



Department of Energy
Washington, DC 20585

DEC 28 1988

Mr. B. J. Youngblood, Deputy Director
Division of High-Level Waste
Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Youngblood:

Reference: Meeting minutes--Summary of DOE/NRC meeting on QA open
items; dated July 15, 1988

Attached is a copy of a memo containing a response from DOE, Richland
Office to an NRC observation report of DOE-HQ/DOE-RL (Audit 88-01)
conducted earlier this year. Attached to this memo are specific
responses to NRC concerns listed in the audit report. In particular,
Concern #1 and Concern #3 (in the attachment) respond to NRC items 10
and 11, respectively, in enclosure 2, appended to the referenced meeting
minutes. This letter is the OCRWM response to items 10 and 11 of the
NRC list (Enclosure 2) from the July 7, 1988, meeting minutes.

If you have any questions, please call Gordon Appel of my staff on
586-1462.

Sincerely,

Ralph Stein
Associate Director for Systems
Integration and Regulations

Enclosure

cc:

T. Subramanian, DOE/RL
J. Linehan, NRC
J. Kennedy, NRC

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United States Government

Department of Energy
Richland Operations Office**memorandum**

88-QEB-025

DATE: JUL 21 1988

REPLY TO
ATTN OF: QAD:RPS

SUBJECT: DEPARTMENT OF ENERGY, RICHLAND (DOE-RL) RESPONSE TO NUCLEAR REGULATORY COMMISSION (NRC) OBSERVER AUDIT REPORT OF DOE-HQ/DOE-RL AUDIT 8801

TO: W. J. Kehew, Acting Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management, HQ

THRU: J. H. Antonen, Assistant Manager
for Research and Projects

DOE-RL has reviewed the NRC staff observer audit report and prepared responses to the specific concerns raised by the observer.

Our review also included an evaluation whether the NRC staff observer concerns impacted the Audit 8801 report issued before we received the NRC observer report and determined that the report does not require any revision.

NRC transmittal letter calls for copies of DOE-HQ and Pacific Northwest Laboratory (PNL) Quality Assurance (QA) plans for NRC review and further NRC audits and/or observation audits to verify that the concerns raised in the past audits have been properly addressed. Our current plans for addressing these issues are as follows:

1. DOE-HQ has provided their Quality Assurance Plan (QAP) to NRC and has plans to provide PNL MA-70 QAP to NRC after the PNL QAP is approved by DOE-HQ.
2. A close out audit/or surveillance will be performed to close out those audit concerns identified in the RL Audit Report 8801. Basalt Waste Isolation Project (BWIP) procedures will be reinstated for this one time activity only. OCRWM and NNWSI will be advised in sufficient time to permit their participation if desired.

DOE recognizes the value of NRC staff judgments and generally accepts their reports as a source of feedback to improve performances. However, the current NRC report regarding Audit 8801 could have been significantly improved by greater depth of investigation regarding some of the identified concerns. Responses to specific concerns in the NRC report are attached.

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88-QEB-025

W. J. Kehew

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JUL 21 1988

For further information, please contact me or T. K. Subramanian of my staff on FTS 444-3175.


R. P. Saget, Director
Quality Assurance Division

Attachment

cc w/attach: J. Blaylock, DOE-NV
K. Sommer, DOE-HQ
R. Stein, DOE-HQ

DOE-RL RESPONSES TO NRC
July 15, 1988

CONCERN 1

Clarifying the rights of access between Lawrence Livermore National Laboratory (LLNL) and its subcontractor Pacific Northwest Laboratory (PNL). As currently structured, LLNL's access to PNL appears limited to those times when an audit is planned by either the Department of Energy, Headquarters (DOE-HQ) or the Department of Energy, Richland (DOE-RL) and LLNL may be asked to participate.

Response: As currently structured LLNL's access to PNL is not limited based on the evidence that PNL and LLNL Program personnel exchange visits for discussion on TUFF Program. Such visits/discussions are not limited by PNL. PNL, however has requested LLNL to coordinate with DOE-RL programs for any audits LLNL wishes to perform. Such requests are consistent with PNL and DOE area office policies. No direct contract or subcontract exists between LLNL and PNL. Instead the PNL contract is with DOE-RL. PNL performs work for LLNL by work orders and funding is provided from the Department of Energy, San Francisco (DOE-SAN) through DOE-RL. However, DOE NNWSI Project, the sponsor for LLNL, is notified to address this item if it is still considered an issue by LLNL. Therefore, no DOE-RL action is required.

CONCERN 2

Planning and coordinating the audit in such a manner as to provide a more effective audit process.

Response: In general, DOE shares this concept; accordingly, the same approach of well planned and effective audits was followed on this as was performed on previous 1987 BWIP Audits.

All these audits, as well as other BWIP Audits, used the same audit procedure, same type of Audit Team Leader (ATL) briefing for technical advisors, and audit observers. All these audits covered the NQA-1 criterion as planned. The same ATL used the same advance planning and coordinating strategies for Audit 8801, as was used before and completed all the criterion for the Material Characterization Center (MCC) but could not complete three criteria for the TUFF Program portion of the audit. While the ATL assumes total responsibility for the end result, DOE does not share NRC observer's view that the cause is lack of advance planning as stated in page 9, section C, "Time constraints, imposed by a lack of sufficient advance planning affected the conduct of the TUFF Program portion of the audit."

