



Department of Energy

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87-QSD-155

May 27, 1987

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WM Record File

101.7

WM Project 10

Docket No.

PDR ✓

XLPDR ✓ (B)

Director
Pacific Northwest Laboratory
Richland, Washington

Distr. Linehan
Hildenbrand
(Return to WM, 623-SS) 3411

Dear Sir:

DOE-RL QA AUDIT 8701, EVALUATION OF PACIFIC NORTHWEST LABORATORY CORRECTIVE ACTIONS

References: A. PNL Letter, Director, PNL, to Saget, "DOE-RL QA Audit 8701, Evaluation of PNL Corrective Actions," April 30, 1987.

B. DOE-RL Letter No. 87-QSD-99, Saget to Director, PNL, same subject, March 25, 1987.

DOE-RL has reviewed Reference A detailing PNL's corrective actions to the Quality Audit Findings and Concerns cited in DOE-RL's Audit 8701 and has performed a verification of PNL's corrective actions. The following is a summary of DOE-RL's conclusion:

QUALITY AUDIT FINDINGS

- Finding 1 ICN to PAP-1501 and completed Briefing Documentation reviewed and found satisfactory. This finding is closed.
- Finding 2 ICN to PAP-1401 and training reviewed. Verified that the Briefing Documentation includes a discussion that procedure compliance is mandatory and not discretionary. This finding is closed.
- Finding 3 Verification that the audit planning checklist is part of the Audit Performance Guidelines (QASA-3) completed. This finding is closed.
- Finding 4 Closed by previous correspondence (Reference B).
- Finding 5 Training records reviewed. This finding is closed.

Copies of the closed Quality Audit Findings are enclosed.

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PDR WASTE
WM-10

PDR

87173438

WM Project: WM-10

PDR w/encl

(Return to WM, 623-SS)

WM Record File: 101.7

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-2-

CONCERNS

Concerns 1, 2, 3 Closed by previous correspondence (Reference B).

Concern 4 ICN to EAP-801 reviewed. This concern is closed.

Thank you for your prompt attention to these matters.

Sincerely,

R. P. Saget

R. P. Saget, Director
Quality Systems Division

QSD:TKS
QA35E7.CS1

Enclosures

cc w/encl:

J. P. Knight, DOE-HQ
D. C. Newton, DOE-HQ
J. J. Linehan, NRC
L. B. Ibe, Weston
T. Husseman, Washington State
Department of Ecology
M. S. Power, Washington State
Institute for Public Policy

D. Stewart-Smith, Oregon State
Department of Energy
B. Burke, Confederated Tribes
of the Umatilla Indian Reservation
R. Halfmoon, Nez Perce Indian Tribe
R. Jim, Yakima Indian Nation
C. E. Hughey, PNL
J. Morris, DOE-HQ



QUALITY AUDIT FINDING

9. QAF Control No.
8701-01

1. TO: Name
D. Bradley, Manager

Title Waste Package and
Performance Assessment

2. Location
PNL RO Bldg.

3. Reference/Requirements

PAP 1501, Rev. 1., Para 4.1.1; Review of NCRs for
Issuance of an Unusual Occurrence Report.

4. Audit Or Surveillance Report No.
8701

5. Description

There is no evidence that PNL Nonconformance Reports are reviewed for possible
issuance of an Unusual Occurrence Report, as determined by a review of NCRs
PNL-86-58 and PNL-87-01 (which comprise the total population of NCRs issued
since the latest procedure revision).

6. Lead Auditor (Signature)

Charles G. Smurolds Jr.

7. Issue Date

01/13/87

8. Response Due Date

02/13/87

10. Auditee Corrective Action Commitment

See attached page

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)

D. Bradley

12. Date

3/5/87

13. Action Completion Due Date

14. Lead Auditor (Signature)

Charles G. Smurolds Jr.

