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DOE-RL BWIP AUDIT 8701

OF

BATTELLE PACIFIC NORTHWEST LABORATORY

PNL AUDIT REPORT

January 5-8, 1987

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1.0 INTRODUCTION

The Department of Energy - Richland's (DOE-RL) Assistant Manager for Commercial Nuclear Waste (AMC) Quality Systems Division conducted an audit of Battelle Pacific Northwest Laboratory (PNL) Basalt Waste Isolation Project (BWIP) and Environmental Studies Program activities on January 5-8, 1987. Rockwell's BWIP QA and the Office of Geologic Repositories (OGR) provided auditors as participating members of the audit team. The intent of the audit was to measure the effectiveness of PNL's Quality Assurance (QA) Program on BWIP and Environmental Studies Tasks which were currently underway. The PNL tasks audited, listed by title and Work Breakdown Structure (WBS) number, were:

Project	WBS Number
TOTAL SYSTEM PERFORMANCE ASSESSMENT	L1E
Verification and Benchmark Codes	L1E2
WASTE FORM AND MATERIALS TESTING	L2D
Solubility/Sorption Studies	L2D3P/L3E2B
Hydrothermal Material Testing	L2D4P
GEOCHEMISTRY	L3E
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PROJECT CONTROL	L9C
QUALITY ASSURANCE	L9D

As further described in Attachment 1, Audit Performance, the foundation of DOE-RL's QA Audit Program is the eighteen criteria of 10 CFR 50, Appendix B. These 18 criteria are broken down into elements (called Program Elements) for simplification. The Statement of Work (SOW) for each task to be audited was reviewed by the DOE-RL QA Audit Team (hereafter referred to as the Audit Team), and a matrix was prepared to indicate the QA program elements applicable to the PNL BWIP Project and Environmental Studies Tasks. Table 1 represents the results of this analysis.

During the process of planning the PNL Audit, it was determined that an assessment of the PNL program management processes should be performed. This management assessment was planned, scheduled and conducted in parallel with the Quality Assurance audit. The report of the management assessment, "Program Management Assessment of Pacific Northwest Laboratory," is expected to be issued independently from this report.

Auditors, auditees, technical advisors, observers, and meeting attendees involved in this audit are listed in Attachment 2, Administrative Data.

2.0 BACKGROUND

Audited activities are summarized briefly below, as identified by WBS and title:

WBS L1E2, Verification and Benchmarking of Heat Transfer and Fluid Flow Codes

- This task involves preliminary verification and benchmarking of computer codes CHAINT-MC and PORMC-SF, and preparation of a report on PAKSTAT, a Monte Carlo driver code. CHAINT-MC and PORMC-SF are probabilistic versions of earlier deterministic mathematical models. The newer versions use input variables specified as probability distributions, with data generated by the Monte Carlo technique. Although the work is preliminary, and verification will be reaccomplished under full controls before the codes are applied to site characterization, PNL license-related QA requirements have been applied to the work.

WBS ~~L2B3P~~ L3E2B, Basalt Radionuclide Solubility and Sorption Studies for the Rockwell Site Department and L2B3P for the RHO Engineered Barriers Dept.

"The objective of this work is to obtain radionuclide sorption-desorption kinetics and equilibria for key radionuclides in the presence of each of the geologic materials that the radionuclide-contaminated groundwater might contact between the outer edge of the disturbed rock zone and the accessible environment...[and to monitor] the geochemical evolution of a 'young' groundwater composition..."

WBS L2D4P, Pacific Northwest Laboratory Support of BWIP Hydrothermal Materials Testing...

"...Migration of contaminated groundwater is recognized as the principal mechanism for radionuclide transport from a repository to the biosphere. Knowledge of hydrothermal reactions of repository groundwaters with candidate waste forms and with waste package components is vital to the successful design of waste packages...

"There are two primary objectives for the hydrothermal waste-barrier-rock interactions studies. The first is to acquire part of the necessary data for quantifying the performance of waste package components...in an environment appropriate to a repository located in basalt. The second is to then evaluate and integrate these site-specific data with the BWIP waste package design effort..." [SOW L2D4P]

PNL has been participating in the required testing.

WBS L3E2A, Organic Analysis of Groundwater and Drilling Mud Leachate for BWIP

"Some naturally occurring organic compounds in groundwater have been shown to increase the mobility of several radionuclides in controlled laboratory experiments..and it is desirable to determine if similar properties might be exhibited by Hanford groundwater...

"Most of the boreholes on the Hanford Site utilized by the BWIP have been drilled with bentonite-based fluids that include organic constituents...' It is important...to be able to distinguish between those organic components occurring naturally in the groundwater and those that have been added during the drilling process..." [SOW L3E2A]

This work consists of a suite of gas chromatographic and mass spectroscopic analyses of a sample of drilling mud leachate and of groundwater samples from wells and boreholes on the Hanford site.

WBS L2D3R, Organic Analysis of Bentonite Packing Materials for BWIP

"...Proposed packing and backfill materials...of crushed basalt and sodium bentonite may contain naturally occurring organic materials... It is necessary to identify these materials and determine the effects of the near field environment on their stability. Important environmental effects include heat, hydrothermal reactions and radiation. If it is determined that certain organic materials will be chemically stable in this environment, then their interactions with important radionuclides under near field geochemical conditions must be investigated...

"The purpose of this study is to determine the organic content of sodium bentonite, both altered and unaltered. The identification of the amount and type of organic constituents present in the bentonite will be used to define the scope of additional organic analysis work...[and] to develop technical procedures, if necessary, to analyze the organic content of packing materials and to establish these procedures as acceptable for generating licensable data..." [SOW L2D3R]

WBS L3E2C, Uranium Disequilibrium in Basalt Groundwater: In Situ Retardation Coefficients

"The principal objective of this effort is to develop...and apply approved analytical and sampling methods with which to determine in situ radionuclide concentrations, retardation parameters, redox conditions and colloid effects [for uranium and thorium and their decay chains]...in major basalt aquifer systems associated with BWIP activities..."

