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REPLY TO: RW-24
ATTN OF:

SUBJECT: Report of Participation by Owen Thompson in DOE-RL Audit of PNL
(DOE-RL Audit No. 8701)

TO: Carl Newton, RW-24

In accordance with section 6.2.4 of OGR QIP 18.1, the attached report provides a synopsis of my participation in the DOE-RL audit of PNL, Richland, Washington, during the period January 6 - 9, 1987.



Owen O. Thompson, RW-24

Attachment: As stated

cc: S. Kale, RW-20
J. Knight, RW-24
J. Rusk, MAC

Report of OGR Participation in BWIP QA Audit of PNL

Richland, Washington

DOE-RL Audit No. 8701

Auditing Organization: DOE-RL including technical advisors from DOE-RL Basalt Waste Isolation Division (BWID), and auditors from DOE-RL Quality Systems Division (QSD), DOE Office of Geologic Repositories (OGR), Management Analysis Company (MAC), and Rockwell Hanford Operations (RHO).

Audited Organization: Battelle Memorial Institute, Pacific Northwest Laboratories (PNL).

Dates of Audit: January 6 - 9, 1987

Audit Scope: All QA elements applicable to Basalt Waste Isolation Project (BWIP) activities currently in progress at PNL, as shown on Table 1 (attached).

Audit Team Members

Audit Group Leader	- J. Rusk, MAC
Team A	C. Smiraldo, MAC T. Newby, QSD
Team B	T. Marcella, MAC J. Bohn, MAC H. Litz, QSD
Team D	R. O'Brien, MAC K. Welsch, MAC
Team E	T. Subramanian, QSD
Team F	W. Williams, MAC
Team G	B. Sandall, RHO B. Slonecker, RHO C. Kasch, QSD O. Thompson, OGR
Technical Advisors	A. Knepp, BWID M. Furman, BWID S. Whitfield, BWID R. Hoe, MAC
Observers	R. Cook, NRC Onsite Representative A. Alkezweeny, Tribal Onsite Representative D. Provost, State of Washington

Summary of Audit

The five audit teams and technical advisors audited the activities shown on Table 1. The audit plan was developed by the teams prior to the audit, based on a study of PNL QA documents and interviews with key PNL staff. [The OGR Auditor from Washington, D.C. did not participate in the audit planning phase which was done at the site.]

The final audit plan was provided to the OGR auditor only the day prior to the audit, and more time would have enabled him to be better prepared. The other auditors, however, had worked on their parts of the audit plan and were not constrained by the late delivery of the final audit plan.

The audit plan was voluminous (over 300 pages) but was well planned and easily divided into self-contained parts for each audit team. The audit plan, developed in accordance with the BWIP Audit Handbook, was comprehensive and covered all the major audit items.

The audit was effectively planned and was conducted smoothly. The PNL staff was fully cooperative and showed a clear understanding of quality implementing concepts. The audit teams' Findings and Concerns are indicative of areas for improvement in the PNL QA program rather than major QA breakdowns. Similarly, the specific comments by the OGR auditor should be taken as constructive advice.

Summary of Audit Team Findings and Concerns

After the interviews and study of records at PNL, the audit team members met to consolidate their results and develop the following list of Findings and Concerns. [The OGR auditor had to leave because of previous travel plans. However, his sub-team coordinated its input which was subsequently provided to the audit team by C. Kasch.]

Findings

- 8701-01 Failure to review and/or document the review of non-conformance reports (NRCs) for potential classification as unusual occurrence reports (UORs). A similar finding for corrective action reports (CARs) was identified by a previous Rockwell surveillance team and corrected for CARs but not for NCRs.
- 8701-02 Failure to use "Test-in-Progress" tags on operating equipment

- 8701-03 Failure by PNL lead auditors to review previous audit findings or problem reports in preparing for audits.
- 8701-04 Responses to internal audit findings which were accepted did not meet PNL procedures; the specifics identified in a previous SRPO audit were corrected but the problem was not resolved generically.
- 8701-05 Personnel found by PNL to be improperly indoctrinated and trained were not removed from the relevant work.

Concerns

1. Numerous PNL Procedures were not issued by Document Control until after the effective date, by as much as 90 days.
2. External and internal interfaces for preparation, review and approval of research project planning documents, such as Statements of Work, were not adequately defined by procedures.
3. Numerous document review record sheets were incomplete because resolution of comments were not made part of the record.
4. Environmental Studies Procedure EAP-801, Sample Identification and Control requires that procedures not already specified should be provided in the Laboratory Record Book; this had not been done for some subcontractor procedures for sample handling and analysis.

OGR Auditor Comments

1. Extending Audit Schedule

The auditors were unable to complete their work in the assigned time and the Audit Group leader extended the audit, with the agreement of PNL management. The auditors were provided an additional day for interviews and the audit exit interview was postponed from Thursday pm to the following week.