15. Date

5/15/87

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

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16. Final Review and Approval (QAF Closed)

R. P. Saget

Mgr./Branch Chief, Cognizant Branch

5/20/87

Date

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

FINDING NO. 1

1. EVALUATION OF IMPACT ON ONGOING AND PREVIOUS WORK

The trend analysis review of Nonconformance Reports (NCRs) performed by the PNL QC Section for NCRs generated from July 1985 to July 1986 revealed no trends evident that would require issuance of an Unusual Occurrence Report (UOR). Reviews by QC of individual NCRs issued since, together with review of past years trend analyses of NCRs, indicated the same conclusion. Therefore, it is concluded that there is not any adverse impact on either ongoing or previous work.

2. ACTION TAKEN OR PLANNED AS A RESULT OF IMPACT EVALUATION

None required.

3. IDENTIFICATION OF ROOT CAUSES OF REPORTED ADVERSE CONDITIONS

As a result of BQARD upgrades administrative procedure PAP-1501 was revised, in part, to include the requirements to evaluate nonconformances for the possibility of a UO existing and to document that evaluation. The procedure was poorly written, as far as this change is concerned, resulting in inadequate understanding and implementation of the requirements by the staff.

4. PROPOSED PLAN OF PREVENTIVE ACTION

This requirement has been informally discussed in staff meetings with the Quality Engineering and Quality Control Staff and will again be specifically discussed and the discussions will be formally documented on Briefing Documentation forms. Also the procedure, PAP-1501, will have an Interim Change Notice (ICN) issued to include the evaluation documentation requirement in the main body of the procedure.

5. PREVENTIVE ACTION SCHEDULE

A briefing was documented with the QC Section on February 23, 1987 and will be documented with the QE Section on March 11, 1987. The ICN has been initiated and is expected to be issued by March 31, 1987.



QUALITY AUDIT FINDING

9. QAF Control No.
8701-021. TO: Name
D. Bradley, ManagerTitle Waste Package and
Performance Assessment2. Location
PNL RO Bldg

3. Reference/Requirements

PAP 1401, Rev. 1, Para 4.4.7; Use of "Test in
Progress" tags.4. Audit Or Surveillance Report No.
8701

5. Description

The requirement for the use of "Test in Progress" tags is not being fully implemented as evidenced by a Rock Autoclave that was in operation for SOW 1L2D4P and did not have a "Test in Progress" tag attached.

6. Lead Auditor (Signature)

Charles A. Amerold Jr.

7. Issue Date

01/13/87

8. Response Due Date

02/13/87

10. Auditee Corrective Action Commitment

See attached pages

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)

Don J. Bradley

12. Date

3/5/87

13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)

Charles A. Amerold Jr.

15. Date

5/15/87

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

1--Addressee

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16. Final Review and Approval (QAF Closed)

R. P. Saget

Mgr./Branch Chief, Cognizant Branch

5/27/87

Date

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

FINDING NO. 2

1. EVALUATION OF IMPACT ON ONGOING AND PREVIOUS WORK

The rocking autoclave listed as not being properly tagged is located in a locked room in the basement of the 325 Building. The only personnel who have access to the room are project personnel or emergency support personnel. A call list of persons to contact in case of emergency was posted in the room and the system is wired into an automatic alarm system for monitoring. Therefore, it is concluded that there is not any adverse impact on either ongoing or previous work on the specific project.

PNL QA has also investigated the impact of the existing procedure requirements on various other research and development projects. The purpose of this investigation was to explore the adequacy of the existing procedure as it relates to identifying in-process tests. As with the specific project, it is concluded that there is not any adverse impact on either ongoing or previous work on the additional projects reviewed.

2. ACTION TAKEN OR PLANNED AS A RESULT OF IMPACT EVALUATION

All rocking autoclaves and the roller oven located in Lab 48 of 325 Building have been tagged with "Test in Progress" tags as a redundant measure to assure preclusion of inadvertent operation or shutdown. This was verified by surveillance SLE-87-007A.

Also see the proposed plan of preventive action.

3. IDENTIFICATION OF ROOT CAUSES OF REPORTED ADVERSE CONDITIONS

It is our conclusion that the present procedure does not take into consideration all aspects of PNL project activities and that PAP-1401 "INSPECTION AND TESTING STATUS AND TAGGING" requires change/revision to provide flexibility with respect to the use of status indicators and to introduce additional control criteria.