WBS L9D covers BWIP-related work performed by PNL QA.

WBS L3G, Environmental Licensing Support Programs

"The purpose of the Environmental Licensing Support Project is to provide the necessary environmental, socioeconomic, sociocultural, and transportation information, data, and documentation to support a fully qualified, licensable project . . . PNL will establish and maintain an Environmental Licensing Support Program that will develop a strategy to identify environmental, socioeconomic, and transportation needs, develop data collection strategies and procedures, collect the required data, monitor program effectiveness, report the results and prepare supporting documents as required."

3.0 OVERALL QUALITY ASSURANCE PROGRAM ASSESSMENT

3.1 Quality Assurance Program Implementation

The goal of the Audit Team in assessing PNL's Quality Assurance Program was to answer the following:

a. Does an approved, documented QA Program exist?

b. Is the QA Program adequate and responsive to project QA requirements?

c. Is the QA Program being implemented as written? and

d. Is the QA Program effective?

The conclusion of the DOE-RL QA audit is that PNL's QA Program does satisfy these four questions in that an approved, documented QA Program does exist and that it is adequate, responsive, effective and being implemented as written. However, five deficiencies were found and four concerns were expressed by the Audit Team which require corrective action. A discussion of these findings and concerns can be found in Section 4.0 of this report.

It is also noted that the satisfactory assessment of the QA Program is predicated on PNL's satisfactory resolution of previously identified and still open deficiencies (i.e., SRPO audit findings, Rockwell Appraisal Program Deficiencies, PNL's Deficiency Reports, etc.), some of which were confirmed by the Audit Team and not included as audit findings in this

report. It was observed by the Audit Team, for example, that entries into and maintenance of Laboratory Record Books continues to be deficient. Having been previously reported by SRPO as audit finding AAR 85-E-25-01, by PNL as audit finding 02 to internal audit A-86-07-26-60 and by PNL in Corrective Action Report 86-5, the deficiency was not reported again by the Audit Team. Also, it was noted in SRPO Audit PNL-86-14-E as finding AAR PNL-86-14-E-05 that Management Assessments of PNL's QA Program were not being performed as required by Section 2.0 of PNL's QA manual. This deficiency was also detected by the Audit Team but not reported.

Also not reported as audit findings were isolated minor discrepancies identified and corrected by the auditee prior to the audit exit interview. This included such items as incomplete documentation, records not transmitted, documentation misfiled, documentation missing but later found, and use of the "Received By" stamp to indicate review and approval.

3.2 Technical Performance

As a part of each subteam auditing PNL's technical projects, a technical representative from the DOE-RL BWIP Technical Branches was involved. The technical member's goal was to evaluate adequacy of processes used to assure or verify technical quality, correctness and/or validity of work being performed under the Statement of Work.

The overall conclusion of the technical performance portion of the audit is that the processes are satisfactory for the following PNL tasks:

L1E2	L3E2A
L2D3P	L3E2B
L2D3R	L3E2C
L2D4P	L3G

provided Concern 2 of this report is addressed (procedurally defining the SOW interfaces).

3.3 Management Effectiveness

As previously noted, a management assessment of PNL's program management processes was conducted in parallel with the quality assurance audit. A portion of that assessment evaluated management's role in and support of the requirements of Criteria I and II of 10 CFR 50, Appendix B.

Criterion I of 10 CFR 50, Appendix B, requires that ". . .Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing . . ." The purpose of such continuing review is to assure that the program becomes and remains effective. In Criterion I, "other organizations" pertains to organizations other than the license applicant. On the Basalt Waste

organizations other than the license applicant. On the Basalt Waste Isolation Project, "other organizations" therefore means project participants other than DOE. The purpose of the required regular review is to assure that the QA program becomes and remains effective.

Traditionally, philosophy of management has held that the ultimate measure of management effectiveness was the degree to which management's objectives are achieved. If management has established, as one of its objectives, implementation of an effective QA program, then the degree of effectiveness of that program is a measure of management effectiveness relative to that objective.

Certain aspects of QA program effectiveness are particularly dependent on upper management policy and performance:

1. Timely, effective correction of recognized deficiencies in required controls (on the assumption that upper management will take a direct interest in conditions that adversely affect the validity or usability of technical work and that such an interest provides considerable motivation at working levels within the organization).

2. Close, conscientious adherence to the QA program at the working level and within middle and lower management (on the assumption that (a) upper management will have taken sufficient interest in the controls that are imposed to ensure that they are appropriate and constructive, and (b) that upper management's commitment to the QA program will have been communicated clearly to all levels of the functional groups).

3. Clear knowledge and understanding, at the working levels, of the official sources of policy and direction (on the assumption that upper management will not risk having policies and directives it holds to be important misunderstood or overlooked and will therefore take pains to ensure clear awareness).

The conclusion of the DOE-RL QA audit relative to management effectiveness is that PNL management support of the BWIP QA program has not been fully effective, as follows:

- Corrective action for recognized conditions adverse to the usability of PNL work has not constantly been prompt or thorough. For example, deficiencies in maintenance of Laboratory Record Books have been identified repeatedly over the past two years, and corrective action commitments have been made, but this audit established the fact that the deficiencies still persist.

- Close, conscientious adherence to QA program requirements was observed in most areas but not all. Some responsible PNL personnel indicated the feeling that excessive QA requirements were being imposed on certain BWIP activities. Without addressing the merits of those perceptions, it is reasonable to

expect that upper management with a strong commitment to an effective QA program might be sufficiently concerned to subject such interpretive disagreements between QA and functional groups to analysis at a level that could resolve them on the basis of their merits, rather than permitting unilateral decision making.

