

United States Government

Department of Energy

# Memorandum

QA: QA

DATE: **MAR 27 2002**

REPLY TO

ATTN OF: RW-3 (Ram Murthy/4-1460)

SUBJECT: VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT (DR) YMSCO(V)-02-D-006 RESULTING FROM THE OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-02-001

TO: YMSCO/OPE (E. T. Smistad)

The OQA staff has evaluated the corrective action of DR YMSCO(V)-02-D-006 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 or Dennis C. Threatt at (702) 794-1495.

OQA:JB-0866

*James Blaylock*  
Ram Murthy, Acting Director  
Office of Quality Assurance

Enclosure:  
DR YMSCO(V)-02-D-006

*Nms507*  
*WM-11*

MAR 27 2002

cc w/encl:

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Robert Latta, NRC, Las Vegas, NV

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Rich Hamon, Whiteshell Laboratories, Pinawa, Manitoba, Canada

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

DGC  
10/11/01

8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT  
NO. BSC-02-D-006  
YMSCO(W)  
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DEFICIENCY/CORRECTIVE ACTION REPORT

DGC 10/11/01

1. Controlling Document:  
AECL Whiteshell Laboratories Analytical Science QA Manual, Version 4.0  
AECL Analytical Science Branch procedure ASB QM-1, Version 2.0

2. Related Report No.:  
OQA-SA-02-001

3. Responsible Organization:  
AECL Analytical Science Branch

4. Discussed With:  
Rich Hamon

5. Requirement:  
Analytical Science QA Manual, Section 9.3.2 states, "... - For each equipment ID, the Analytical Science Inventory of Equipment specifies - identifying name, - manufacturer's name, - model number, - serial number, - current location, - current name and version of software ..."  
Analytical Science QA Manual, Section 11.3.1 states, "- Samples are logged in accordance with the current version of the 'Basic User Manual for LIMS', available from the Sample Reception Office." The "Basic User Manual for LIMS," Version 1.01, Page 7, requires that the user enter the Submitter's Label, WO Number, Submitter, Badge No., Branch Name, Phone No., Station No., Hazards, and Sample Disposal.  
Analytical Science Branch procedure ASB QM-1, Section 2., states, "Each balance is provided with a set of check weights whose true masses have been determined by comparison with a set of weights with certified masses."

6. Description of Condition:  
Contrary to the above requirements, the following deficiencies were noted:  
1. Auto Pipettes PF-1000-25, PF-200-24, and PF-500-25 were not found on the Analytical Science Inventory of Equipment.  
2. ASB samples AC32701, AC32741, AC32742, AC32743 and AC32744 logged into LIMS did not contain the WO Number, Submitter, Branch Name, Phone No., and Station No. Sample AC32740 logged into LIMS identified an incorrect Submitter, Branch Name, Phone No., and Station No.  
3. Balance B45R was checked with weight set W5 which contains 1Kg and 2 Kg weights. Weight set W5 was not compared to a set of weights with certified masses.

7. Initiator:  
*Dennis Threatt*  
Dennis Threatt Date 10/4/2001

9. Does a stop work condition exist? (Not required for a DR)  
 Yes  No  
If Yes, Check One:  A  B  C  D

10. Recommended Actions:  
1. Review the Analytical Science Inventory of Equipment to ensure it lists all equipment and update accordingly.  
2. Review samples logged into LIMS to ensure LIMS contains the required information and update accordingly.  
3. Obtain weights with certified masses and use as appropriate.

11. QA Review:  
QAR *Dennis Threatt* Date 10/11/2001

12. Response Due Date:  
10 working days from issuance

13. DOQA Issuance Approval:  
Printed Name Robert D. Davis Signature *James Blaylock Jr* Date 10/22/01

22. Corrective Actions Verified  
QAR *Dennis Threatt* Date 3/21/2002

23. Closure Approved by:  
DOQA Date

TYPE RESPONSE:

- Initial
- Complete
- Amended

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**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

None, other than remedial.

