



QA: QA

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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT
(DR) BSC(V)-02-D-014 RESULTING FROM THE BECHTEL SAIC COMPANY, LLC (BSC)
QUALITY ASSURANCE (QA) AUDIT BSC-SA-01-032 OF MIDI LABS, INC.

BSC Quality Assurance has verified implementation of corrective action for DR
BSC(V)-02-D-014 and determined the results to be satisfactory. As a result, the DR has
been closed.

If you have any questions, please contact either Stephen D. Harris at (501) 495-2214 or
Daniel A. Klimas at (702) 295-2665.

A handwritten signature in cursive script that reads "D. T. Krishna".

Donald T. Krishna, Manager
Quality Assurance

2/22/02
Date Signed

SDH:ml-0221021570

Enclosure:
DR: BSC(V)-02-D-014

Handwritten initials in the bottom right corner, possibly "D. Harris" or "D. Klimas", written in a cursive style.

February 22, 2002

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cc:w/encl:

L. H. Barrett, DOE/HQ (RW-2) FORS
L. W. Bradshaw, Nye County, Pahrump, NV
J. R. Dyer, DOE/YMSCO, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
S. H. Horton, BSC, Las Vegas, NV
D. A. Klimas, BSC, Las Vegas, NV
B. R. Kornegay, 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
Ram Murthy, DOE/OQA, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
J. M. Replogle, DOE/YMSCO, Las Vegas, NV
N. K. Stablein, NRC, Rockville, MD
D. D. von der Linden, BSC, Las Vegas, NV
Engelbrecht von Tiesenhausen, Clark County, Las Vegas, NV

cc: w/encl:

K. O. Gilkerson, BSC, Las Vegas, NV
S. D. Harris, BSC, LBNL
N. E. Kramer, BSC, Las Vegas, NV
Roxanna VanDillen, BSC, Las Vegas, NV

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

ORIGINAL
8. DEFICIENCY REPORT
 CORRECTIVE ACTION REPORT

NO. BSC(V)-02-D-014

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QA: *X GH*

Dec 10/31/01

DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document: QSP 0620, Equipment Calibration and Maintenance, Revision A.	2. Related Report No.: BSC-SA-01-032
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3. Responsible Organization: BSC S&ET/MIDI Laboratories, Inc.	4. Discussed With: Bill Stimson/MIDI Labs, Inc./Mark Peters-BSC
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5. Requirement:
QSP 0620, section 3.0, 1. New Equipment, states, "Before use, laboratory equipment requires testing to prove that the equipment works as intended and certified as conforming to a specified accuracy. Validation of equipment requires Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

6. Description of Condition:
An example document was produced with the following title, "Installation and Performance Qualification: Applied Biosystems DNA Sequences - Model 377, Serial Numbers 96031350, 96071742, 94120142. Contrary to the above requirement, this document did not describe the operational qualification as indicated by the continued requirements of QSP 0620, section 3.0, part 1.

There was another document that showed operational qualification for some other lab equipment, however, it was not readily obvious that this document covered the DNA sequencers that were described in the first document.

7. Initiator: <i>[Signature]</i> S. D. Harris Date 10/15/01	9. Does a stop work condition exist? (Not required for a DR) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
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10. Recommended Actions:
1. These documents of tested lab equipment (installation, operational and performance) need to be brought together into a document that contains traceability to the equipment tested and has all necessary requirements of QSP 0620 included.
2. Retrain personnel to procedure requirements.

11. QA Review: <i>[Signature]</i> QAR Daniel A. Klimas Date 10/18/01	12. Response Due Date: <i>10/26/01</i> Working Days From Issuance <i>20</i>
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13. DDOA Issuance Approval: Printed Name Donald T. Krishna Signature <i>[Signature]</i> Date <i>10/26/01</i>

22. Corrective Actions Verified: QAR: <i>[Signature]</i> per <i>R.F. Hertzstem</i> Date 10/17/01	23. Closure Approved by: DDQA <i>[Signature]</i> Date <i>11/22/02</i>
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TYPE RESPONSE

- Initial
- Complete
- Amended

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QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions:

N/A

Compliance Date:

14. Remedial Actions:

MIDI Labs will assemble all IQ/OQ/PQ documentation and data into a validation binder for easier access and easier reference to QSP 0620 requirements.

15. Extent of Condition:

MIDI Labs performed an installation and performance qualification of the ABI Prism® 377 DNA Sequencer in 1999 as part of the MicroSeq microbial identification process validation. Although all the necessary steps were performed to meet the process validation requirements, the IQ/OQ/PQ format was not followed as currently required in QSP 0620.

There has been no quality-affecting work performed to date by MIDI Labs for the YMP, therefore, there is no impact as a result of this deficient condition.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

QSP 0620 was not in place in 1999.

17. Action to Preclude Recurrence:

1. Appropriate personnel will be trained to the requirements of QSP 0620. The training will be documented and included in MIDI Lab's training records system.
2. When the sequencers are re-qualified in 2002, the IQ/OQ/PQ format will be implemented.

AC for D. WILLIAMS 11/30/01

18. Due Date: November 30, 2001

- For submittal of complete response
- For completion of corrective action

19. Response by: Mark Peters (Roxie VanDillen - Resp. Ind.)

Mark Peters 11/29/01
Date: November 29, 2001
Phone: 5-3644
Com for RVD 11/29/01
MS BSC 11/30/01

20. Evaluation: Accept Partially Accept Reject

QAR *Denise H. Gipp* Date 12/3/01

21. Concurrence:

Robert P. Kele
Date 12/03/01
DOQA *E. T. KRISHA*

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8. DR/CAR
 Stop Work Order

NC BSC(V)-02-D-014
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QA: *12/21/02*

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Verification of Corrective Action:

The recommended actions included: "These documents of tested lab equipment (installation, operational and performance) need to be brought together into a document that contains traceability to the equipment tested and has all necessary requirements of QSP-0620 included."


The example document evaluated during the supplier audit, "Installation and Performance Qualifications: Applied Biosystems DNA Sequences - Model 377, Serial Numbers 96031350, 96071742, 94120142", has been submitted to BSC with a set of documents that support these DNA sequences. Under QSP-0620, Equipment Qualification, Calibration and Maintenance, Revision C, Section 3a, Qualification, the following is required to be included for operational qualification, which was the deficient condition cited in block 6: "The Operational Qualification (OQ) tests that key functions of the instrument, routinely used in the laboratory, will meet equipment specifications. The OQ can include a series of functional tests to insure that the equipment is operating within the limits of a pre-determined set of expected results or criteria."

Within the submitted package of documentation is included a validation protocol that includes acceptance criteria for tests performed. There are test examples included that show results within acceptable limits and a validation summary that attests to following appropriate protocol and validation to the acceptance criteria.

Based on the above information, the documentation submitted meets the requirements of QSP-062 for operational qualification and all documentation has been collected in one package.

Training to QSP-0620, Equipment Qualification, Calibration and Maintenance, for all applicable MIDI Lab, Inc. personnel was completed on 11/29/2001.

These corrective actions are acceptable for closure of this DR.


Richard L. Hand

2/21/02
Date Signed