- Lack of clear knowledge and understanding of the official sources of policy and direction is evidenced by the fact that (a) some personnel identified PNL-MA-95 as the governing document for applying contract documents to BWIP work while others cited the Management Guidelines document, (b) the relationships among SOWs, the Technical Program Plan, and the Project Management Plan could not be described by personnel who were interviewed, and (c) the Management Guidelines document is not a controlled document.

- Failure of PNL management to perform the required management assessment of the QA program to date is a direct violation of the 10 CFR 50 Appendix B requirement cited at the beginning of this section and of the identical requirement specified in NQA-1. That failure also provides another instance of untimely corrective action, as previous audits brought the matter to PNL's attention and PNL failed to implement the corrective action described in its responses. It should be noted that prolonged failure to implement corrective action is one of the justifications for Stop Work action.

Information developed during the course of this audit indicates that PNL management has action under way to resolve these problems. It is suggested that ongoing effort be reviewed in the context of these 4 bullet items to determine whether any additional action is warranted.

It is anticipated that attention to the recommendations of the Program Management Assessment Report and to the findings and concerns of this report will significantly strengthen PNL's management effectiveness.

4.0 DISCUSSION OF RESULTS

As previously noted in Section 3.0, there were five Quality Audit Findings (QAFs) issued to PNL as a result of this audit. The QAFs are included in Attachment 4. Guidelines for PNL's responses to these QAFs are in Attachment 5.

A brief discussion of the QAFs and of their significance is provided for information.

QAF 8701-01 was issued because PNL had failed to perform and/or document a review of Nonconformance Reports for Unusual Occurrence reporting. This QAF is significant in that the Rockwell Appraisal Program had previously identified PNL's apparent failure to procedurally require review of Corrective Action Reports for Unusual Occurrence reporting (Discrepancy Report 0008, dated 9/17/86, to Appraisal PNL-RA-001.) Although DR0008 was closed, PNL failed to investigate other areas in which this similar problem may occur.

QAF 8701-02 was issued on the grounds that PNL failed to use "Test in Progress" tags on operating equipment because the equipment exhibited its status while in operation. The significance of this finding is that PNL management has failed to emphasize that procedural requirements must be implemented and are not discretionary. (However, the audit team notes that "Test in Progress" tagging is a safety issue and not, in itself, a QA program requirement. Attention is directed to sentence 1 of NQA-1, paragraph 14.)

QAF 8701-03 was issued because PNL's lead auditors failed to perform and/or document the required reviews of previous findings or problem reports in their preparation of three audits. The significance of this finding is that the audit program cannot provide continuity, verify effectiveness of past corrective actions, or follow-up on earlier concerns without such review of historical data.

QAF 8701-04 was issued because PNL received and accepted responses to audit findings which did not satisfy PNL's procedural requirements for responses. The significance of this QAF was that the same finding was issued by SRPO (AAR PNL-86-14-E-02 dated 9/25/86) and that PNL corrected the cited response without investigating and correcting similar deficiencies in other audit responses.

QAF 8701-05 noted that personnel discovered to be inadequately indoctrinated and trained were not removed from the work being performed. The significance of this QAF is (a) that neither the Project Manager nor the Quality Engineer were aware of this requirement at the time the training deficiency was originally identified, and (b) that the requirement appears to be more restrictive than necessary in that no alternatives or options are afforded the Project Manager.

In addition, four concerns were noted by this audit which require a response by PNL. These concerns are:

1. It was observed for numerous procedures that the distribution date exceeded the effective date by many weeks, and in some cases as much as 90 days. This may, in some instances, require work that was done after the effective date but before the distribution date to be redone. As a minimum, the effective date and distribution date should be the same.

2. External and internal interfaces for the preparation, review, and approval of research project planning documents, such as SOWs, are not adequately defined in procedures. For example , when Rockwell approval of PNL technical procedures or instructions is required in a SOW, there is no Rockwell approval signature on the procedure or instruction. The Project Managers stated that approval is "implied" by Rockwell's signature on the SOW, but this does not appear to cover situations where procedures may be written after the SOW is approved.

3. Numerous Document Review Record sheets were incomplete in that the resolution of procedural comments was not made a matter of record. It is noted that PNL was aware of this problem prior to the audit and was taking corrective action. However, PNL's failure to document this problem as a Deficiency Report prompted the Audit Team to note this as a concern.

4. Procedure EAP 801, Sample Identification and Control, was specifically written to address Environmental Program Sample Identification and Control (PNL procedure PAP 801 addresses Sample Identification and Control for other programs).

   EAP 801 indicates that it is the responsibility of task leaders to assure that necessary specific identification and control procedures are appropriately documented. Interviews with the Environmental Studies Group indicated that if a specific procedure had not been separately formalized, it would be covered in the laboratory record book for the specific task. A review of the laboratory record books indicated that, in some instances, procedures for subcontractor handling/analysis of samples were neither stated in the book, referenced, nor readily available in the files. Action should be taken to assure the traceability and availability of such procedures.

   It is also recommended that the Group examine the advantage of including information in EAP 801 on what areas require specific procedures and what areas will be covered by information in lab record books to prevent such sample identification information from being left out of LRBs and to ensure availability of specific procedures.

5.0 FOLLOW-UP RESULTS

During the audit, problem areas were discovered which lie outside the scope of PNL's responsibility and which appear to require action by DOE-RL, Rockwell, and/or others to reconcile. These problem areas require DOE-RL QA attention and, therefore, will be included in future audits and/or surveillances as appropriate.

