



QA: QA

Robert W. Craig,
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U.S. Geological Survey
1180 Town Center Drive
Las Vegas, NV 89144

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORTS
(DRs) USGS(V)-02-D-084 AND -085 RESULTING FROM THE BECHTEL SAIC
COMPANY, LLC (BSC) QUALITY ASSURANCE AUDIT BSC-SA-02-012 OF FLUKE
CORPORATION

BSC Quality Assurance has verified implementation of corrective action for DRs
USGS(V)-02-D-084 and -085 and determined the results to be satisfactory. As a result, the DRs
have been closed.

If you have any questions, please contact either Richard L. Maudlin at (702) 295-2961 or
Daniel A. Klimas at (702) 295-2665.

A handwritten signature in black ink, appearing to read 'D. T. Krisha'.

Donald T. Krisha, Manager
Quality Assurance

5/20/02
Date Signed

RLM:bw-0520022696

Enclosure:
DRs USGS(V)-02-D-084 and -085

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May 20, 2002

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cc w/encl:

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cc w/encl:

Gwynn Blanchard, Fluke Corporation, Everett, WA
T. H. Chaney, USGS, Denver, CO
R. L. Maudlin, BSC, Las Vegas, NV
M. H. Mustard, USGS, Denver, CO
D. J. Sinks, BSC, Denver, CO

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8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION
REPORT

NO. USGS(V)-02-D-084

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DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document:

USGS Purchase Order 01CRSA0584

2. Related Report No.:

BSC-SA-02-012

3. Responsible Organization:

USGS / Fluke Corporation

4. Discussed With:

G. Blanchard, Fluke Corporation;
T. Chaney, USGS

5. Requirement:

- A. USGS Purchase Order 01CRSA0584, QA Requirements, Section II, states in part: "The Fluke Corporation documented QA program shall address the following...". Subsection 3.0, states in part: "The approach used to assure that technical and quality requirements are incorporated into procurement documents and changes to these documents shall be described."
- B. USGS Purchase Order 01CRSA0584, QA Requirements, Section II, states in part: "The Fluke Corporation documented QA program shall address the following topics... The methods used to document evaluation and selection of the supplier prior to the award of a contract/purchase order shall be described...."

6. Description of Condition:

Contrary to the above,

- A. The Fluke Customer Support Services (CSS) Quality Assurance Manual, CSS PD 400, dated 12/99, does not address requirements for the Fluke CSS purchase orders for the calibration of their standards to include applicable technical and quality requirements. In addition, two Fluke purchase orders, PO 163422, dated 01/18/02, and PO 163964, dated 02/01/02, found that technical requirements were not adequately identified.
- B. The Fluke Customer Support Services (CSS) Quality Assurance Manual, CSS PD 400, dated 12/99, does not address the relationship between Fluke CSS and the Fluke Primary Standards Laboratory for the calibration of CSS standards (i.e., is the Fluke Primary Standards Laboratory a supplier of services to CSS?).

7. Initiator:

Richard L. Maudlin

Date 03/08/2002

9. Does a stop work condition exist? (Not required for a DR)

☐ Yes ☒ No *7/2/02*

If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

- A. Take the necessary action to revise the CSS Quality Assurance Manual to include requirements for CSS procurement documents to include appropriate technical and quality requirements and how changes to these procurement documents will be controlled.
- B. Take the necessary action to revise the CSS Quality Assurance Manual to describe the relationship between the CSS and the Fluke Primary Standards Laboratory regarding the calibration of CSS standards.

11. QA Review:

QAR Richard L. Maudlin

Date 03/08/2002

12. Response Due Date:

20 Working Days From Issuance

13. DOQA Issuance Approval:

Printed Name Donald T. Krisha

Signature

D. T. Krisha

Date

3/19/02

22. Corrective Actions Verified:

QAR:

Richard L. Maudlin

Date

05/16/02

23. Closure Approved by:

DOQA

Donald T. Krisha

Date

5/20/02

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2. Check if Amended ☐
Check if also Initial Response ☒
3. Extended Processing
☒ No ☐ Yes (If yes, submit
Extended Processing request)

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1. DR/CAR NO. USGS(V)-⁰²2-D-84
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition investigations are not complete and documented herein)

