BECHTEL SAIC COMPANY, LLC

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-012 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-012 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.

D. T. Krisha

Donald T. Krisha, Manager
Quality Assurance

2/22/02
Date Signed

SDH:ml-0221021572

Enclosure:
DR: BSC(V)-02-D-012

cc:w/encl:
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S. D. Harris, BSC, LBNL
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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION REPORT

NO. DR BSC(V)-02-D-012

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QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document:	2. Related Report No.:
MIDI Labs QA Manual, Rev. A	BSC-SA-01-032
3. Responsible Organization:	4. Discussed With:
BSC S&ET/MIDI Labs, Inc.	Bill Stimson, MIDI Labs,Inc./Mark Peters, BSC

5. Requirement:

Procedure QSP 0410, Purchasing Process, para. 3.0, 2 states in part...The PO contains the specifications of the material, the catalog number, any special requirements, and any other information that ensures the correct material.

The MIDI Labs, Inc. QA Manual, Rev. A, Section 4.0, para. 4.1, states in part...MIDI Labs, Inc. evaluates all suppliers.

6. Description of Condition:

Contrary to the above requirements MIDI Labs' purchase orders reviewed did not include quality or technical requirements appropriate to the item or service being procured.

Supplier evaluations are not being documented.

7. Initiator:	9. Does a stop work condition exist? (Not required for a DR)
Daniel A. Klimas Daniel A. Klimas Date 10/18/01	☐ Yes ☒ No If Yes. Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

1. Revise necessary documents, i.e. QA Manual, QSP 0410, to assure appropriate quality and technical requirements are included in purchase orders to suppliers and supplier evaluations are documented.
2. Revise appropriate documents to require QA/Compliance Manager approval of purchase orders.
3. Train applicable personnel to all revised documents.

11. QA Review:	12. Response Due Date:
QAR: Daniel A. Klimas Daniel A. Klimas Date 10/18/01	DK 10/31/01 20 Working Days From Issuance

13. DOQA Issuance Approval:

Printed Name Donald T. Krisha Signature D. T. Krisha Date 10/26/01, 10/24/01

22. Corrective Actions Verified:	23. Closure Approved by:
QAR: R.F. Hartstern for D. Klimas R.F. Hartstern Date 2/12/02	DOQA D. T. Krisha Date DTK 2/22/02

TYPE RESPONSE:
☐ Initial
☒ Complete
☐ Amended

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WASHINGTON, D.C.

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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions:

N/A

Compliance Date:

14. Remedial Actions:

1. MIDI Labs will revise purchasing QSP 0410 to add appropriate technical and quality specifications on PO's. Included in the revision to QSP 0410 will be an approval on POs with quality and technical specifications. The approval will consist of Lab Manager and QA/Compliance Manager. The new revision of QSP 0410 will reflect the approval step. Additionally, PO's for services provided, which affect YMP quality-related activities, will be evaluated against the appropriate quality and technical specifications.
2. QSP 0411, Rev. A, has been developed to describe the supplier approval process. Included in QSP 0411, Rev. A, is the requirement to document supplier evaluations. MIDI Labs will evaluate appropriate suppliers per QSP 0411.

15. Extent of Condition:

1. POs not containing quality and technical specifications were limited to six suppliers: Atlantic Scale, Delaware Film & Tape Vault Co., Delval Balance Co., Applied Biosystems, Inc., Prolab, and Rainer. An impact evaluation will be provided to address the results of item 1, in box 14 of this DR.
2. Suppliers evaluations not documented were limitied to six suppliers: Atlantic Scale, Delaware Film & Tape Vault Co., Delval Balance Co., Applied Biosystems, Inc., Prolab, and Rainer. An impact evaluation will be provided to address the results of item 2, in box 14 of this DR.

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.)

1. Based on the requirements listed in QSP 0410, it was not clear what technical and quality specifications should be provided in the POs.
2. There was no QSP describing the supplier evaluation/documentation process.

17. Action to Preclude Recurrence:

1. An approval step has been added to the purchase order process to include the Lab Manager and QA/Compliance Manager. Appropriate personnel will be trained to the new revision of QSP 0410. This training will be documented and included in MIDI Lab's training records system.
2. Appropriate personnel will be trained to the newly developed QSP 0411. This training will be documented and included in MIDI Lab's training records system.
3. For sub-tier suppliers used by MIDI Labs to perform quality-affecting activities relative to YMP work, evaluations will be performed and documented.