Taking additional interview time may have been an unfair imposition on the auditee, who had already committed significant resources to the audit. It also could set an undesirable precedent because auditors intuitively have a problem deciding what is "enough". In future audits, the schedule and support agreed to by the auditee should be strictly maintained.

The delay in the exit interview probably had most impact on the PNL managers who had to rearrange their schedules. The delay was, however, necessary to enable the auditors from the various teams to compare notes and provide an effective overview of PNL's total program. In future audits when there are multiple audit teams, the exit interview should be scheduled some days after the interviews are complete to allow for coordination. Delaying exit interviews, however, may cause some difficulties for out-of-town auditors (See Comment 2, below)

2. Coordination with Out-of-Town Auditors

The OGR auditors was not included in the audit planning or the exit interview because of the impracticality of commuting from Washington. Audit team leaders should be apprised of the extra effort needed to effectively use out-of-town auditors -- specifically, to identify appropriate individuals early, to give extra attention to exchange of information, to assign a local auditor as a primary contact (and to the same team if teams are used), and to assure that the out-of-town auditors's input is incorporated into the exit interview and audit report.

3. Audit Observers

Immediately prior to the audit there were some problems regarding the number of observers to be accommodated. Observers from the State of Washington and the Tribal Onsite Representative had been approved and subsequently the NRC Onsite Representative wished to be present, which he was, but reportedly after some discussions between BWIP and DOE Headquarters.

To avoid future problems, DOE needs to expedite guidance for observers at audits which is being developed throughout the QA Coordinating Group. With the 5 audit teams at the PNL audit, the observers were able to attach themselves to one of the groups without adverse impact. Mr. Cook (NRC) and Mr. Alkezweeny (Tribal Representative) participated some of the time; Mr. Provost (Washington State) was present only for the entrance meeting, to my knowledge.

4. Implementation of DOE Order 5000.3, Unusual Occurrence Reporting

During the PNL audit, a concern was raised regarding the implementation of DOE Order 5000.3, Unusual Occurrence Reporting, in light of the requirements of OCRWM QA Management Policies and Requirements (QAMPR, DOE/RW-0032).

PNL has two sets of quality assurance administrative procedures (QA Manuals) -- PNL-MA-60 for license-related work and PNL-MA-7 for non-license related work. Under MA-60, PNL has procedures for non-conformance reports (NCRs), deficiency reports (DRs) and for higher-level corrective action reports (CARs). These reports are provided to the BWIP Quality Systems Division.

Under MA-7, PNL has procedures for unusual occurrence reports (UORs) as specified in DOE Order 5000.3. These reports are provided to DOE-RL but not directly to DOE-QSD by PNL Procedures.

In practicality, a license-related unusual occurrence would require an NCR, DR or CAR and would be identified on the appropriate report to BWIP-QSD as a UOR.

In the case of PNL, the QAMPR is ambiguous because it requires a UOR system meeting DOE Order 5000.3 (which PNL has implemented, with reporting to DOE-RL) but QAMPR also requires reporting to OCRWM (which PNL accomplishes only indirectly via a notation on NCRs, DRs and CARs).

PNL revised their license-related QA Procedures to identify UORs on NCRs, DRs and CARs in response to a concern on this issue raised by Rockwell (see Audit Finding 8701-01). PNL does not desire to include OCRWM requirements in their QA Manual MA-7 for non-license related work because that would incur additional, unnecessary overview of MA-7 by DOE-QSD and would complicate future revisions to MA-7.

The OGR QA Manager should note that PNL has the dual reporting system for off-normal events.

TABLE 1. AUDIT SCOPE FOR DOE-RL QA AUDIT 8701 OF PNL

PROJECT TASKS	NUMBER	AUDITOR	TECH ADVISOR	TEAM
TOTAL SYSTEM PERFORMANCE ASSESSMENT	L1E	Smiraldo/Newby	Knepp	A
Verification and Benchmark Codes	L1E2		Knepp	
WASTE FORM AND MATERIALS TESTING	L2D	Marcella/Bohn/Litz	Furman	B
Solubility/Sorption Studies	L2D3P/ L3E2B		Furman	
Hydrotherm Material Testing	L2D4P		Furman	
GEOCHEMISTRY	L3E	O'Brien/Welsch	Furman	D
Organic Analysis of Groundwater and Drilling and Leachate	L3E2A		Furman	
Organic Analysis of Sodium Bentonite Packing Materials	L2D3R		Furman	
U/TH Disequilibrium	L3E2C		Furman	
ENVIRONMENTAL STUDIES PROGRAM	L3G/L3H	Subramanian	Whitfield	E
MANAGEMENT AND INTEGRATION	L9A	Williams	Hoe/Madsen	F
PROJECT CONTROL	L9C	Williams	Hoe/Madsen	
QUALITY ASSURANCE	L9D	Sandall/Stonecker/ Kasch/Thompson	----	G