Some of the problem areas are briefly noted as follows:

1. Rockwell has not completed procedural reviews and comment resolution to numerous PNL procedures in a timely manner. Therefore, PNL is working to unapproved procedures. Procedures of concern are:

ECS 1E	Revision 1	Submitted to Rockwell 02-12-86
ECS 2E	Revision 1	Submitted to Rockwell 02-12-86
ECS 8E	Revision 1	Submitted to Rockwell 02-12-86
ECS 9E	Revision 1	Submitted to Rockwell 02-12-86
ECS 13E	Revision 1	Submitted to Rockwell 05-28-86
ECS 23E	Revision 1	Submitted to Rockwell 05-28-86
ECS 32E	Revision 1	Submitted to Rockwell 05-28-86
ECS 34E	Revision 1	Submitted to Rockwell 05-28-86
ECS 35E	Revision 1	Submitted to Rockwell 05-28-86
ECS 37E	Revision 1	Submitted to Rockwell 05-28-86
ECS 38E	Revision 1	Submitted to Rockwell 05-28-86
ECS 39E	Revision 1	Submitted to Rockwell 05-28-86
ECS 13S	Revision 0	Submitted to Rockwell 05-28-86
ECS 23S	Revision 0	Submitted to Rockwell 05-28-86
ECS 28S	Revision 0	Submitted to Rockwell 05-28-86
ECS 29S	Revision 0	Submitted to Rockwell 05-28-86
ECS 32S	Revision 0	Submitted to Rockwell 05-28-86
ECS 34S-39S	Revision 0	Submitted to Rockwell 05-28-86

2. The Environment Licensing Support Group is required to submit records, including deficiency reports, to DOE-RL annually. This is not considered timely reporting of QA deficiencies and corrective action, and more frequent submittals should be required.

3. PNL-MA-60, Paragraph 17.2.1.2, requires the Program Manager, together with Rockwell, to determine the need for retention of test materials or samples and the retention time. Presently, <u>all</u> used materials are being maintained as verbally directed by Rockwell even though some materials are not usable for testing, retesting, or archiving. Accordingly, PNL should request and Rockwell should provide written direction to dispose of several years' worth of used materials stored in the Life Science Laboratory. This problem applies to L2D3P, L3E2B, L3E2C and L3G.

4. Rockwell has imposed QA requirements equivalent to Quality Level (QL) 1 on some SOWs without clear justification. This imposes effort on PNL which may not be necessary. The work being performed under SOW L1E2, Verification and Benchmarking of the Heat Transfer and Fluid Flow Codes, is a case in point. Initial benchmarking and verification is an iterative process that can involve a considerable amount of developmental work and debugging, and the value of exhaustive documentation and formal controls during that exploratory phase is not readily apparent. At the conclusion of that work, and when and if the decision is made to use those codes for their anticipated purposes, a final set of rigorously controlled verification and benchmarking runs should provide a high degree of confidence. PNL and Rockwell to possibly assign QLs 2 or 3 to SOWs would be appropriate.

5. PNL is still working to Fiscal Year 86 SOWs because Rockwell has not yet revised and approved the SOWs for FY87.

TABLE 1. PNL TASKS versus QA PROGRAM ELEMENTS

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
1.2	Internal Organization For QA							DX		
1.3	Designation of Functional Responsibilities							DX		X
1.6	Organizational Interface Control							X		X
2.1	Program Description	X	X	X	X	X	X	X	X	X
2.5	Training and Indoctrination	X	X	X	X	X	X	X	X	
2.6	Personnel Qualification							X		
2.7	Management Assessment of Program Effectiveness									X
3.2B	Control of Planning Process	R	R	R	R	R	R		R	
3.3B	Technical Verification of Planning and Test Procedures	R	R	R	R	R	R		R	
3.4B	Planning and Test Procedures Change Control	R	R	R	R	R	R		R	
5.1	Procedures	X	X	X	X	X	X	X	X	
5.2	Procedure Compliance	X	X	X	X	X	X	X	X	

LEGEND: X = Required by NQA-1 and Review Plan
R = Require by Review Plan but not by NQA-1
A = Was Required by NQA-1, but Review Plan moved requirements to Design Control
DX = Determined prior to the audit

TABLE 1. ONGOING PNL WORK versus QA PROGRAM ELEMENT

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
6.1	Controlled Document List(s)							X		
6.2	Unique Identification of Controlled Documents							X		
6.3	Document Review	X	X	X	X	X	X	X	X	
6.4	Document Approval/ Issue Controls	X	X	X	X	X	X	X	X	
6.5	Document Change Controls	X	X	X	X	X	X	X	X	
6.6	Distribution Controls	X	X	X	X	X	X	X	X	
8.1	Identification System(s) for Items/Samples		X	X	X	X	X		X	
8.2	Item/Sample Controls		X	X	X	X	X		X	
8.3	Verification of Item/ Sample Identity Prior To Use		X	X	X	X	X		X	
11.3	Test Procedures	A	A	A	A	A	A		A	
11.4	Test Documentation and Records	X	X	X	X	X	X		X	
11.5	Evaluation of Test Results	X	X	X	X	X	X		X	
12.1	M&TE Selection		X	X	X	X	X		X	
12.2	Calibration Controls		X	X	X	X	X			
12.3	M&TE Handling and Storage		X	X	X	X	X			

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TABLE 1. ONGOING PNL WORK versus QA PROGRAM ELEMENT

ELEMENT		L1E2	L203P/ L3E2B	L204P	L3E2A	L203R	L3E2C	L9D	L3G	L9A L9C
12.4	Traceability of M&TE Usage		X	X	X	X	X		X	
12.5	Impact Evaluation for Out of Calibration Incidents		X	X	X	X	X		X	
13.3	Marking/Labelling of Containers/Packages		X	X	X	X	X		X	
14.1	Inspection/Test Status Indicating System		X	X	X	X	X			
15.1	Distinguishing Identification of Nonconforming Items		X	X	X	X	X	X	X	
15.2	Nonconformance Reporting		X	X	X	X	X	X	X	
15.3	Evaluation/Disposition Controls		X	X	X	X	X	X		
15.4	Nonconformance Closeout		X	X	X	X	X	X		
16.1	Identifying/Reporting/ Correction of Conditions Adverse to Quality	X	X	X	X	X	X	X		
16.2	Evaluation of Potential Impact/Significance	X	X	X	X	X	X	X		
16.3	Determination of Cause (Significant Problems)	X	X	X	X	X	X	X		
16.4	Action to Prevent Recurrence	X	X	X	X	X	X	X		