18. Due Date: December 15, 2001
☐ For submittal of complete response
☒ For completion of corrective action

19. Response by: Mark Peters (Roxie VanDillen – Resp. Ind.) Mark J Peters 11/27/01 Date: November 27, 2001 Phone: 5-3644

20. Evaluation: ☑ Accept ☐ Partially Accept ☐ Reject
QAR Daniel Hughes Date 12/3/01

21. Concurrence:
DOQA E. T. KRISHA Date 12/03/01

Exhibit AP-16.1Q.1 Rev. 12/20/1999

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8. [X] DR/CAR
[ ] Stop Work Order

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

The following information has been submitted to support the closure of the MIDI Labs, Inc. DR.

QSP-0410, Purchasing Process, has been modified to require the review and approval of PO's by either the Lab Manager or the QA/Compliance Manager. In addition, the procedure requires that procurements be made from companies on the Approved Vendor List. If the supplier is not on the Approved Vendor List, instruction is given to go to QSP-0411, Supplier Approval, to get the supplier added to the list. QSP-0411 was developed to address supplier approval. The procedures are considered acceptable to close the concerns addressed in this Deficiency Report.

Training to Revision C of QSP-0410, Purchasing Process, and Revision A of QSP-0411, Supplier Approval for applicable MIDI Lab, Inc. personnel was completed on 11/29/2001.

These procedure revisions and supporting training are found acceptable to close this DR.

Richard L. Hand

2/21/02
Date Signed

1.0 Introduction

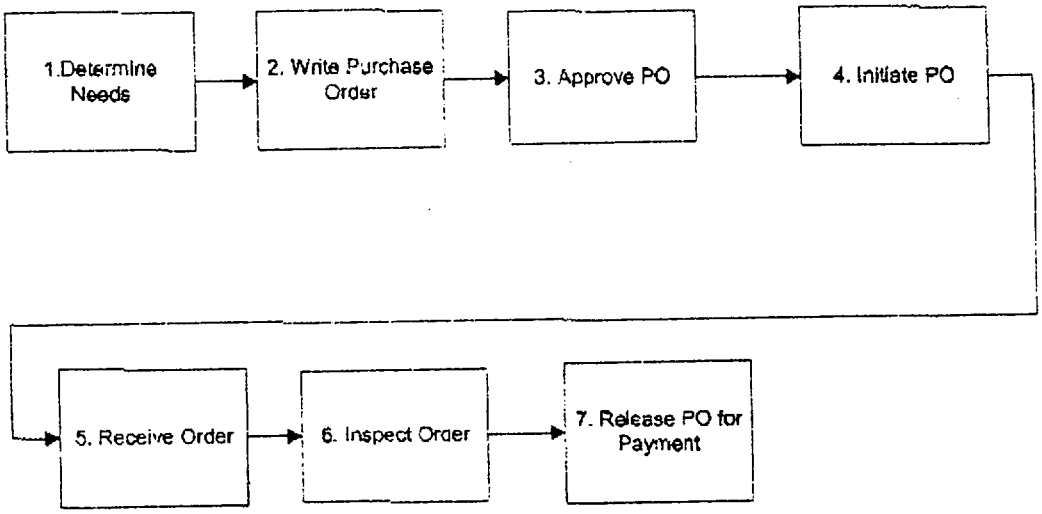
Purpose

The purpose of this Quality System procedure is to describe the purchasing process by a process workflow and details as called for by the Quality Manual, section 4.1.

References

No standard operating procedures required.
No quality form required.

2.0 Process Workflow



3.0 Diagram Details

1. Determine Needs

The Lab Manager or designate determines the laboratory needs by lab inventory control and inspection.

2. Write Purchase Order (PO)

A MIDI Labs, Inc. employee (requestor) writes a purchase order (PO) on the MIDI Labs, Inc. PO form. The item or service must come from a vendor on QF0411, Approved Vendor List. If the Vendor is not on the approved vendor list, see QSP 0411.

The PO should contain appropriate technical or quality requirements for the item or service being ordered. Technical requirements may include specifications of the material (size, weight, concentration, purity, quantity, et al.) or reference to documents that describe the technical requirements of the item or service (such as drawings, standards, regulations, procedures, instructions). Quality requirements may include specific testing or inspections to be done, notice of deviations from standard procedures, rights of access to Purchaser related QA records, retention time of QA records, or required documentation.

The PO for items that are considered 'off the shelf' or catalogue items needs the catalogue or part number and the supplier's description of the item. Any special requirements (i.e. delivery date, shipping instructions, etc.) may also be included on the PO. However, specific technical or quality requirements are not necessarily required.

3. Approve Purchase Order (PO)

The Lab and QA/Compliance Managers, or designates, check the PO for appropriate technical and quality requirements and approve the PO by signing and dating the completed MIDI Labs, Inc. PO form. For OTS items, only the Lab Manager's approval is required.

If changes are made to the PO after approval, the PO must be reviewed and approved again by the Lab and/or QA/Compliance Manager. New approval signatures are required.

