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Department of Energy

Washington, DC 20585

QA: QA

MAR 06 2002

M. T. Peters
Los Alamos National Laboratory
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**EVALUATION OF AMENDED RESPONSE, VERIFICATION OF CORRECTIVE ACTION
AND CLOSURE OF DEFICIENCY REPORT (DR) BSC-02-D-030 RESULTING FROM THE
OFFICE OF QUALITY ASSURANCE (OQA) SURVEILLANCE BSC-SR-02-02**

The OQA staff has evaluated the amended response to, verified the corrective action of DR BSC-02-D-030 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420
Donald J. Harris at (702) 794-1467.

James Blaylock
Ram Murthy, Acting Director
Office of Quality Assurance

OQA:JB-0748

Enclosure:
DR BSC-02-D-030

*NMISSON
W.M.-11
Rev W Wypatt*



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THIS IS A RED STAMP
8. DEFICIENCY REPORT
 CORRECTIVE ACTION REPORT

NO. DR BSC-02-D-030

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DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document: AP-7.7Q, Revision 0, ICN 1, <i>Acceptance of Items and Services</i>		2. Related Report No.: BSC-SR-02-02	
3. Responsible Organization: Bechtel SAIC Company, LLC (BSC)		4. Discussed With: S. Silva, J. Timmons, Ivelina McClung	

5. Requirement:

1. Section 5.5, Acceptance of Services
Section 5.5.1, Analytical/Technical Services, Requestor/BSC Engineer:

a) Verify, within 30 calendar days after receipt of supplier documentation, that the supplier documentation meets the requirements specified in the procurement document. For services not meeting the requirements, contact Procurement Engineering for assistance.

b) Complete the Acceptance Report for Analytical/Technical Services, Attachment 5.

(Continued on page 2)

6. Description of Condition:

1. Contrary to block 5 requirement #1, Acceptance of Analytical/Technical Services: Purchase Order 2454-100-PO-17369 Modifications 7 and 8 for Chemical Reagent Standards, there is no objective evidence in the Records Information System (RIS) or Records Processing Center (RPC) of Acceptance Reports or Certification for the Chemical Reagents Standards for this Purchase Order.

2. Contrary to block 5 requirement #2, Calibration Services:

a) For Purchase Order 24540-400-TSA-0054, Calibration Services of LANL Particle Measuring System On Site, Performance Period 4/2/01 to 5/2/01, there is no objective evidence in the RIS or RPC of an Acceptance Report or Certification of Calibration.

(Continued on page 2)

7. Initiator: <i>Donald J. Harris</i> Donald J. Harris Date: 11/15/01	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:
NONE.

11. QA Review: QAR <i>Donald J. Harris</i> Date: <i>11/19/01</i>	12. Response Due Date: 10 Working Days From Issuance
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13. DOQA Issuance Approval: (Print Name) Signature Robert D. Davis	Date: <i>James Blaylock for 11/28/01</i>
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22. Corrective Actions Verified: QAR <i>Donald J. Harris</i> Date: <i>3/1/02</i>	23. Closure Approved by: DOE/QQA <i>James Blaylock for</i> Date: <i>3/6/02</i>
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5. Requirement: (Continued)

- d) When applicable, record the PO number and the release (Rel) number on each report.
 - e) When all the requirements have been satisfied, print name, sign and date the acceptance report, and transmit it to the RPC in accordance with Section 6.0.
2. 5.5.2 Calibration Services, M&TE Custodian: Prior to release of the M&TE for use, complete the Acceptance Report form for Calibration Services, Attachment 7:
- a) Verify and document that the M&TE is properly identified, tagged, or otherwise marked in a manner traceable to its calibration documentation.
 - b) Verify that the supplier-generated objective evidence of calibration (e.g., calibration certificates, data, or reports) has been evaluated in accordance with the procurement document requirements.
 - c) Provide a link from each Calibration Report to the Acceptance Report form, by recording in the comments section of the Acceptance Report form a unique identified from the Calibration Report, i.e., Calibration Report number, serial number, etc., to indicate the total information contained in the Acceptance Report.
 - d) Print name, sign and date the Acceptance Report. It is the M&TE Custodians responsibility to assure that the completed Acceptance Report has been transmitted to RPC in accordance with Section 6.0

6. Description of Condition: (Continued)

- b) For Purchase Order 24540-100-PO-00440, Calibration Services of AC Voltage Transducer, Model AVT, there is no objective evidence in the RIS or RPC of Acceptance Report or Certification of Calibration. In addition, the Certification of Calibrations contained in the PO file fails to meet the requirements in the Statement of Work (SOW), Revision 1, 5/31/01, for description of the calibrated instrument, a statement of traceability to NIST Standards, a list of serial numbers of the supplier's standards used in Calibration, Statement of Acceptability, and identification of QA program and revision level used to provide calibration services for the following AGH Voltage Transducers:

Model GH-001D, serial numbers 01060209 through 01060221

Model GH-010D, serial numbers 01060230 through 01060232

- c) For Purchase Order A20202GJOE, Calibration Services of Liquid Glass Thermometers. There is no objective evidence in the RIS or RPC of an Acceptance Report or Certification of Calibration. In addition, the Certification of Calibration (dated April 20, 2000) contained in the PO file fails to meet the requirements in the SOW, Revision 00, dated 3/9/00, in that no model number provided, no serial number of reference standards or identification of calibration equipment used, no statement indicating work was performed in accordance with PO requirements and supplier's QA program, also the Test Temperatures were not in accordance with SOW.

TYPE RESPONSE:

- Initial
- Complete
- Amended

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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions:

N/A

Compliance Date: N/A

14. Remedial Actions:

N/A

15. Extent of Condition:

N/A

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

This deficiency report is not a valid report ^{Rev. 12/12/01} and ^{dated 2/26/02} Please see attached justification. _{DGO 2/28/02}

17. Action to Preclude Recurrence:

N/A

18. Due Date: N/A

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

19. Response by: Mark Peters (Responsible Indiv. Roxie VanDillen)

Mark Peters _{12/13/01} _{Rev. related}
 Date December 12, 2001 Phone 5-3644 _{KB MF 1/14/02}

20. Evaluation: Accept Partially Accept Reject

QAR

Date

21. Concurrence:

DOQA

Date

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Justification for deeming this DR invalid:

Objective evidence has now been located that supports the fact that a DR need not have been issued.

The following justification supports the above statement:

1. Contrary to the description of condition (1) listed in block 6 of this DR, acceptance reports were generated and submitted to the records center (see MOL.20011114.0200, and MOL.20011114.0202) in accordance with the requirements of AP-7.7Q, *Acceptance of Items and Services*.
2. Contrary to the description of condition (2a) listed in block 6 of this DR, the performance period 4/2/01 to 5/2/01 (calibration certificate provided by LANL Particle Measuring System was dated 5/2/01) preceded the effective date (05/09/01) of procedure AP-7.7Q, *Acceptance of Items and Services*, and therefore, was not subjected to the requirements of AP-7.7Q, but rather the requirements of QAP-7-5*, *Acceptance of Items and Services*, and should not be part of this DR.

Contrary to the description of condition (2b) listed in block 6 of this DR, the transducers identified (Model GH-001D, SN#01060209 through SN#01060221 and Model GH-010D, SN#01060230 through 01060232) were returned to the vendor, Ohio Semitronics, Inc., on 10/29/01. The equipment was returned because the requestor ordered the wrong equipment. The equipment was returned to the vendor in accordance with the requirements of PRO-FB-002, *Personal Property Management*.

Contrary to the description of condition (2c) listed in block 6 of this DR, as indicated in surveillance record BSC-SR-02-02, Section 9, Paragraph 4, and in conversations with Procurement Engineering, the Heusser Neweigh calibration of liquid glass thermometers issue was corrected during the surveillance**. Additionally, the performance period (calibration certificates provided by Heusser Neweigh were dated 04/20/00) preceded the effective date of procedure AP-7.7Q, *Acceptance of Items and Services*, and therefore, was not subjected to the requirements of AP-7.7Q, but rather the requirements of QAP-7-5, *Acceptance of Items and Services*, and should not be part of this DR.

*Although QAP-7-5 required that an acceptance report be generated, there was no time requirement in which the services needed to be accepted. S&ET is in the process of obtaining the information from LANL Particle Measuring System to complete the necessary documentation, however, this is not considered a corrective action to this DR.

**Two thermometers were purchased and calibrated under P.O. A20202GJ0E. One thermometer (SN#1326) was for the use at Montana Biotech and one thermometer (SN#1377) was for the use at LLNL. Before thermometer SN#1326 could be put into service, the Montana Biotech contract was cancelled. The thermometer was sent back to the YMP and is currently in the possession of the S&ET Procurement Administrator, and is not-in-use. Thermometer SN#1377 resided at LLNL (not-in-use) until recently (09/25/01), when it was re-calibrated. An acceptance report was generated (Trace #LLYMP0110044) and submitted to the records center in accordance with the requirements of AP-7.7Q, *Acceptance of Items and Services*.