4. PROPOSED PLAN OF PREVENTIVE ACTION

An ICN to PAP-1401 has been prepared which will include a revised method for assuring proper identification as follows:

"Status indicators (such as In process Test tags, markings or area postings, as appropriate) shall be used to identify systems and components undergoing unattended test where inadvertent operation or shutdown of the equipment could jeopardize test results. The "Test In Process Tag" or appropriate status indicator shall indicate the following:

- Type of test
- Reason for the tag or indicator

DOE-RL BWIP AUDIT 8701
FINDING NO. 2
Page 2 of 2

- Who to contact in an emergency

When knowledge of status is required at locations remote from the inspection, test or operating activity, tags, status boards or other suitable administrative controls shall be used."

5. PREVENTIVE ACTION SCHEDULE

The ICN has been submitted for internal review and will be issued subsequent to approval. March 31, 1987 is the anticipated issue date.



QUALITY AUDIT FINDING

9. QAF Control No.
3701-031. TO: Name
D. Bradley, ManagerTitle waste Package and
Performance Assessment2. Location
PNL RO Bldg.

3. Reference/Requirements

QAP 1801, Rev, 2, Para 4.3.4; Review of Previous
Problem Reports4. Audit Or Surveillance Report No.
8701

5. Description

There is no evidence that the Lead Auditor reviewed previous audit findings, surveillance reports, nonconformance reports and deficiency reports in the preparation of audits as evidenced by a review of audit packages for A-86-01-03-60, A-86-09-32-60 and A-86-11-41-60.

6. Lead Auditor (Signature)

Charles A. Smerolls Jr.

7. Issue Date

01/13/87

8. Response Due Date

02/13/87

10. Auditee Corrective Action Commitment

See attached page

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)

D. J. Bradley

12. Date

3/5/87

13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)

Charles A. Smerolls Jr.

15. Date

5/15/87

17. Final Distribution

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16. Final Review and Approval (QAF Closed)

R. P. Laget

Mgr./Branch Chief, Cognizant Branch

5/20/87
Date

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

FINDING NO. 3

1. EVALUATION OF IMPACT ON ONGOING AND PREVIOUS WORK

While the auditor has not documented reviews of previous audit findings, surveillance reports, nonconformance reports and deficiency reports in preparation of audits, a review by the lead auditor is in fact performed as required by QAP-1801. Therefore an evaluation of this nature is not necessary.

2. ACTION TAKEN OR PLANNED AS A RESULT OF IMPACT EVALUATION

As stated above, the subject reviews are performed as required. However, to aid in audit planning, an audit planning checklist has been developed to help assure all reviews are performed. This checklist is included as part of the Audit Performance Guidelines issued for internal use on February 20, 1987

3. IDENTIFICATION OF ROOT CAUSES OF REPORTED ADVERSE CONDITIONS

QAP-1801 does not require documentation of these reviews.

4. PROPOSED PLAN OF PREVENTIVE ACTION

See item 2.

5. PREVENTIVE ACTION SCHEDULE

Completed.



QUALITY AUDIT FINDING

9. QAF Control No.
8701-041. TO: Name
D. Bradley, ManagerTitle Waste Package and
Performance Assessment2. Location
PNL 20 Bldg.

3. Reference/Requirements

QAP 1801, Rev. 2, Para 4.7.2; Response to Audit
Finding Reports.4. Audit Or Surveillance Report No.
8701

5. Description

Response to AFRs were received and accepted by QA without providing minimum corrective action information required by procedure in that responses to findings 1 to A-86-01-03-60 and A-86-04-10-60 were received and accepted without a) a check/verification to assure that other areas/items that might have similar problems have been examined; b) the actions taken to correct the problems as well as those discovered during the check; and c) action to prevent future occurrences.

6. Lead Auditor (Signature)

Charles A. Smiraldi Jr.

7. Issue Date

01/13/87

8. Response Due Date

02/13/87

10. Auditee Corrective Action Commitment

See attached page

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)

Don J. Bradley

12. Date

3/5/87

13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)

Charles A. Smiraldi Jr.

