



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-111 AND -112 RESULTING FROM THE BECHTEL SAIC COMPANY, LLC (BSC) QUALITY ASSURANCE (QA) AUDIT BSC-SA-02-023 OF MIDI LABS, INC.

Enclosed are the subject DRs generated as a result of BSC Audit BSC-SA-02-023 for conditions adverse to quality in MIDI Labs, Inc.'s failure to fully meet the BSC procurement requirements. The conditions adverse to quality were discovered in QA elements Procurement Document Control, Control of Purchased Items and Services, and Sample Control.

The responsible individual for these DRs should acknowledge receipt by e-mail response to Richard L. Maudlin.

Please provide the original copy of the responses within 20 working days from the date of this correspondence to Richard L. Maudlin, 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 Mail Stop 455, North Las Vegas, NV 89036.

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


Donald T. Krishna, Manager
Quality Assurance

5/13/03
Date Signed

RLM:bw-0513022625

Enclosures:
DR BSC(V)-02-D-111 and -112

Handwritten note:
DMSOY
2003-11

May 13, 2002

Page 2

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
R. W. Henderson, BSC, Las Vegas, NV
D. G. Horton, DOE/YMSCO, Las Vegas, NV
D. A. Klimas, BSC, Las Vegas, NV
D. T. Krisha, BSC, Las Vegas, NV
Robert Latta, NRC, Las Vegas, NV
S. W. Lynch, State of Nevada, Carson City, NV
S. P. Mellington, DOE/YMSCO, Las Vegas, NV
Ram Murthy, DOE/OQA, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
R. E. Powe, BSC, Las Vegas, NV
J. M. Replogle, DOE/YMSCO, Las Vegas, NV
N. K. Stablein, NRC, Rockville, MD
D. D. vonderLinden, BSC, Las Vegas, NV
Engelbrecht von Tiesenhausen, Clark County, Las Vegas, NV
T. J. Wall, BSC, Las Vegas, NV
B. L. Wilson, BSC, Las Vegas, NV

cc w/encl:

J. C. Estill, BSC/LLNL, Livermore, CA
R. L. Hand, BSC, Las Vegas, NV
J. M. Horn, BSC/LLNL, Livermore, CA
R. L. Maudlin, BSC, Las Vegas, NV
C. E. Palmer, BSC/LLNL, Livermore, CA
Bill Stimson, MDI Labs, Inc., Newark, DE
Roxanna VanDillen, BSC, Las Vegas, NV

**ORIGINAL
THIS IS A RED STAMP**

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

8. DEFICIENCY REPORT
 CORRECTIVE ACTION REPORT
NO. BSC(V)-02-D-111
PAGE 1 OF
QA: QA

DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)
MIDI Labs, Inc. Quality System Procedure (QSP) QSP 0410, Revision C, and QSP 0411, Revision A
2. Related Report No.:
BSC-SA-02-023

3. Responsible Organization:
BSC / MIDI Labs, Inc.
4. Discussed With:
W. Stimpson, Margaret Riehnman, Leanne Gandolfo (MIDI), and R. VanDillen (BSC)

5. Requirement:
A. QSP 0410, Section 2.0, states in part: "The PO should contain appropriate technical and quality requirements for the item or service being ordered."
B. QSP 0410, Section 5.0, states in part: "Lab personnel receive the order and verifies that the finished item complies with PO requirements. Verification can include reviewing objective evidence for conformance to the PO requirements...."
C. QSP 0411, Section 3.2, states in part: "The QA/Compliance Manager is responsible for evaluating the potential new supplier....Evaluation of applicable quality system documentation or records....quality manual...."

6. Description of Condition:
Contrary to the requirements above:
A. MIDI Labs, Inc. purchase orders PO 1461, dated 01/18/2002; PO 1464, dated 01/21/2002; and PO 1474, dated 02/12/2002 for calibration services failed to include quality requirements.
B. Documentation supporting the calibration of MIDI Labs, Inc. measuring and test equipment was not reviewed against the requirements of the MIDI Labs, Inc. purchase orders 1461, 1464, and 1474.
C. No documentation could be provided to reflect that MIDI Labs, Inc. QA/Compliance Manager had reviewed the quality manuals for MIDI Labs, Inc. suppliers Pro-Lab, Ranin Service Center, and Delval Balance Service, who provide calibration services
Has work been stopped? Yes No

7. Initiator:
Richard L. Maudlin *R. Maudlin* 05/06/02
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:
A. Take the necessary action to determine the cause of why the quality requirements were not included in the MIDI purchase orders and provide the necessary action to preclude occurrence.
B. Review all M&TE Certificates of Calibration against the MIDI purchase order and verify that the requirements of the purchase order have been met.
C. Obtain copies of all applicable supplier QA Manuals and review them for acceptability in complying with MIDI purchase order requirements. Document the review and provide a statement of compliance.

11. QA Review:
Richard L. Maudlin *R. Maudlin* 05/06/02
Printed Name Signature Date
12. Response Due Date:
20 Working Days after Issuance

13. QAM Issuance Approval:
Printed Name Signature Date
ROBERT P. KEEFE FOR Donald T. Krishna *Robert P. Keefe/for* 5/13/02

14. Corrective Actions Verified/Closure
QAR Printed Name Signature Date
15. QAM Closure Approval:
Printed Name Signature Date

**ORIGINAL
THIS IS A RED STAMP**

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

8. DEFICIENCY REPORT
 CORRECTIVE ACTION REPORT
NO. BSC(V)-02-D-112
PAGE 1 OF
QA: QA

DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)
BSC Technical Service Agreement TA003036, Revision 00

2. Related Report No.:
BSC-SA-02-023

3. Responsible Organization:
BSC / MIDI Labs, Inc.

4. Discussed With:
W. Stimpson (MIDI) and R. Van Dillen (BSC)

5. Requirement:
BSC TA 003036, Statement of Technical/Quality Requirements for DNA Sequence Analysis Services, Revision 00, Section II states in part: "Sample control and traceability shall be maintained at all times...."

6. Description of Condition:
Contrary to the above requirements, MIDI does not have procedures in place which describes the process for documenting and dispositioning samples which were not received. Example: LLNL provided a list of 61 samples to be submitted, however, MIDI Labs, Inc. could not account for all the samples on the LLNL list. One sample, #43, was missing. There was no documentation to support that, upon receipt, a sample was found to be missing and how that missing sample was to be dispositioned.

Has work been stopped? Yes No

7. Initiator:
Richard L. Maudlin *[Signature]* 05/06/02
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:
Take the necessary action to modify the applicable Quality System Procedure to address how missing samples upon receipt are to be documented and dispositioned. In addition, take the necessary action to document the loss of the sample in accordance with the MIDI Labs, Inc. corrective action requirements and identify the disposition of the missing sample.

11. QA Review:
Richard L. Maudlin *[Signature]* 05/06/02
Printed Name Signature Date

12. Response Due Date:
20 Working Days after Issuance

13. QAM Issuance Approval:
Printed Name *ROBERT P. KEELER FOR* Signature *[Signature]* Date 5/13/02
Donald T. Krisha

14. Corrective Actions Verified/Closure
QAR Printed Name Signature Date

15. QAM Closure Approval:
Printed Name Signature Date