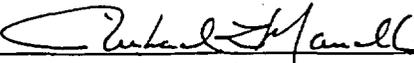
E. Your response to Item E in Block 6 of the DR has been evaluated and found acceptable. Please provide documented evidence that CBS is documenting the reviews of suppliers documentation.

F. Your response implies that the needed accuracy for the USGS application is less than that of the manufacturer. Would you please re-respond indicating the accuracies needed by USGS for the intended application and identify the ratio between that accuracy and the accuracy of the standards. If this ratio indicates that the standard has an accuracy greater than or equal to that of the balance being calibrated, this will meet the requirements of the QARD. Also, indicate that USGS will, in all future procurements, identify the required accuracies and not require the balance to be calibrated to manufactures specifications. This should resolve the problem.

G. Your response to Item D in Block 6 of the DR has been evaluated and found acceptable. Please provide a date by which the actions stated in your response will be completed.

H. Your response to Item D in Block 6 of the DR has been evaluated and found acceptable. An evaluation of completed corrective action will be performed subsequent to October 04, 1996.

I. Your response to Item D in Block 6 of the DR has been evaluated and found acceptable. A review of the revised CBS QA Manual will be performed after all corrective actions have been completed to evaluate the revised controls for QA Records.


Richard L. Maudlin, QAR

09-23-96
Date

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AMENDED RESPONSE

Numbers correspond with DR Block 6, Description of Condition and with original responses dated 10/04/96.

B) and C) A contractual agreement will be prepared stating that the two parties will provide services to each other according to their YMP-approved QA programs. This will be accomplished by December 15, 1996.

F) The original response adequately addresses the perceived deficiency. The response shows that the deficiency statement that standards are less accurate than the equipment being calibrated is incorrect. The response clearly describes why a deficient condition does not exist, that is, the accuracy of standards is given to 6 decimal places not 4. The recommendation that USGS establish a USGS acceptance criteria in lieu of using manufacturer's specification was addressed during resolution of deficiency YMP-96-D048.

Submitted by: Wayne Rodman
W. RODMAN, QA Specialist

Date: 10/10/96

SUPERCEDED
ON 10/17/96 BY 10/29/96

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AMENDED RESPONSE

This supercedes the previous amended response dated 10/10/96

Numbers correspond with DR Block 6, Description of Condition and with original responses dated 10/04/96.

B) and C) A contractual agreement will be prepared stating that the two parties will provide services to each other according to their YMP-approved QA programs. This will be accomplished by December 15, 1996.

F) To clarify the original response the 3rd paragraph has been rewritten with the example converted to grams:

A typical calibration worksheet from the Colorado Department of Agriculture gives apparent mass, tolerance and uncertainty figures. Certificate No. 9907 shows that for a 0.001 gram weight (1mg) the apparent mass is 0.001 grams minus .0000003 grams, the tolerance is 0.000014 grams and the uncertainty is 0.00000760 grams. Note that contrary to what was understood during the CBS audit, the apparent mass tolerance figure indicates to 6 decimal places. The point that Mr. Hunsberger was trying to make was that based on the manufacturers claimed accuracy without regard to accuracy degrading factors, and if all tolerances and uncertainties were applied to the weights, the weight standards could theoretically be less accurate than the balances being calibrated. Whether they are, and by how much, cannot be known with any certainty.

This revised paragraph clearly describes that the accuracy of weight standards is given to 6 decimal places, not four, and the interpretation of the discussion during the audit that led to the perceived deficiency was simply a misunderstanding.

The recommendation that USGS establish a USGS acceptance criteria in lieu of using manufacturers specification was addressed during resolution of deficiency YMP-96-D-048.

Submitted by: _____

Wayne Rodman
W. RODMAN, QA Specialist

Date: _____

10/17/96

MEMORANDUM OF AGREEMENT

This agreement is between Certified Balance Services Inc. (CBS) and the Colorado Department of Agriculture (CDA) to ensure that technical and quality assurance requirements of the DOE-Yucca Mountain Project (YMP) are met when performing services that may impact work performed for the YMP.

Services provided by CDA are limited to:

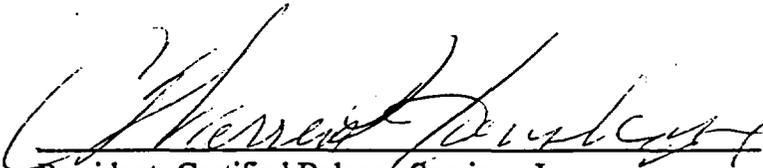
1. Calibration of mass standards (weights) used by CBS to calibrate YMP balances.