Per the Fluke CSS QA Manager, there are no Fluke CSS quality-affecting procurements used to support the Fluke calibrations of Fluke equipment. Outside calibration services would only be used for Fluke calibrations of some other manufacturers' equipment. Fluke CSS uses only Fluke PSL to obtain calibrations of their M&TE. Fluke PSL is not a vendor but a different laboratory within the Fluke Corporation. Fluke Corporation has approved the Fluke Corporate QA Manual which applies to both the CSS and the PSL. The relationship between the two is identified in section 11.4 of the Corporate QA Manual and section 4.11, especially sub-section 4.11.3, of the CSS QA Manual. The Fluke Corporate QA Manual addresses the PSL's internal audit frequency.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

There is no impact due to this DR because there have been no Fluke quality-affecting procurements used to support Fluke calibrations done under USGS POs. Implementation of USGS POs have been limited to calibrations of Fluke equipment.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)

A statement from the Fluke CSS QA Manager will be obtained stating that Fluke does not use any outside vendors to support Fluke calibrations of Fluke equipment. Her statement also will provide an interpretation of the Fluke Corporate QA Manual indicating that the frequency of comprehensive internal audits of the Fluke PSL is annually, at a minimum.

7. ☐ Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16.4Q)
☒ Apparent Cause

The previous YMP QA review of the Fluke CSS QA Manual indicated that it met the applicable requirements so that Criteria 4 and 7 were deemed applicable to Fluke on the OCRWM Qualified Suppliers List (QSL).

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

USGS will request that the scope of services for which Fluke CSS is qualified be limited to Fluke equipment and that a restriction be included in the QSL to indicate that Fluke CSS must use only Fluke PSL to calibrate its standards used in support of YMP calibrations. This scope of approved services allows criteria 4 and 7 to be N/A for Fluke CSS.

9. Due Date for Completion of Corrective Action:

April 30, 2002

10. Responsible Manager:

D. Sinha 4/16/02

Robert W. Craig *Robert W. Craig* 4/16/02
Printed Name Signature Date

11. QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject

Richard L. Maudlin *[Signature]* 04/29/02
Printed Name Signature Date

12. QAM Concurrence:

Donald T. Krishna *[Signature]* 5/3/02
Printed Name Signature Date

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NO. BSC(V)-02-D-084

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

**VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF
DR BSC(V)-02-D-084**

On May 14, 2002, a follow-up verification was performed to verify implementation of corrective action to Deficiency Report (DR) BSC(V)-02-D-084. This follow-up verification was based on the response to the DR and a review of the following documentation to support implementation of corrective action.


- Fluke Corporation QA Manual and the Fluke Customer Support Services (CSS) QA Manual for the relationship between the CSS and Fluke Primary Standards Laboratory.

- A letter from Gwynn Blanchard, CSS QA Manager, Fluke Corporation, dated April 23, 2002, to the U.S. Geological Survey (USGS) stating that traceability of all Fluke calibrations is through the Fluke Corporation Primary Standards Laboratory. Vendors are only used for the calibration of non-Fluke equipment. The letter also states that the frequency of internal audits of the Primary Standards Laboratory will be annually.

- An e-mail from Martha Mustard, USGS to Richard Maudlin, BSC, dated 04/16/2002, requesting a change in the scope of services for Fluke to only allow them to calibrate Fluke equipment. Also, the e-mail requested that responsibility for implementation of QA Elements 4 and 7, Procurement Document Control and Control of Purchased Items and Services, be removed from Fluke Corporation's responsibility.

The documentation provided, including the response to the DR, satisfactorily resolves the condition adverse to quality (CAQ) and implements the corrective actions stated in the DR response. A review has been performed to reassess the significance of the CAQ in accordance with Administrative Procedure AP-16.1Q. Based on the extent of condition, it has been determined that no change in the status of this DR is warranted.

Based on the above, this DR is considered closed.