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TABLE 1. ONGOING PNL WORK versus QA PROGRAM ELEMENT

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
16.5	Documentation and Reporting to Management	X	X	X	X	X	X	X		
16.6	Follow-up							X		
17.1	Designation of Documents To Become Records	X	X	X	X	X	X	X	X	
17.2	Control of Working Documents	X	X	X	X	X	X	X	X	
17.3	Authentication/Validation of Completed Documents	X	X	X	X	X	X	X	X	
17.5	Traceability Between Record and Activity	X	X	X	X	X	X	X	X	
17.7	Control of Changes to Formal Record	X	X	X	X	X	X	X	X	
17.8	Record Submittal Controls	X	X	X	X	X	X	X	X	
18.1	Audit Scheduling					•		X		
18.2	Audit Preparation/ Team Selection							X		
18.3	Audit Performance/ Documentation							X		
18.4	Audit Reporting							X		
18.5	Resolution/Corrective Action for Adverse Findings							X		
18.6	Audit Follow-up							X		
18.7	Audit Records							X		

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ATTACHMENT 1

AUDIT PERFORMANCE AND POST-AUDIT CRITIQUE

ATTACHMENT 1

AUDIT PERFORMANCE AND POST-AUDIT CRITIQUE

AUDIT PERFORMANCE

The audit was planned to cover PNL's entire BWIP-related QA program as applied to ongoing BWIP tasks. Statements of Work (SOWs) for active tasks were evaluated to determine which phase of site characterization they were in, and applicable QA program elements and critical features within the program elements were identified for each work package.

Audit subteams were formed, each subteam responsible for auditing the activities covered by one or more of the SOWs. Each subteam contacted the PNL Project Manager(s) for their assigned SOW(s) to obtain accurate, detailed information on the status of work in progress, the types of documentation and other objective evidence associated with the work, location of the work, and security arrangements that would be needed.

For this audit, all team members (except the member from OGR) participated in checklist preparation. The team verified that PNL procedures contained provisions responsive to those program elements and used applicable procedural provisions to construct the checklist.

The checklists were organized by (a) QA program element (b) critical feature within the program element, and (c) "requirement" or control process that provides for each critical feature. [NOTE: "Critical feature" is a feature of the program element which, if it were absent, seriously flawed, or poorly implemented, could prevent the program element from achieving its intended purpose.]

The mechanics of checklist preparation were as follows:

1. For each critical feature, the assigned team member identified PNL procedure sections or paragraphs that pertained to that institutional provision or control.

2. The team member then assembled all such relevant procedural material (by cut and paste) into one or more distinct "requirements."

3. For each such "requirement" (or control process), checklist structure provided for verification that responsible audited personnel knew and understood the process (determined by interview) and were in compliance (examination of evidence).

As prepared, the resulting checklist for a given critical feature addressed requirements of all procedures that touched on the control of interest; i.e., requirements from MA-60 as well as those from applicable implementing procedures. This exhaustive treatment of checklist preparation had an adverse impact on audit performance, as discussed under the heading "POST-AUDIT CRITIQUE."

During audit preparation, the audit team researched the DOE-RL file of audit records pertaining to BWIP work; requested PNL's internal audit, surveillance, and corrective action data for review; reviewed Rockwell's audit data on PNL; and reviewed the results of Rockwell's recent appraisal of PNL's QA program management capability.

Previous audit and surveillance findings and CARs were noted for auditor attention during the examination of evidence. The team did not explore the status of PNL's actions relative to Rockwell's appraisal because appraisal results concerned PNL procedure "shortcomings" rather than auditable performance.

Two formal briefings were scheduled for the audit team prior to the audit. The second briefing was a repetition of the earlier briefing and was held for the benefit of observers and the team member from OGR.

The briefing began with a brief description of (a) Battelle's historic mission and capabilities, (b) PNL's role in the Battelle organization and at the Hanford site, (c) the way PNL currently handles individual tasks (projects) for their various sponsors, and (d) how QA program requirements are identified and documented for the individual project. The audit team leader then described the basic audit approach, subteams, subteam assignments, and the schedule of audit activities. Each subteam leader described the work that was being done under the SOWs his or her subteam was to audit, the status and staffing of the tasks, which QA program elements applied, the problem history (based on previous audits, surveillances, CARs, and the other mechanisms PNL uses to report problems), and security provisions that would apply in the areas the subteam would visit.

Examination of evidence consisted ordinarily of two steps. The first step was to determine how accurately responsible PNL personnel could describe QA requirements and control systems that applied to their work. The second step was location and examination of evidence to verify compliance with the requirements.

As indicated in an earlier paragraph of this discussion, checklists were organized by (a) QA program element, (b) critical feature within the program element, and (c) "requirement" or control process within each critical feature. The basic checklist unit, then, was the control process. The audit addressed an average of 77 control processes in <u>each</u> of the audited activities. In that effort each audit subteam examined an average of 70 items of objective evidence (i.e., documents, samples, sample cabinets, etc.). In many instances a single item (such as a log book or a lab record book) provided evidence relevant to a number of different control processes or "requirements." In the aggregate, the audit team performed in excess of 500 examinations of objective evidence.

POST-AUDIT CRITIQUE

Post-audit debriefing of the audit team was primarily intended to establish a basis for refinement of the process on future audits. However, it did produce some information that had a direct bearing on the PNL audit.

