



QA: QA

Mark T. Peters, Manager
Science & Engineering Testing
Bechtel SAIC Company, LLC
1180 Town Center Drive
Las Vegas, NV 89144

ISSUANCE OF DEFICIENCY REPORTS (DR) BSC(V)-02-D-101, -102 AND -103
RESULTING FROM THE BECHTEL SAIC COMPANY, LLC (BSC) QUALITY
ASSURANCE (QA) AUDIT BSC-SA-02-019 OF PRIMARY STANDARDS
LABORATORY (PSL)

Enclosed are the subject DRs generated as a result of BSC Audit BSC-SA-02-019 for conditions adverse to quality in Primary Standards Laboratory's failure to fully meet the BSC procurement requirements for an acceptable QA Program. The unacceptable QA elements are Procurement Document Control, Audits, and Software.

The responsible individual for these DRs should acknowledge receipt by e-mail response to Robert D. Habbe.

Please provide the original copy of the response within 10 working days from the date of this correspondence to Robert D. Habbe, Bechtel SAIC Company, LLC, 1180 Town Center Drive, Las Vegas, Nevada 89144, with a copy to Deborah G. Opielowski, Navarro Quality Services, P.O. Box 364629, YMSCO, N. Las Vegas, NV 89036.

If you have any questions, please contact either Robert D. Habbe at (702) 295-1631 or Daniel A. Klimas (702) 295-2665.

A handwritten signature in black ink, appearing to read "D. T. Krisha".

Donald T. Krisha, Manager
Quality Assurance

4/15/02
Date Signed

RDH:bw-0411022174

Enclosures:
DRs BSC(V)-02-D-101, -102, -103

Handwritten initials in black ink, possibly reading "D. T. Krisha" or similar.

April 15, 2002

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cc w/encl:

L. H. Barrett, DOE/HQ (RW-2) FORS
L. W. Bradshaw, Nye County, Pahrump, NV
Margaret Chu, DOE/HQ (RW-1) FORS
J. R. Dyer, DOE/YMSCO, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
Birdie Hamilton-Ray, DOE/YMSCO, Las Vegas, NV
C. E. Hampton, DOE/YMSCO, Las Vegas, NV
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D. A. Klimas, BSC, Las Vegas, NV
D. T. Krisha, BSC, Las Vegas, NV
Robert Latta, NRC, Las Vegas, NV
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S. P. Mellington, DOE/YMSCO, Las Vegas, NV
Ram Murthy, DOE/OQA, Las Vegas, NV
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N. K. Stablein, NRC, Rockville, MD
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Engelbrecht von Tiesenhausen, Clark County, Las Vegas, NV
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cc w/encl

K. O. Gilkerson, BSC, Las Vegas, NV
R. D. Habbe, BSC, Las Vegas, NV
R. F. Hartstern, BSC, Las Vegas, NV
Richard Pettit, PSL, Albuquerque, NM
T. B. Reynolds, BSC, Las Vegas, NV
Roxanna VanDillen, BSC, Las Vegas, NV

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

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8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION
REPORT
NO. BSC(V)-02-D-101
PAGE 1 OF
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)
Primary Standards Laboratory (PSL) Measurement Standards Program (MSP) Operations
& Procedures (O&P) Document No. 3.5.1, Revision 8

2. Related Report No.:
BSC-SA-02-019

3. Responsible Organization:

PSL, BSC Science Engineering & Testing

4. Discussed With:

Richard Pettit, PSL and Thomas Reynolds, BSC

5. Requirement:

A. MSP O&P Document 5.8.4.1, Section 6.1.2 states: "The audit team uses the MSP checklist contained in O&P 5.8.4.2 as the guiding document for the internal audit. This checklist is derived from the ANSI Z540-1 and NIST Handbook 150 documents. Sections 4.0, 5.0 and 6.0 of the checklist are not reviewed with the project groups. Observations or comments on each evaluation factor are recorded on the checklist and objective evidence is noted."