Richard L. Maudlin

05-16-02
Date Signed

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8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION
REPORT

NO. USGS(V)-02-D-085

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DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document:

USGS Purchase Order 01CRSA0584

2. Related Report No.:

BSC-SA-02-012

3. Responsible Organization:

USGS / Fluke Corporation

4. Discussed With:

G. Blanchard, Fluke Corporation;
T. Chaney, USGS

5. Requirement:

USGS Purchase Order 01CRSA0584, QA Requirements, Section II, Subsection 8.0, states in part: "Planned and scheduled audits to verify compliance with the QA program requirements and to determine the effectiveness of the QA program shall be performed at least annually."

6. Description of Condition:

Contrary to the above, the Customer Support Services (CSS) Quality Assurance Manual, CSS PD 400, dated 12/99, does not address requirements for an annual internal audit to be performed of the CSS quality program to assure effective implementation. In addition, no evidence in the form of an Audit Report could be provided to support that an audit had been performed in 2001.

7. Initiator:

Richard L. Maudlin
Richard L. Maudlin

Date 03/08/2002

9. Does a stop work condition exist? (Not required for a DR)

☐ Yes ☒ No *3/8/02*

If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

Take the necessary action to revise the CSS Quality Assurance Manual to include requirements for performance of annual audits of the CSS to evaluate the effectiveness of implementation of the CSS quality assurance program.

11. QA Review:

Richard L. Maudlin
QAR Richard L. Maudlin

Date 03/08/2002

12. Response Due Date:

20 Working Days From Issuance

13. DOQA Issuance Approval:

Printed Name Donald T. Krisha

Signature

Donald T. Krisha

Date

3/19/02

22. Corrective Actions Verified:

Richard L. Maudlin
QAR: Richard L. Maudlin

Date

05/16/02

23. Closure Approved by:

DOQA

Donald T. Krisha
Donald T. Krisha

Date

5/20/02

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2. Check if Amended ☐
 Check if also Initial Response ☒

3. Extended Processing

- ☒ No ☐ Yes (If yes, submit
 Extended Processing request)

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1. DR/CAR NO. USGS(V)-Z-D-85
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition investigations are not complete and documented herein)

Review of Fluke CSS audit history indicates no internal audit during 2001 but an audit had been performed in 2000 and another audit has been scheduled for May 2002.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

There is no impact. YMP supplier audit BSC-SA-02-012 covered the entire applicable Fluke CSS QA Program.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)

The Fluke CSS QA Manual has been revised to indicate that CSS will be audited internally every year.

7. ☐ Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16.4Q)
☒ Apparent Cause

The Fluke Corporate QA Manual requires more frequent audits but does not state that they must be performed annually of the CSS specifically. Previous to the YMP audit that generated this DR, the YMP approval of Fluke Corporation was broader than it currently is and the annual audit requirement was met by the Fluke Corporate QA Manual requirement.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

The actions taken described in block 6 will also prevent this condition from recurring.

9. Due Date for Completion of Corrective Action:

04/12/2002

10. Responsible Manager:

Robert W. Craig Robert W. Craig 4/16/02
 Printed Name Signature Date

11. QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject

Richard L. Maublin [Signature] 04/29/02
 Printed Name Signature Date

12. QAM Concurrence:

Donald T. Krishna [Signature] 5/2/02
 Printed Name Signature Date

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

**VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF
DR BSC(V)-02-D-085**

On May 14, 2002, a follow-up verification was performed to verify implementation of corrective action to Deficiency Report (DR) BSC(V)-02-D-085. This follow-up verification was based on the response to the DR and a review of the following documentation to support implementation of corrective action:

- Fluke Corporation Quality Systems Internal Audit Schedule for 2002, dated 04/30/2002, indicating the scheduling of an audit of the Fluke Customer Support Services (CSS) in May 2002.
- A revision to the Fluke Corporation CSS Quality Assurance Manual, CSS PD400, dated April 2002, Section 4.17, which requires that an internal audit be performed at least annually.

The documentation provided, including the response to the DR, satisfactorily resolves the condition adverse to quality (CAQ) and implements the corrective actions stated in the DR response. A review has been performed to reassess the significance of the CAQ in accordance with Administrative Procedure AP-16.1Q. Based on the extent of condition, it has been determined that no change in the status of this DR is warranted.

Based on the above, this DR is considered closed.



Richard L. Maudlin

05-16-02

Date Signed

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