In particular, audit team members reported that the audit had covered more material than the team could examine in depth, even though audit performance was extended an extra two days. It was possible to do a thorough job of determining how well audited personnel knew and understood QA program requirements and control processes, but it was difficult to devote as much time to examination of evidence in some areas as the team members would have liked.

Review of completed checklists (as a result of that information) revealed that sufficient evidence had been examined to provide an adequate sampling of all program elements, but that incorporation of all applicable procedural details into the checklist had implied a need to look for evidence of numerous intermediate actions that were not essential to assessment of program implementation. The team obtained solid objective evidence for key control points; they were not always able to examine evidence pertaining to less critical control features.

Steps will be taken on future audits to exercise that selection process during checklist preparation rather than during the audit itself. It is felt to be counterproductive to leave audited personnel with an impression that some of their responses to audit questions are not being verified by use of objective evidence.

ATTACHMENT 2

ADMINISTRATIVE DATA

ATTACHMENT 2
ADMINISTRATIVE DATA

NAME	ORGANIZATION-TITLE	ATTENDANCE Entrance	ATTENDANCE Exit	TASK ASSOCIATED WITH
	PNL			
Alalia, M. T. J.	Procedure and Train Coordinator	x		L9D
Alamia, D. L.	Records Center - Clerk	x		L9D
Ames, L. L.	Waste Treatment Solubility/Sorptn Stdy - Proj Mgr			L3E2B/L2D3P
Bain, S. H.	Waste Treatment Solubility/Sorptn Stdy - Sr. Res Eng		x	----------
Ballard, W. W.	Waste Tech Center - Manager		x	L9A/L9C
Barnes, B. O.	Quality Engineering - QA Engr	x	x	L3E2B/L2D3P/ L2D4P
Bradley, D. J.	Waste Pkg & Perform Assess - Mgr	x	x	L9A/L9C
Britton, R. C.	Chem Sys Analysis - Technician			L2D4P
Bruce, P. H.	Quality Sys & Audits - Engr			L9D
Budden, M. J.	Applied Physics Center/Proj Mgr	x		L1E2
Burnell, J. R.	Chem Sys Analysis - Proj Manager		x	L2D4P
Claudson, T. T.	Engineering Technology - Director		x	----------
Coles, D. G.	Chem Sys Analysis - Manager	x		
Cuello, R.	Quality Engineering - QA Engr	x	x	L3E2B/L2D3P/ L2D3R/L3E2A
Daniel, J. L.	Anal Chem - Manager	x		
Dill, J. A.	Chem Sys Analysis - Engr			L2D4P
English, S. L.	Quality Engineering - QA Engr	x	x	L2D3R/L3E2A/ L3E2C
Frank, N. C.	Quality Sys & Audits - Manager	x	x	L9D
Franks, C.	Project Mgmt System - Analyst	x		
Gates, T. E.	BWIP Waste Package - Proj Manager	x	x	L2D4P
Goldsmith, S.	Quality Achievement - Director	x	x	
Grasher, B. A.	Waste Tech Center - Business Mgr		x	
Hendren, D. J.	Organic Analysis - Tech Specialist			L2D3R/L3E2A
Hoober, D. L.	Quality Sys & Audits - Clerk			L9D
Hughey, C. E.	QA Department - Manager	x	x	L9D/L9A/L9C
Jones, T. E.	Chem Sys Analysis - Engr			L2D4P
Kaiser, B. J.	Chemical Services - Manager		x	----------
Kemper, R. S.	Mat & Chem Appl - Manager		x	----------
King, S. E.	Tech Plan & Analysis - Research Spec.	x		
Latkovich, J. M.	Analytical Chem - Manager	x	x	L2D3R/L3E2A
Laul, J. C.	In Situ Retardation - Project Manager		x	L3E2C
Lechner-Fish, T. J.	Organic Analysis - Tech Specialist		x	L2D3R/L3E2A
Longaker, T. M.	Chem Sys Analysis - Records Cust		x	L2D4P
Luhala, V. C.	Quality Engineering - QA Engr	x	x	L1E2
McDonald, J. P.	Envir Lic. Support - Records Custodian	x		L3G
McGarrah, J. E.	Waste Treatment Solubility/Sorptn Stdy - Tech Spec		x	L3E2B/L2D3P
McKinley, S. G.	Chem Sys Analysis - Sct/Engr			L2D4P
Page, T. L.	Envir Lic. Support - Manager	x	x	L3G
Piepho, M. G.	Applied Physics Center/Sr Res Sct		x	

