



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-011 RESULTING FROM THE BECHTEL SAIC  
COMPANY, LLC (BSC) QUALITY ASSURANCE (QA) AUDIT BSC-SA-02-032 OF  
MIDI LABS, INC.

BSC Quality Assurance has verified implementation of corrective action for  
DR BSC(V)-02-D-011 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. Krisha".

Donald T. Krisha, Manager  
Quality Assurance

2/13/02

Date Signed

SDH:ml-0221021563

Enclosure:  
DR: BSC(V)-02-D-011

WM-11  
NMS527

February 13, 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. Krishna, 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, Las Vegas, NV  
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.**

8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT

**ORIGINAL**  
**THIS IS A RED STAMP**

NO. BSC(V)-02-D-011

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QA: QA

**DEFICIENCY/CORRECTIVE ACTION REPORT**

1. Controlling Document: MIDI Labs QA Manual, Rev. A	2. Related Report No.: BSC-SA-01-032
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3. Responsible Organization: BSC S&ET/MIDI Labs, Inc.	4. Discussed With: Bill Stimson.MIDI Labs, Inc./Mark Peters, BSC
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5. Requirement:  
MIDI Labs QA Manual, Rev. A, Section 1.0, para. 1.8 states in part...Training is provided by qualified persons related to the individual employee's job responsibilities and related to the regulatory requirements (e.g. quality system, current good manufacturing practices).

6. Description of Condition:  
Contrary to the above requirements, evidence of training for Quality System Procedures (QSPs) and Standard Operating Procedures (SOPs) were not available for review.  
Additionally, qualification records for the quality consultant conducting the training were not available for review.

7. Initiator: <i>Daniel A. Klimas</i> Daniel A. Klimas Date 10/18/01	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. Conduct any required training and document the results in accordance with quality system requirements.  
2. Obtain required qualification and training documentation of the quality consultant conducting the training.

11. QA Review: <i>Daniel A. Klimas</i> QAR: Daniel A. Klimas Date 10/18/01	12. Response Due Date: 10 Working Days From Issuance 20 DR 10/31/01
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13. DQQA Issuance Approval:  
Printed Name Donald T. Krisha Signature *D. T. Krisha* Date 10/26/01

22. Corrective Actions Verified: <i>R.F. Hertzbein</i> QAR: R.F. Hertzbein Date 2/12/02	23. Closure Approved by: DQQA <i>D. T. Krisha</i> Date 2/14/02
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TYPE RESPONSE:

- Initial
- Complete
- Amended

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

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*11/2/01*  
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**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

N/A

Compliance Date:

14. Remedial Actions:

Midi Labs employees have reviewed all Quality System and Standard Operating Procedures (QSPs and SOPs). The review has been documented in MIDI Lab's training records. Additionally the qualification records for the quality consultant conducting the training have been located and are now included in MIDI Lab's training documentation.

15. Extent of Condition:

The current quality manual was put into effect on 10/30/00. At that time, all Rev. A procedures were reviewed by the lab personnel and the review was documented by the Lab Manager. Although the training document stated that all Quality Manual procedures were reviewed, it did not include a list of the specific procedures.

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.)

Inattention to requirements of the quality system and operating procedures. Additionally, the qualification documentation for the quality consultant was misfiled.

17. Action to Preclude Recurrence:

Midi Labs employees have been retrained on all QSPs and SOPs.

18. Due Date: November 27, 2001

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

19. Response by: Mark Peters (Roxie VanDillen - Resp. Ind.) *11/27/01*

*Mark J Peters 11/27/01* Date: November 27, 2001  
*11/27/01* Phone: 5-3644  
*RF 11/27/01*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Daniel Thomas* Date *12/3/01*

21. Concurrence:

*Robert P. Kelly*  
DOQA *D. T. KRISHA* Date *12/03/01*

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WASHINGTON, D.C.

8.  DR/CAR  
 Stop Work Order

NO BSC(V)-02-D-011  
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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

The following information has been reviewed for verification of corrective action submitted by Midi Labs, Inc..