4. Initiate PO

The requestor initiates the PO by calling the vendor with the order, faxing the PO form to the vendor, contacting the vendor via the internet, or mailing the approved PO form to the vendor.

The requestor places a copy of the approved PO form in the lab record of purchases.

The requestor sends a copy of the approved PO form to the financial group.

5. Receive/Inspect Order

Lab personnel receive the order and verifies that the furnished item complies with the PO requirements. Verification can include reviewing objective evidence for conformance to the PO requirements, such as evaluating the supplier certification of conformance.

For calibration or maintenance services, a calibration or maintenance report (or other evidence of the service provided) must be reviewed and signed and dated by the Lab or QA/Compliance Manager.

For OTS items, this includes verifying correct part # and quantity, and inspecting for damage. If acceptable, the PO is marked "**AAR**" (Accepted As Received) and the receiver initials and dates the PO.

If the order is damaged or has a mistake in quantity, the requestor files a problem report with the Quality Assurance/Compliance Manager, who in turn follows the problem reporting and corrective action (PRCA) process.

Lab personnel can contact the vendor, report the problem, and attempt to rectify the problem.

Lab personnel may need to escalate the problem resolution to the Lab Manager.

6. **Release PO for Payment**
   Lab personnel send the initialed and dated P.O. and packing list to the financial department to release the PO for payment.

4.0 Approval

Approval	Signature	Date
Lab Manager	M Quebrin	11/14/01
QA/Compliance Manager	William Stimson	11-21-01

1.0 Introduction

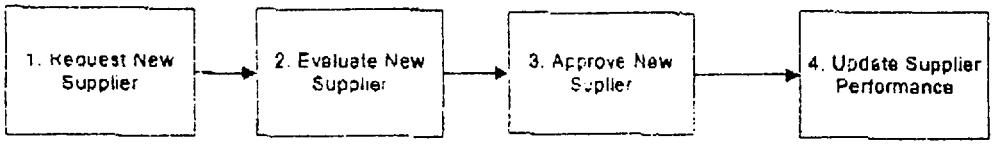
Purpose

The purpose of this Quality System procedure is to describe the supplier approval process.

References

QSP 0910, Problem Reporting and Corrective Action Process

2.0 Process Workflow



3.0 Diagram Details

3.1 Request New Supplier

Lab personnel should only order items from suppliers on the Approved Suppliers List. However, any lab personnel can request that a supplier be added to the approved list for a variety of reasons (problems with current supplier, backup supplier, lower cost, higher quality supply, etc.). The request is documented using the PRCA system, and includes the reason for adding the new supplier.

3.2 Evaluate New Supplier

The QA/Compliance Manager is responsible for evaluating the potential new supplier. Depending on the scope, nature, or complexity of the purchased item or service, suppliers can be evaluated by one of the following methods:

- Evaluation of supplier's history for providing identical or similar products or services.
- Evaluation of applicable quality system documentation or records answers to a questionnaire, quality manual, index of procedures, specific applicable procedures, or other quality records.
- Onsite audit to review the supplier's technical and quality capability.

- For off-the-shelf items, the Lab and QA Managers will evaluate the effect of the changed supplier part on the quality of analysis. If acceptable (change will probably not have an effect on the analysis. or the risk is low), the Lab Manager can approve the supplier and the QA/Complaince Manager updates the Approved Suppliers List. History, documentation review, or onsite audit evaluation is not necessary in this case.

Documentation of the supplier review will be located in the PRCA system or in the supplier file.

3.3 Approve New Supplier

If the results of the supplier evaluation are acceptable, the Lab and QA/Compliance Manager will approve the supplier. Approval will be documented in the PRCA system, and the supplier will be added to the Approved Suppliers List.

There may be supplies critical to the function on the lab that can only be purchased from one supplier. In this case, QA will work with the supplier to ensure an adequate level of supplier quality system. The supply may be approved for use by the Lab Manager and used during the development of an appropriate supplier quality system.

The Approved Suppliers List will show the level of evaluation for each supplier. The choices are;

H – History
Q – Questionnaire or Quality Documentation Evidence
OA – Onsite Audit
U – Unique Vendor
OTS – Off the shelf or commercial grade item
C - Conditional

3.4 Update Supplier Performance

The performance of critical suppliers (non-OTS) will be periodically reviewed. Supplier performance will be based on;

- # of Rejections due to failure to meet PO requirements.
- Incorrect shipments.
- Audit deficiencies.

Any supplier problems will be documented in the PRCA system. If problems develop with an approved supplier, the supplier may be moved to a Conditional

status while corrective actions are in process. In this case, the QA/Compliance Manager must approve each batch of product before it can be used in the lab.

4.0 Approval

Approval	Signature	Date
Lab Manager	M. Richman	11/3/01
QA/Compliance Manager	William Stimson	11/21/01