B. MSP O&P Document 5.8.4.1, Section 6.2 states: "The review of the MSP quality system includes those factors affecting the operation of the entire program and not limited to individual project groups. In addition, the following items from the MSP checklist contained in O&P 5.8.4.2 are reviewed: Section 4.0 Organization and Management, 5.0 Quality System audit and review, and 6.0 Personnel."

C. MSP O&P Document 5.8.4.1, Section 6.3 states: "The programmatic review of the overall quality system is documented in a report that summarizes the findings of the review. (Continued on page 2)"

6. Description of Condition:

Contrary to the requirements:

A. Several of the questions in Section 5.0 of the checklist have been evaluated during the internal audits of the project groups. The annual internal audit checklists for Fiscal Year (FY) 2001 of the 9 project group audits did not have objective evidence noted in the checklists.

B. Several of the questions in Sections 4.0, 5.0 and 6.0 of the checklist for the FY 2001 internal audit (QA01-00) were not evaluated. Additionally, Sections 14, Sub-contracting of calibration, and Section 15, Outside support services and supplies that affect calibration results, were not evaluated during the FY 00 (QA00-0), FY 01 (QA01-00) or FY 02 (QA02-00) Quality System Internal Audits.

C. No reports have been issued for the FY 00 (QA00-0), FY 01 (QA01-00) or FY 02 (QA02-00) Quality System Internal Audits.

D. PSL could not provide any objective evidence that Len Duda and Mary Woodruff are qualified as lead or technical auditors. Both have performed internal audits of PSL.

Has work been stopped? ☐ Yes ☒ No

7. Initiator:

Robert D. Habbe

Printed Name

Signature

Date

4-4-02

9. Does a stop work condition exist?

☐ Yes ☐ No ☒ N/A

If Yes, Check One:

☐ A

☐ B

☐ C

☐ D

10. Recommended Actions:

1. PSL should revise their procedure to accurately reflect the sections of the audit checklist that will be used during the different internal audits.

2. PSL should record objective evidence evaluated during internal audits on their checklist or revise the procedure to accurately describe when objective evidence is required.

3. PSL should start issuing audit reports for the annual quality system audits or revise the procedure to describe the method for reporting audit results. (Continued on page 2)

11. QA Review:

Robert D. Habbe

Printed Name

Signature

Date

4-4-02

12. Response Due Date:

10 Working Days after Issuance

13. QAM Issuance Approval:

Printed Name DONALD T. KRISHA

Signature

Date

4/15/02

14. Corrective Actions Verified/Closure

QAR Printed Name

Signature

Date

15. QAM Closure Approval:

Printed Name

Signature

Date

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WASHINGTON, D.C.**

☒ DR/CAR/QO
☐ SWO

NO. BSC(V)-02-D-101

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

5. Requirements continued:

D. MSP O&P Document 3.5.1, Section 3.3. states: "MSP management appoints a Lead Auditor who directs the audit team. The team members are qualified as technical auditors according to the training and certification program documented in O&P Manual 6.2.1."

10. Recommended Actions continued:

4. PSL should qualify all personnel that perform audits to the requirements of O&P 6.2.1.

5. PSL should determine if these conditions adverse to quality had an impact on the calibrations performed on OCRWM equipment.

6. PSL should retrain/reinstruct their personnel after any revision to the procedure.

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8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION
REPORT
NO. BSC(V)-02-D-102
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)

TRW Purchase Order A06649ME9X, Change Notice 9

2. Related Report No.:

BSC-SA-02-019

3. Responsible Organization:

PSL, BSC Science Engineering and Testing

4. Discussed With:

Richard Pettit, PSL and Thomas Reynolds, BSC

5. Requirement:

A. TRW Purchase Order A06649ME9X, Change Notice 9, Work Package 11017040M2, Procurement Requirements Document of Q Calibration Services for HY-CAL Engineering Dew Point Transmitter Model No. CT-890-A, Rev 00, Attachment I, Section 3.0 states: "The approach used to assure that technical and quality requirements are incorporated into procurement documents and changes to the documents shall be described."