A copy of the training log for the laboratory personnel has been submitted. It shows that all personnel have been trained to the current QSP's and SOP's.

A copy of the training consultant's qualifications has been put into the laboratory's records and a copy sent to BSC for information.

These two submittals complete the requested information to address the conditions identified in this DR. These submittals are acceptable to complete the corrective action required.

*Richard L. Hand*  
Richard L. Hand  
2/7/02

*Dr. L. Hartman for*  
*D. Kimms QAR*

*2/12/02*

MIDI Labs, Inc.

QSP Training Record

Rev. A

Page 1 of 1

## QSP Training

Initial and Date signifies that the employee has reviewed and understood the QSP listed below.

QSP #	Title	Rev.	Maggie Riehm	LeAnne Gandolfo	Bryan Moon
0140	Management Review	IA	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0170	Quality Audit	IA	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0171	FDA Audit	IA	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0180	Personnel Functions	IA	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0310	Document Control	IB	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0410	Purchasing Process	IB	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0620	Equipment Calibration and Maintenance	IA	MR 11/9/01	LG 11/14/01	Bm 10/25/01
0630	Facility Control	IB	MR 11/13/01	LG 11/14/01	Bm 10/25/01
0710	Acceptance Process	IA	MR 11/13/01	LG 11/14/01	Bm 10/25/01
0910	Problem Reporting and Corrective Action Process	IA	MR 11/13/01	LG 11/14/01	Bm 10/25/01

MIDI Labs, Inc.	SOP Training Record	Rev. A	Page 1 of 2
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### SOP Training

Initial and Date signifies that the employee has reviewed and understood the SOPs listed below.

QSP #	Title	Rev.	Maggie Riehinan	LeAnne Gandolfo	Bryan Moon
001	Refrigerators and Freezers	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
002	Incubators	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
003	Millipore Water Purification System	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
004	Autoclave	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
005	Top Loading Balance	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
006	Semi-automatic Pipettes	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
007	Safety Shower/Eyewash Station	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
008	Thermometers	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
009	Bio-safety Cabinets	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
010	Geneamp PCR System 9600/9700 Thermal Cycler	B	MR 11/9/01	LG 10/31/01	BM 10/26/01
011	Water Baths	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
012	ABI Prism 377 DNA Sequencer	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
013	Centrifuge	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
014	Heat Block	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
015	Reagent and Solution Preparation	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
016	Hazardous Waste Disposal	A	MR 11/9/01	LG 10/31/01	BM 10/26/01
017	Bio-Hazardous Waste Disposal	B	MR 11/9/01	LG 10/31/01	BM 10/26/01
018	Laboratory Surface and Equipment Cleaning and Scheduled Maintenance/Calibration	B	MR 11/9/01	LG 10/31/01	BM 10/26/01
019	Media Preparation	A	MR 11/9/01	LG 11/13/01	BM 10/26/01
020	Customer Sample Handling	A	MR 11/9/01	LG 11/13/01	BM 10/26/01
021	Receipt and Handling of Damaged Goods	A	MR 11/9/01	LG 11/13/01	BM 10/26/01
022	Laboratory Safety	B	MR 11/9/01	LG 11/13/01	BM 10/26/01
023	DNA Extraction	A	MR 11/9/01	LG 11/13/01	BM 10/26/01
024	PCR Amplification	A	MR 11/9/01	LG 11/13/01	BM 10/26/01
025	PCR Product Purification	A	MR 11/9/01	LG 11/13/01	BM 10/26/01
026	Analysis of PCR Product	A	MR 11/9/01	LG 11/13/01	BM 10/26/01





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Dec. 26, 2001

R. VanDillen  
Quality Compliance Support  
Bechtel SAIC CO., LLC  
1180 Town Center Drive  
Las Vegas, NV 89144

This is to certify that the Qualification Records for Cliff Evans, MIDI Labs  
quality consultant, have been filed in MIDI Labs QA Files

*William Stimson*

William Stimson  
QA/Compliance Manager  
MIDI Labs, Inc.