NAME	ORGANIZATION-TITLE	ATTENDANCE Entrance	ATTENDANCE Exit	TASK ASSOCIATED WITH
	PNL			
Pratt, R. C.	Quality Engineering - Tech Ldr	x	x	L9D
Richmond, W. D.	Engineering Technology - Depty Dir	x		L9A/L9C
Roberts, J. T. A.	Research - Deputy Dir	x		L9A/L9C
Ryder, D. E.	Quality Engineering - Manager	x	x	L9D
Ryder, C. B.	Document Control - Clerk	x		L9D
Schmitt, J. S.	In Situ Retardation - Material Cust			L3E2C
Smith, M. R.	In Situ Retardation - Res Sct	x	x	L3E2C
States, J. B.	Envir Lic. Support - Deputy Mgr	x		L3G
Toste, A. P.	Organic Analysis - Project Manager	x	x	L2D3R/L3E2A
Worden, L. M.	Quality Control - Manager	x	x	L9D
	DOE-RL AND ROCKWELL			
Bohn, J.	DOE(MAC) - Audit Team Member	x		L2D3P/L3E2B/L2D4P
*Furman, M. J.	DOE-RL - Geoscience & Technology	x		L2D3P/L3E2B/L2D4P L3E2A/L2D3R/L3E2C
Hoe, R. J.	DOE(MAC) - Audit Team Member	x	x	L9A/L9C
Kasch, C. K.	DOE-RL - Audit Team Member	x		L9D
*Knepp, A. J.	DOE-RL - Geoscience & Technology	x		L1E2
Lite, H. L.	DOE-RL - Audit Team Member	x		L2D3P/L3E2B/L2D4P
Marcella, T. J.	DOE(MAC) - Audit Team Member	x		L2D3P/L3E2B/L2D4P
Newby, T. A.	DOE-RL - Audit Team Member	x		L1E2
O'Brien, R. P.	DOE(MAC) - Audit Team Member	x		L3E2A/L2D3R/L3E2C
Olson, O. L.	DOE-RL - Deputy AMC	x		----------
Plahuta, M. J.	DOE-RL - Operations Officer		x	----------
Saget, R. P.	DOE-RL - Director QS Div	x	x	----------
Sandall, B. K.	Rockwell - Audit Team Member	x	x	L9D
Silverwood, J. B.	DOE(MAC) - QA Consultant		x	----------
Slonecker, B. D.	Rockwell - Audit Team Member	x		L9D
Smiroldo, Jr, C. A.	DOE(MAC) - Audit Team Leader	x	x	L1E2
Subramanian, T. K.	DOE-RL - Audit Team Member	x		L3G
Thompson, O. O.	DOE-HQ - Audit Team Member	x		L9D
Welsch, K. R.	DOE(MAC) - Audit Team Member	x		L3E2A/L2D3R/L3E2C
Williams, W. B.	DOE(MAC) - Audit Team Member	x	x	L9A/L9C
*Whitfield, S. C.	DOE-RL - Lic. Env./Safety	x		L3G
	OBSERVERS			
Alkezweeny, A. J.	CERT - Tribal On-Site Rep	x	x	L3G L2D3A/L3E2A
Burke, W. H.	CTUIR - Umatilla Tribe Rep		x	----------
Cook, F. R.	NRC - BWIP On-Site Lic Rep	x	x	L9A/L9C
Provost, D.	St. of Wash. - Perf Assess Mgr	x		L3G L2D3A/L3E2A

*Technical Advisor

ATTACHMENT 3

TABULATION OF FINDINGS BY PROGRAM ELEMENT

ATTACHMENT 3

TABULATION OF FINDINGS BY PROGRAM ELEMENT

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
1.2	Internal Organization For QA							S		
1.3	Designation of Functional Responsibilities							S		C*
1.6	Organizational Interface Control							S		C*
2.1	Program Description	S	S	S	S	S	S	S	S	S*
2.5	Training and Indoctrination	S	S	S	S	S	S	S	N (8701 -05)	
2.6	Personnel Qualification							S		
2.7	Management Assessment of Program Effectiveness									PI*
3.2B	Control of Planning Process	C(2)	C(2)	C(2)	C(2)	C(2)	C(2)		C(2)	
3.3B	Technical Verification of Planning and Test Procedures	C(2)	C(2)	C(2)	C(2)	C(2)	C(2)		C(2)	
3.4B	Planning and Test Procedures Change Control	S	S	S	S	S	S		S	
5.1	Procedures	C(3)	C(3)	C(3)	C(3)	C(3)	C(3)	C(3)	C(3) C(4)	C(3)
5.2	Procedure Compliance	S	S	S	S	S	S	S	S	

LEGEND:
- S = Satisfactory
- N = Noncompliance (QAF No.)
- PI = Previously Identified by Internal or External Audit or Surveillances
- C = Concern
- * = Refer to "Program Management Assessment of Pacific Northwest Laboratory"

ATTACHMENT 3

TABULATION OF FINDINGS BY PROGRAM ELEMENT

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
6.1	Controlled Document List(s)							S		
6.2	Unique Identification of Controlled Documents							S		
6.3	Document Review	C(3)	C(3)	C(3)	C(3)	C(3)	C(3)	C(3)	C(3)	
6.4	Document Approval/ Issue Controls	C(2)	C(2)	C(2)	C(2)	C(2)	C(2)	C(2)	C(2)	
6.5	Document Change Controls	S	S	S	S	S	S	S	S	
6.6	Distribution Controls	C(1)	C(1)	C(1)	C(1)	C(1)	C(1)	C(1)	C(1)	
8.1	Identification System(s) for Items/Samples		S	S	S	S	S		S	
8.2	Item/Sample Controls		S	S	S	S	S		S	
8.3	Verification of Item/ Sample Identity Prior To Use		S	S	S	S	S		S	
11.3	Test Procedures		S	S	S	S	S		S	
11.4	Test Documentation and Records		S	S	S	S	S		S	
11.5	Evaluation of Test Results	S	S	S	S	S	S		S	
12.1	M&TE Selection		S	S	S	S	S		S	
12.2	Calibration Controls		S	S	S	S	S		S	
12.3	M&TE Handling and Storage		S	S	S	S	S		S	

LEGEND:
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ATTACHMENT 3

TABULATION OF FINDINGS BY PROGRAM ELEMENT

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
12.4	Traceability of M&TE Usage		S	S	S	S	S		S	
12.5	Impact Evaluation for Out of Calibration Incidents		S	S	S	S	S		S	
13.3	Marking/Labelling of Containers/Packages		S	S	S	S	S		S	
14.1	Inspection/Test Status Indicating System		S	N (8701 -02)	S	S	S	S		
15.1	Distinguishing Identification of Nonconforming Items		S	S	S	S	S	S		
15.2	Nonconformance Reporting		S	S	S	S	S	N (8701 -01)		
15.3	Evaluation/Disposition Controls		S	S	S	S	S	S		
15.4	Nonconformance Closeout		S	S	S	S	S	S		
16.1	Identifying/Reporting/ Correction of Conditions Adverse to Quality	S	S	S	S	S	S	S		
16.2	Evaluation of Potential Impact/Significance	S	S	S	S	S	S	S		
16.3	Determination of Cause (Significant Problems)	S	S	S	S	S	S	S		
16.4	Action to Prevent Recurrence	S	S	S	S	S	S	S		