Compliance Date:

14. Remedial Actions:

1. The Inventory of Equipment will be amended to include all autopipettes, and other measuring equipment in use (excluding labware).
2. All existing DOE sample entries in LIMS have been checked and corrected so that the necessary information is accurate and stored in the proper fields. Specific Location Codes have been established for use with DOE samples login. These Location Codes place the proper information into all relevant fields.
3. A new set of Class 1 certified weights, including 1 kg and 2 kg masses, is being procured from a DOE-approved supplier, Quality Control Services, Portland, Oregon. The new weights will be used to check calibration of the two-decimal place balances.

15. Extent of Condition:

1. All autopipettes (including PF-1000-25, PF-200-24, and PF-500-025) were excluded from the Inventory of Equipment. These are used both for DOE purposes and other customer work. However, autopipettes in use are listed in EPPCAL.xls, which documents results from our regular check program. No loss of equipment control, calibration or analysis quantity has occurred.

(Continued on page 3)

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

1. In the Analytical Science QA Manual, it is not clearly specified what is and what is not considered to be "equipment." Historically, the term was applied to cover large spectrometers, etc., but not smaller items already tracked in more detail by other means (such as autopipettes and balances).

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17. Action to Preclude Recurrence:

1. Inventory of Equipment will be updated to include autopipettes and other measurement equipment.

(Continued on on page 3)

18. Due Date: December 14, 2001

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

19. Response by:

E. Smistad

Date 11/1/01

Phone 702-754-5073

20. Evaluation:  Accept  Partially Accept  Reject

QAR

*Dennis Thruatt*

Date 11/13/01

21. Concurrence:

DOQA

*James Blythe*

Date

11/16/01

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**15. Extent of Condition: (Continued)**

2. Staff failed to enter some information, or simply placed it into the wrong database fields. This made record searching difficult. In one case (AC32740), an incorrect Location Code was selected accidentally during login, could not be fixed immediately electronically, but was corrected in writing on the printed ASB Work Request. This error should later have been corrected electronically, but was not. Of 163 batches of samples submitted, approximately 30 required one or more corrections to be made. However, since the field Analysis Request (batch submission) forms contain all information, and the sample numbers were correctly associated by LIMS with each batch, there was no break in the chain of traceability.
3. No balances calibrated by the weights in question have been used for any DOE work. No impact on DOE projects has resulted.

**16. Cause: (Continued)**

2. A few staff members were not sufficiently familiar with login requirements or procedures. Mistakes and omissions were made without realizing the potential impacts.
3. There was misunderstanding about the degree of calibration weight traceability appropriate for rough balances.

**17. Action to Preclude Recurrence: (Continued)**

2. Location Codes specific to the DOE work projects will be defined in the LIMS. These Codes contain all required information, in the correct database fields. All staff logging in samples will be instructed, via documented correspondence, to use these Codes.
3. These balances will be properly calibrated, as specified by the QA program.

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The following documents were reviewed to verify completion of corrective action for this DR:

*260 3/21/02*

The Inventory of Equipment was reviewed and it was determined that autopipettes and other applicable measuring equipment were added to the inventory.

A memorandum was sent to all Analytical Science Staff on 12/21/2001 informing the staff of the codes to be entered into the LIMS system for specified DOE sample entries to ensure that the necessary information is entered accurately. A review of several sample print outs from the LIMS system indicated that the codes were being used. The following sample print outs were reviewed:

Work Order Number: 01708400

Sample ID: AC32701

Sample ID: AC32740

Sample ID: AC32741

Sample ID: AC32742

Sample ID: AC32743

Sample ID: AC32744

A new set of certified weights traceable to NIST was purchased (P.O. 134280) and a review of calibration records indicated that calibration checks were performed on balances B21R, B32R, and B45R which were found to be within tolerances.

Based on the review of objective evidence, it was indicated that corrective action was satisfactorily completed. Therefore, it is recommended that this DR be closed.

*Dennis Threatt*

Dennis Threatt, QAR

*3/21/2002*

Date