15. Date

5/15/87

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

1--Addressee

2--

3--

16. Final Review and Approval (QAF Closed)

R.P. Saget

Mgr./Branch Chief, Cognizant Branch

5/21/87
Date

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

FINDING NO. 4

1. EVALUATION OF IMPACT ON ONGOING AND PREVIOUS WORK

An evaluation of all previous license-related repository audits was performed to identify any adverse impact to project deliverables as documented in CAR-86-5. No such conditions were identified.

2. ACTION TAKEN OR PLANNED AS A RESULT OF IMPACT EVALUATION

The lead auditors have been reinstructed and received a briefing on the performance and thorough evaluation of all audit finding responses. This was informally done following the 9/86 SRPO Audit and will be formally documented in a briefing session on March 5, 1987.

3. IDENTIFICATION OF ROOT CAUSES OF REPORTED ADVERSE CONDITIONS

Responses received for audit findings that did not address the necessary corrective action information can be attributed to auditor inattention while reviewing the response. Also there was an incorrect interpretation by project management that documenting all corrective action measures was not applicable. It should be noted, however, that the audits reviewed were performed and responses reviewed prior to the SRPO Audit which revealed this same problem in September, 1986. Corrective actions and instruction to the lead auditors were taken at that time.

4. PROPOSED PLAN OF PREVENTIVE ACTION

Criteria for proper response, as defined in QAP-1801, 4.7.2.3, will continue to be reviewed with the auditees at all exit meetings. This is also being defined in the text of the audit finding sheets as respondents have not always followed the instructions listed on the back of the sheets. Responses that do not fully address cause, corrective action and recurrence prevention to the above criteria will not be accepted.

Continued evaluation of the audit program, training of the audit staff to client requirements, and the development and implementation of an effective and usable action tracking system will provide assurance that repetition of this problem will not recur.

5. PREVENTIVE ACTION SCHEDULE

The proposed plan of preventive action has been implemented.



QUALITY AUDIT FINDING

9. QAF Control No.
8701-051. TO: Name Title Environmental
T. L. Page, Project Manager Studies Program2. Location
2400 Stevens

3. Reference/Requirements

PAP 201 Rev. 2 Sec 4.3, 4.3.2 says in part:
Personnel discovered to be inadequately indoctrinated and trained shall be removed from work being performed until adequate training has been completed.
(Continued on attached sheet.)

4. Audit Or Surveillance Report No.

8701

5. Description

Contrary to the requirement the cognizant manager did not remove L. Eberthardt, L. Cadwell and M. Harris from work after PNL deficiency report DR-86-114 identified that these three personnel did not receive project specific training to the SOW and QA Plan.

6. Lead Auditor (Signature)

Charles A. Smiralls Jr.

7. Issue Date

1-13-87

8. Response Due Date

2-13-87

10. Auditee Corrective Action Commitment

See attached page

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)

Thomas D. Page

12. Date

4 Mar 1987

13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)

Charles G. Smiralls Jr.

15. Date

5/15/87

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

1--Addressee

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16. Final Review and Approval (QAF Closed)

R. P. Saget

Mgr./Branch Chief/Cognizant Branch

5/21/87
Date

ATTACHMENT TO QUALITY AUDIT FINDING 8701-05

Section 4.3.2 assigns this responsibility to the cognizant manager to assure that all personnel receive the appropriate indoctrination and training.

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

FINDING NO. 5

1. EVALUATION OF IMPACT ON ONGOING AND PREVIOUS WORK

There was no impact to ongoing and previous work or to the quality or integrity of the data resulting from the work performed by inadequately trained staff members.

Project staff members L. Eberhardt, L. Cadwell and M. Harris were aware of project quality requirements and their specific responsibilities related to quality assurance requirements and the project. However, because we expected to receive Revision 1 of the QA Plan shortly, they had not received documented training to the QA Plan and the SOW. This training was delayed to avoid the time and dollar costs of retraining.

M. Harris had transcribed data in the LRB for another investigator following the prescribed procedures. L. Eberhardt and L. Cadwell had reviewed LRB entries following the prescribed procedures. These activities by staff that had not received documented training to the QA Plan and the SOW had no impact on ongoing or previous work.