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ATTACHMENT 3

TABULATION OF FINDINGS BY PROGRAM ELEMENT

ELEMENT		L1E2	L2D3P/ L3E2B	L2D4P	L3E2A	L2D3R	L3E2C	L9D	L3G	L9A L9C
16.5	Documentation and Reporting to Management	S	S	S	S	S	S	S		
16.6	Follow-up							S		
17.1	Designation of Documents To Become Records	S	S	S	S	S	S	S	S	
17.2	Control of Working Documents	S	S	S	S	S	S	S	S	
17.3	Authentication/Validation of Completed Documents	S	S	S	S	S	S	S	S	
17.5	Traceability Between Record and Activity	S	S	S	S	S	S	S	S	
17.7	Control of Changes to Formal Record	S	S	S	S	S	S	S	S	
17.8	Record Submittal Controls	S	S	S	S	S	S	S	S	
18.1	Audit Scheduling							S		
18.2	Audit Preparation/ Team Selection							N (8701 -03)		
18.3	Audit Performance/ Documentation							S		
18.4	Audit Reporting							S		
18.5	Resolution/Corrective Action for Adverse Findings							N (8701 -04)		
18.6	Audit Follow-up							S		
18.7	Audit Records							S		

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ATTACHMENT 4

QUALITY AUDIT FINDINGS

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)	7. Issue Date	8. Response Due Date
Charles G. Smoots Jr.	01/13/87	02/13/87

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution	16. Final Review and Approval (QAF Closed)
ORIGINAL-Audit/Surveillance Report File 1--Addressee 2-- 3--	Mgr./Branch Chief, Cognizant Branch ____ Date ____

QUALITY AUDIT FINDING

9. QAF Control No.
8701-02

1. TO: Name	Title	2. Location
D. Bradley, Manager	Waste Package and Performance Assessment	PNL RC Bldg

3. Reference/Requirements	4. Audit Or Surveillance Report No.
PAP 1401, Rev. 1, Para 4.4.7; Use of "Test in Progress" tags.	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 1! 2D4P and did not have a "Test in Progress" tag attached.

6. Lead Auditor (Signature)	7. Issue Date	8. Response Due Date
Charles A. Smerdon Jr.	01/13/87	02/13/87

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution	16. Final Review and Approval (QAF Closed)
ORIGINAL-Audit/Surveillance Report File 1--Addressee 2-- 3--	Mgr./Branch Chief, Cognizant Branch ____ Date

QUALITY AUDIT FINDING

9. QAF Control No.
3701-03

1. TO: Name	Title	2. Location
D. Bradley, Manager	Waste Package and Performance Assessment	PNL RO Bldg.

3. Reference/Requirements	4. Audit Or Surveillance Report No.
QAP 1801, Rev. 2, Para 4.3.4; Review of Previous Problem Reports	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)	7. Issue Date	8. Response Due Date
Charles A. Smeraldo Jr.	01/13/87	02/13/87

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution	16. Final Review and Approval (QAF Closed)
ORIGINAL-Audit/Surveillance Report File 1--Addressee 2-- 3--	Mgr./Branch Chief, Cognizant Branch ____ Date

QUALITY AUDIT FINDING

9. QAF Control No.
8701-04

1. TO: Name	Title	2. Location
D. Bradley, Manager	Waste Package and Performance Assessment	PNL RO Bldg.

3. Reference/Requirements	4. Audit Or Surveillance Report No.
QAP 1801, Rev. 2, Para 4.7.2; Response to Audit Finding Reports.	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)	7. Issue Date	8. Response Due Date
Charles A. Smeraldo Jr.	01/13/87	02/13/87

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution	16. Final Review and Approval (QAF Closed)
ORIGINAL-Audit/Surveillance Report File 1--Addressee 2-- 3--	Mgr./Branch Chief, Cognizant Branch ____ Date

QUALITY AUDIT FINDING

9. QAF Control No.
8701-05

1. TO: Name	Title	2. Location
T. L. Page, Project Manager	Environmental Studies Program	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 adquate 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)	7. Issue Date	8. Response Due Date
Charles A. Smerdon Jr	1-13-87	2-13-87

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

1--Addressee

2--

3--

16. Final Review and Approval (QAF Closed)

Mgr./Branch Chief, Cognizant Branch — 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.

ATTACHMENT 5

INSTRUCTIONS FOR RESPONSE

ATTACHMENT 5

INSTRUCTIONS FOR RESPONSE

1. Evaluation of Impact on Ongoing and Previous Work

   PNL must make an in-depth evaluation to determine what effect the reported condition had, or could have had, on affected project work performed while the condition existed. That evaluation must be documented and made a part of the response.

2. Action Taken or Planned as a Result of Impact Evaluation

   If the impact evaluation places the validity or credibility of any prior work in question, PNL management is expected (a) to determine promptly what has to be done to salvage affected work, if feasible, (b) to identify what activities are doing work based on the now-tainted results, and (c) to immunize ongoing and future project work from the effects of such tainted results. If that course of action is necessary, it must be defined and reported in PNL's response.

3. Identification of Root Causes of Reported Adverse Conditions

   PNL is expected to determine how and why the reported condition occurred. More specifically, what underlying condition, or set of circumstances, within the organization and/or its interfaces caused or enabled the reported condition to occur? The root cause, or combination of causes, must be reported as part of PNL's response.

4. Proposed Plan of Preventive Action

   PNL is expected to define and implement a plan of action to ensure that the reported adverse condition will not recur. That plan of action must be described in PNL's response.

5. Preventive Action Schedule

   PNL's preventive action plan is expected to include completion dates for the actions described. Completion means action completed and implemented.