Services provided by CBS are limited to:

1. Servicing of balances that are used to calibrate YMP weights.

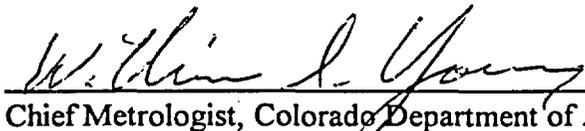
The following conditions shall apply:

1. Services are performed and documentation is provided according to each company's YMP-approved program requirements and procedures.
2. CBS and CDA are maintained on the YMP Quality Suppliers List based on successful completion of vendor evaluations performed by YMP.
3. This agreement serves as the procurement document for the services described above and any deviations shall be documented as a deficiency.



President, Certified Balance Services, Inc

1-24-97
Date



Chief Metrologist, Colorado Department of Agriculture

2-20-97
Date

3/3/97 Charvey at Dexter

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VERIFICATION OF CORRECTIVE ACTION TO DR YM-96-D-076

On September 9, 1997, a follow-up verification at the Certified Balance Service, Inc. (CBS) facility in Englewood, Colorado was performed by Richard Maudlin and Donna Sinks to verify implementation of corrective action to Deficiency Report YM-96-D-076. The results of the follow-up verification indicate areas of both satisfactory and unsatisfactory implementation of corrective action and are as follows:

A. A review of the CBS QA Manual, Revision 2, Section 4.1 revealed that the requirements for CBS to maintain an Approved Suppliers List had been removed. This item was considered satisfactory.

B. Reviewed the Memorandum of Agreement (MOA) between CBS and the Colorado Department of Agriculture (CDA). The MOA addresses requirements that when CDA performs calibrations for CBS, that CDA will use their YMP approved QA Program. This item was considered satisfactory.

In addition, verification ^{for the services of CDA performed on 6/19/97 (see G below)} was performed to determine if CBS is including the requirements specified in the CBS QA Manual in procurement documents. As of the date of this verification, there was no documented evidence to demonstrate that CBS procurement documents included requirements that calibration documentation from the supplier include such information as: identification of the supplier; identification of the equipment being calibrated; identification of calibration standard(s) used, including range and accuracy and NIST traceability; calibration procedure or method used; calibration date; identification of person performing the calibration; and records of actual calibration data values, both before ("as-found") and after any adjustment ("as-left") as required by the CBS QA Manual, Section 4.0, Subsection 4.2.1. Implementation for this item is considered unsatisfactory.

C. See verification for item B above. Both representatives from CBS and CDA signed the MOA indicating their review and agreement with the terms specified in the MOA. This item is considered satisfactory.

D. A review of CBS QA Manual, Revision 2, revealed that a statement has been added to indicate that no evaluation of a supplier will be required when the supplier is approved by the customer (i.e.; USGS). This exception only applies to OCRWM approved suppliers. This item is considered satisfactory.

E. Evidence was provided to reflect that a review of CDA Reports of Calibration were performed by the CBS representative, however, the review was not adequate in that information required to be included on the Reports of Calibration was not evident (See item G below). The examples evaluated are those referenced in the verification of item G below. This item is considered unsatisfactory.

F. Acceptable based on the amended response dated 10/17/96 and on discussions with CBS during verification. No verification performed for this item.

G. A review of CDA Reports of Calibration revealed that they did not contain all of the required information (i.e.; no identification of the calibration standard(s) used, including the range, accuracy, and traceability to NIST and no reference to the procedure or method used to perform the calibrations. The CDA Reports of Calibration reviewed are as follows: 06/19/97 for the calibration of CBS weight set K-26; 06/19/97 for the calibration of CBS weight set K-14; 06/19/97 for the calibration of CBS weight set CBS-K-1; and 06/19/97 for the calibration of CBS weight set CBS-K-25. Implementation for this item is considered unsatisfactory.

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H. In a review of USGS procedure, YMP-USGS-QMP-4.01, R8, Attachment 1, it was noted that the requirement for calibration documentation to include a statement of accuracy has been deleted. Implementation of corrective action for this portion is considered satisfactory

NOT
IN RELATION TO THE ISSUE OF USGS PO NUMBERS BEING REFERENCED ON CBS CALIBRATION DOCUMENTATION
In addition, a sampling of two CBS Certificates of Calibration and associated calibration data sheets, dated 07/27/97 and 07/07/97, for USGS calibrations, *WERE REVIEWED AND* revealed that they did not reference the USGS purchase order number as committed to in the response to this DR. Implementation of this item is considered unsatisfactory.

I. CBS is presently maintaining duplicate records. One copy is in a metal file cabinet in the president's office and a second copy is being maintained in a fireproof safe in the calibration lab. Implementation of this item is considered satisfactory.

Based on the above verification results, this DR will remain open pending resolution to the unsatisfactory conditions identified in items B, E, G, and H. USGS to provide a date by when implementation of corrective action will be completed for the unresolved items.


R.L. Madlin 09-24-97
Date