2. ACTION TAKEN OR PLANNED AS A RESULT OF IMPACT EVALUATION

Since the impact evaluation showed no adverse impact to the validity or credibility of any prior work in question, no action was required with respect to the quality of the data.

Staff members received the necessary documented training on January 19, 1997, which was as soon as it was possible to schedule it following the audit.

3. IDENTIFICATION OF ROOT CAUSES OF REPORTED ADVERSE CONDITIONS

The conditions occurred because the anticipated revision of the QA Plan was not received as expected and the cognizant manager and the QE were unaware of the requirement to remove the subject staff from the work.

4. PROPOSED PLAN OF PREVENTIVE ACTION

The subject staff have received necessary training and this training has been documented. In the future, training will be done immediately even if this subsequently results in the need for retraining. The surveillance required by the QA Program will prevent future reoccurrence. The cognizant manager and the QE are both now aware of the need to remove from further work any staff found to be inadequately trained.

5. PREVENTIVE ACTION SCHEDULE

Preventive action is complete.

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

CONCERNS

1. The effective date on all controlled documents (procedures, QA Plans, ICNs, etc.) is now being put on by Document Control personnel who are coordinating the date to coincide with the document's actual distribution.
2. Procedure approval is documented by cover memo from the client which is received at the Program Manager level, approvals are never "implied". The administrative procedures are very explicit on the internal interfaces for the preparation, review, and approval of procedures. External interfaces are controlled by PAP-101 with PNL maintaining documented evidence of all client approvals. Documents such as SOWs are client documents which, when they enter PNL, are strictly controlled through the PNL single point interface defined in PAP-101.
3. During the effort to upgrade PNL's QA Manual and Administrative Procedures to meet BQARD requirements many procedures were revised in a very short time. This involved obtaining many reviews both internally and externally. PNL uses a Document Review Record (DRR) for obtaining internal reviews. The DRR provides space for the reviewer to record comments and for the author to record the resolution of comments. All comments were resolved in the final draft of procedures that were revised. However, in some cases the author did not get the signature of the reviewer to indicate concurrence with the comment resolution. The Procedure Coordinator became aware of the problem and began obtaining the missing comment resolution signatures as the records were reviewed for transmittal to the PNL Records Center. Since all comments had been resolved, it was felt that there was no adverse impact on the procedure and a Deficiency Report was not written.
4. Project specific administrative procedure EAP-801 is being changed/revised to strengthen the requirements specifying procedures for sample control and identification for subcontractors. This will assure the traceability and availability of such procedures. The target date for the revision issue is March 31, 1987.

DOE-RL BWIP AUDIT 8701 - CORRECTIVE ACTION RESPONSE

PROBLEM AREA CLARIFICATIONS

Three of the problem areas which lie outside the scope of PNL's responsibility noted on page 10 of the audit report require clarification as follows:

1. The statement that "PNL is working to unapproved procedures" is not correct. All of the procedures used at PNL for BWIP which require BWIP approval have been approved by BWIP. The procedures listed are in error; all of them are Revision 1. The project in question is currently working to Revision 0 of these procedures and all are BWIP approved. The procedures were revised for the following two reasons:

1. To update to new procedure format addressed in latest revision of PAP-501.
2. To improve the technical content.

2. The following is a requirement taken out of QA Plan ED-29, Rev. 1:

15.2 - Deficiency Reports that have a significant effect on validity and integrity of project results or which effect previously transmitted deliverables shall be submitted to DOE-BWI for concurrence.

PNL has taken the stand (and DOE has approved this) that if the Deficiency Reports do not apply to the situations noted above, they will be submitted annually through the established records system. The Environment Licensing Support Group will not submit Deficiency Reports more frequently unless directed to do so by DOE.

3. The Project Manager has contacted the L2D3P and L3E2B BWIP representatives concerning these archived materials. He was directed to discard all archived experimental samples prior to FY1987 on L3E2B and to retain all experimental samples produced on L2D3P from FY1984 to present. The L2D3P experimental archive samples were produced under low oxygen conditions at 85 degrees C and are being archived at room temperature in the normal atmosphere. The Project Manager considers them to be worthless for reproducing the experimental results, and retains the extra L2D3P archive samples only because he has been directed to do so by the client.