TYPE RESPONSE:

- Initial
- Complete
- Amended

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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions:

- 1) None necessary. Objective evidence of acceptance of the certification for the subject reagents was submitted to the Record System (see MOL.20011114.0200, and MOL.20011114.0202). they were not available because they had not yet been processed into the Record System.
- 2) An Acceptance Report will be generated for the PMS equipment.
- 3) None necessary. The subject equipment was returned to the vendor without ever being used for YMP quality affecting work.
- 4) None necessary. The subject equipment was never used for YMP quality affecting work.

Compliance Date: 3/01/02

14. Remedial Actions:

- 1) Acceptance report will be generated for the OSI equipment, documenting no impact because the equipment was returned to the vendor and never used..
- 2) Acceptance report will be generated for the Heusser Neweigh calibrations, documenting no impact because the thermometers were never used to acquire QA data.

15. Extent of Condition:

The concerns cited in this DR are limited to special cases where equipment was calibrated but never used, or not accepted due to communication difficulties associated with the remote location and the transition between QAP-7-5 and AP-7.7Q.

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

- 1) Unavailability of calibration documentation due to remote location, and transition of acceptance responsibility.
- 2) Learning curve associated with transition of acceptance responsibility from QAP-7-5 to AP-7.7Q
- 3) Ambiguous requirements as to whether acceptance reports are needed for calibrations of equipments that were never used to acquire QA data.
- 4) Ambiguous requirements as to when to generate acceptance reports for calibration services.
- 5) Lack of any central POC to resolve these questions.

17. Action to Preclude Recurrence:

AP-7.7Q was implemented on 5/07/2001, clarifying the responsibility for calibration acceptance documentation and imposing a requirement that calibration acceptance documentation be completed before an instrument is released for service. M&TE Custodians have been trained to AP-7.7Q. As of January 2002, a Subject Matter Expert (SME) has been appointed for the AP-12.1Q M&TE control process. That SME has conducted training on the AP-12.1Q process, and will be revising AP-12.1Q to further streamline and clarify the M&TE control process (included in DAR D2461).

18. Due Date: 3/04/02

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

19. Response by: Thomas B. Reynolds

KO Thomas B Reynolds *RF* *AP-7.7Q*
MTP 2/26/02 *U200* Date *2/26/02* Phone *5-5215*

20. Evaluation: Accept Partially Accept Reject

QAR *Nonald J Harris* Date *2-27-02*

21. Concurrence:

DOQA *James Blaylock* Date *3/6/02*

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Verification and Closure of DR BSC-02-D-030

Block 14a – Immediate Actions:

1. Verified PO 24540-100-17369 acceptance reports and certifications for chemical re-agents are currently in the RISWEB (MOL.20011114.02000 and MOL.2001114.0202)
2. Verified the LANL particle measuring system calibration, in accordance with PO 24540-400-TSA 0054, has had an acceptance report dated 2/27/02 with the calibration certifications attached.
3. Verified AC voltage transducer, in accordance with PO 2540-100-PO-00440, were returned to the supplier without ever being used for YMP quality affecting work, on request for shipment, to Ohio Semitronics, Inc., dated 10/29/01. The acceptance report was initiated as "N/A returns to supplier on 2/27/02".
4. Verified the Hesser Neweigh Calibration of glass thermometers, S/N 1326 and S/N 1377 in accordance with PO A20202GJOE, were calibrated on 4/20/00 for use of Montana Biotech (subcontractor). These thermometers were never used to collect quality-affecting data because the calibration fails to meet the statement of work requirements. Thermometer 1377 is in possession of LLNL and was recalibrated on 9/25/01 prior to use. S/N 1326 is currently in possession of the procurement administrator. The acceptance report for the calibrations on 4/20/00 was completed on 2/25/02 to complete the process.

Block 14 – Remedial Actions:

1. Verified the acceptance report for AC Voltage Transducers was accepted for PO 24540-100 PO 00440 on 2/27/02.
2. Verified the acceptance report for the glass thermometers calibrated on 4/20/00 in accordance with PO A20202GJOE were completed on 2/25/02.

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Verification and Closure of DR BSC-02-D-030

(cont.)

Block 17 – Action to Preclude Recurrence:

1. Verified AP-7.7Q, Rev. 0/ICN 1, acceptance of items and services, Section 5.5.2 calibration services requires the M&TE custodian, prior to release of the M&TE for use, to complete the acceptance report form.
2. Verified all M&TE custodians were trained by a subject matter expert of their responsibilities at the end of January, 2002.
3. Verified DAR D2461 to clarify AP-12.1Q was initiated and the action was accepted for action by the responsible manager on 1/31/02.

Based on the above verification, it is recommended that this DR be closed.

QAR Donald J. Harris
Donald J. Harris

March 1, 2002
Date