



Department of Energy

Washington, DC 20585

QA: QA

JUN 05 2002

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VERIFICATION OF CORRECTIVE ACTIONS AND CLOSURE OF DEFICIENCY REPORT (DR) LLNL-02-D-094

The Office of Quality Assurance staff has evaluated the corrective actions of DR LLNL-02-D-094 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 Christian M. Palay at (702) 794-1486.

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

OQA:JB-1285

Enclosure:
DR LLNL-02-D-094



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cc w/encl:

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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

8. DEFICIENCY REPORT
 CORRECTIVE ACTION REPORT
NO. LLNL-02-D-094
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DEFICIENCY/CORRECTIVE ACTION REPORT

260 4/3/02

1. Controlling Document: QARD, Revision 10
2. Related Report No.: NCR-YMSCO-02-0033

3. Responsible Organization: LLNL
4. Discussed With: Martha Kohler, Cindy Palmer, Vic Barish

5. Requirement:
Supplement II, Sample Control
II.2.2A - Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.
II.2.2B - Sample traceability shall ensure that the sample can be traced at all times from its collection through final use.
Glossary
Traceability - The ability to trace the history, application, or location of an item, data or sample using recorded documentation.
Supplement III, Scientific Investigation
III.2.2.B - Scientific Notebooks shall contain the following:
4. - Description of work as it was performed and results obtained, names of individuals performing work, and dated initials or signature, as appropriate, of individuals making the entries.

6. Description of Condition:
Documented traceability of samples (metal specimens) which were to be fabricated under the direction of a LLNL Principal Investigator was not maintained in Scientific Notebook LLNL-SCI-466-V1 as required and therefore, the origin of the samples cannot be determined (i.e., locations on welded plate from which the samples originated). The samples affected are listed in OCRWM Nonconformance Report YMSCO-02-0033.

NOTE: This condition is isolated to LLNL and is not related to supplier sample traceability issues such as those identified on OCRWM Corrective Action Report BSC(V)-02-C-002.

7. Initiator: C. C. Warren 3/21/02
C.C. Warren Date
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:
None

11. QA Review: Chris Palay
QAR Christian Palay Date 04/03/02
12. Response Due Date:
10 working days from issuance

13. DOQA Issuance Approval:
Printed Name Ram Murthy Signature James Blythe Date 4/19/02

22. Corrective Actions Verified Christian Palay
QAR Chris Palay Date 5/31/02
23. Closure Approved by:
DOQA Date

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2. Check if Amended
Check if also Initial Response

3. Extended Processing
 No Yes (If yes, submit
Extended Processing request)

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition investigations are not complete and documented herein)

This condition has been determined to be isolated to the description of condition documented in Block 6, page 1 of LLNL-02-D-094. An investigation determined that only two instances of metal specimens being fabricated under the direction of a Principal Investigator (PI) have occurred at LLNL. The second occurrence is documented in Scientific Notebook (SN) LLNL-SCI-471-V1 and includes adequate documentation to demonstrate specimen traceability.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)
None of the fabricated specimens with inadequate documentation were subjected to testing. Therefore, there is no impact on testing activities or data. See Remedial Actions for specimen disposition.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)
On 03/12/02 OCRWM Nonconformance Report (NCR) YMSCO-02-0033 was issued to identify all 537 metal specimens fabricated under the direction of the PI and documented in SN LLNL-SCI-466-V1 as nonconforming. At that time all specimens were red tagged and segregated in accordance with the requirements of AP-15.2Q. On 03/25/02 NCR YMSCO-02-0033 was dispositioned to Reject/Scrap all specimens. The NCR disposition was completed on 03/27/02 by discarding the specimens and posting a copy of the dispositioned NCR in scientific notebooks that were to have documented testing of the specimens. Scientific notebooks affected were: SN LLNL-SCI-397-V1, SN LLNL-SCI-464-V1 and SN LLNL-SCI-466-V1.

7. Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16.4Q)
 Apparent Cause

The cause of the condition was lack of direction of the specimen fabrication process by the PI resulting in inadequate documentation of specimen traceability in SN LLNL-SCI-466-V1.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)
LLNL Management will review specimen fabrication activities that occurred in SN LLNL-SCI-466-V1 with the PI. The review will stress the level of direction and documentation required by the PI for specimen fabrication activities. The topics discussed will be documented on a memorandum to file and will be signed by the LLNL Manager performing the review and the PI.

9. Due Date for Completion of Corrective Action:
05/31/02

10. Responsible Manager:
Mark Peters *[Signature]* ^{for DOC QA} _{5/31/02}
Printed Name Signature Date
MTP 5-3-02

11. QAR Evaluation: Accept Partially Accept Reject

Christian Palay *Chris Palay* 5-14-02
Printed Name Signature Date

12. QAM Concurrence:
RAM MURTHY *[Signature]* 5/30/02
Printed Name Signature Date

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Verification of Correction of Corrective Actions for Deficiency Report (DR) LLNL-01-D-094

The complete response for this DR (dated 05/03/02) committed Lawrence Livermore National Laboratory (LLNL) to complete the following corrective actions requiring verification from the Quality Assurance Representative (QAR):

Block 6 Remedial Actions:

LLNL committed to initiate a Non-conformance Report (NCR) to disposition the 537 specimens that lost their traceability. LLNL also committed to document the disposition of the NCR into the governing scientific notebooks affected by this condition adverse to quality. The documentation in the scientific notebooks of NCR YMSCO-02-0033 was verified by reviewing copies of the entries from the following scientific notebooks: SN-LLNL-SCI-397-V1, SN-LLNL-SCI-464-V1, and SN-LLNL-SCI-466-V1. The NCR disposition concluded with the rejection/scraping of the 537 samples.

Block 8 Actions to Preclude Recurrence:

LLNL management committed to review with the Principal Investigator responsible for those 537 specimens the importance of maintaining specimen traceability during fabrication. This action was verified by reviewing the LLNL YMP memorandum signed by both the Responsible Manger and the Principal Investigator.

Based on the above evaluation, the QAR recommends closure for DR LLNL-02-D-094.

Christian M. Palay
QAR Printed Name

Chris Palay
QAR Signature

May 31, 2002
Date