6. Description of Condition:

Contrary to the requirements:

A. The PSL quality program does not require technical and quality requirements to be incorporated into calibration services procurements. Additionally, the PSL quality program does not require a documented review and approval of the procurement documents for calibration services. Calibration services are normally procured by credit card.

Has work been stopped? ☐ Yes ☒ No

7. Initiator:

Robert D. Habbe

Printed Name

Signature

Date

4-4-02

9. Does a stop work condition exist?

☐ Yes ☐ No ☒ N/A

If Yes, Check One:

☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

1. PSL should revise their quality program to require that procurement documents for calibration services include technical and quality requirements.
2. PSL should revise their quality program to require a documented review and approval of procurement documents for calibration services.
3. PSL should retrain/reinstruct those personnel that are in the procurement process after the procedure changes.

11. QA Review:

Robert D. Habbe

Printed Name

Signature

Date

4-4-02

12. Response Due Date:

10 Working Days after Issuance

13. QAM Issuance Approval:

Printed Name

DONALD T. KRISHA

Signature

D. T. Krishna

Date

4/15/02

14. Corrective Actions Verified/Closure

QAR Printed Name

Signature

Date

15. QAM Closure Approval:

Printed Name

Signature

Date

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8. ☒ DEFICIENCY REPORT
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REPORT
NO. BSC(V)-02-D-103
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)
Primary Standards Laboratory (PSL) Measurement Standards Program (MSP) Operations
& Procedures (O&P) Document No. 3.6.1, Revision 6

2. Related Report No.:
BSC-SA-02-019

3. Responsible Organization:

PSL, BSC Science Engineering and Testing

4. Discussed With:

Richard Pettit, PSL and Thomas Reynolds, BSC

5. Requirement:

A. MSP O&P Document 3.6.1, Section 6.3.1 states: "For Software in appropriate categories (Appendix A), a software summary form should be prepared."

B. TRW Purchase Order A06649ME9X, Change Notice 9, Work Package 11017040M2, Procurement Requirements Document of Q Calibration Services for HY-CAL Engineering Dew Point Transmitter Model No. CT-890-A, Rev 00, Section IV, SOFTWARE states: "Where software is used in a process which provides results that are not later validated, PSL shall identify the software version and describe the method or approach used to test the software to a known benchmark to verify that the software is functioning properly and produces the intended results. Software version changes shall be checked to verify that the software produces correct results."

6. Description of Condition:

Contrary to the requirements:

A. PSL did not complete a Software Summary form to document the changes of the CERTVANA software for Versions B7, B8, and B9. CERTVANA versions B0 through B6 have the Software Summary forms completed documenting the software changes.

B. PSL could not provide any objective evidence of validation/verification/checking of the CERTVANA software for Versions B7, B8, and B9. CERTVANA versions B0 through B6 have documentation supporting the validation/verification of the changes to the software.

Has work been stopped? ☐ Yes ☒ No

7. Initiator:

Robert D. Habbe

Printed Name

Signature

Date

9. Does a stop work condition exist?

☐ Yes ☐ No ☒ N/A

If Yes, Check One:

☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

1. PSL should prepare Software Summary forms for CERTVANA, Versions B7, B8 and B9.
2. PSL should record and retain objective evidence of verification/checking of software changes.
3. PSL should determine if the condition adverse to quality had an impact on calibrations performed for OCRWM.
4. PSL should determine if training/reinstruction to any revised procedures is required.

11. QA Review:

Robert D. Habbe

Printed Name

Signature

Date

12. Response Due Date:

10 Working Days after Issuance

13. QAM Issuance Approval:

Printed Name

DONALD T. KRISHA

Signature

D. T. Krishna

Date

4/15/02

14. Corrective Actions Verified/Closure

15. QAM Closure Approval:

QAR Printed Name

Signature

Date

Printed Name

Signature

Date