Planning for both MCC and TUFF portions of the audit started at the same time (January 1988) and proceeded at the same rate as the

same QA checklist was to be used for both MCC and TUFF Program evaluations. Planning for this audit was identical to what has proven effective on previous audits and on the MCC portion of this one. As it turned out, TUFF Project did not comply with previously agreed to schedule and support requirements.

Unfortunately, due to conflicting project priorities, subteam B technical advisor could only be available for one day.

Our assessment is that with the same planning and coordinating effort all the criteria would have been completed if the TUFF Project had committed the subteam B for three full days of the scheduled audit period. This is particularly true considering the outstanding coverage the subteam B provided in the limited time they participated in the audit.

Therefore, DOE concludes that three unfinished checklist criteria for only TUFF Program portion of the audit is an isolated case attributable to project technical priorities conflict rather than lack of advance planning on the part of the QA organization.

CONCERN 3

Coordinating the overall audit related training program to provide consistency in the topics presented so as to achieve a consistent level of understanding of the audit process.

Response: DOE concurs with the NRC staff that audit briefings need be consistent in the topics presented for all the team members and believes that the briefings provided by the ATL were consistent in the topics presented but differed in the scope commensurate with the functions of the team members. Briefing for technical advisors emphasized more on technical adequacy evaluation (as evidenced by the technical advisor, Henry Shaw's report, Attachment 3 of Audit 8801 report) than on the traditional auditor tasks such as completing the audit checklist.

Based on the NRC staff observation (Section 3.E. of the NRC report) technical advisors performed their intended function of technical adequacy evaluation effectively and their reports (Attachment 3 of the audit report) provides the required documentation for their activities.

CONCERN 4

Coordinating the development of the audit checklist with sufficient time to review and incorporate the technical program areas that are to be addressed.

Response: DOE concurs with the concept that technical input need be included in the final checklist.

As part of the audit preparation, technical program areas (i.e., test procedures) to be addressed during the audit were determined sufficiently early but the actual technical questions to be pursued were developed by the technical advisors and were not received in time to be included with the QA checklist which was mailed out to observers and etc. two weeks before the audit. Memorandum no. 88-QSD-045 dated February 12, 1988, from R. P. Saget, DOE-RL to Ralph Stein, which transmitted the audit checklist to DOE-HQ, copy of which was also transmitted to Nancy Voltura has the statement, "additional checklist questions covering task specific technical procedures and software control are under preparation by technical advisors/specialists and will be made available to the subteams before the audit."

Copies of the technical questions prepared by both Brookhaven National Laboratory (BNL) and LLNL were provided to the NRC staff observer prior to their use in the audit.

The technical advisors' reports included in the audit report provide full coverage for all the technical investigations pursued.

NRC staff comment will be taken into account for future audits.

CONCERN 5

Reviewing QA program documents for consistency with program endorsed consensus standards prior to implementation.

Response: DOE does agree that reviewing QA program documents for consistency with program endorsed consensus standards prior to implementation is essential and it did so in the case of BP 18.4, Auditor Qualification, Rev. 1. In fact, BP 18.4 includes NQA-1 (1986) as a reference. However, the difference or apparent inconsistency is in the interpretation of the NQA-1 (1986) requirement.

DOE-RL interpretation of the lead auditor certification requirement in NQA-1 (1986) is that current employer (DOE) can accept results obtained during the individual's initial qualification by previous employer subject to the conditions given below:

- (a) That the individual was initially certified by an employer working to the requirements of 10CFR50, Appendix B,
- (b) That the individual's certification was current at the time he or she left the certifying employer,

- (c) That the individual would have been currently re-certifiable had he or she remained with the previous employer, and
- (d) That objective evidence is available to support condition (c).
- (e) Lead Auditor certification by a new employer of an individual who maintained certified Lead Auditor status in his or her previous employment, when conditions (a) through (d) are met, is interpreted to be the equivalent of re-certification under the NQA-1 (1986) requirements for maintenance of qualification.

The above approach is consistent with accepted industry practice. (See attached memorandum regarding this subject) BP 18.4 accordingly was written to permit lead auditor certification based on previous employer certification.

In the case of the lead auditor certification of T. K. Subramanian, DOE attestation was based on the supporting documentation from his previous employer (conditions (a), (b), (c), (d), and (e) above were satisfied) and assessment by the DOE contractor knowledgeable of the previous employer (noted as A/E in the NRC staff report) lead auditor certification program.

As indicated to NRC staff during the discussion on this same topic at Richland, Washington, T. K. Subramanian has successfully passed the ASQC Lead Auditor examination in 1988. He participated in one DOE Audit of PNL (8701) as an auditor before performing as ATL for four DOE Audits during 1987 and 1988.

Based on the information presented above and the information provided in response to Concern 2, DOE does not agree with NRC's recommendation for strengthening lead auditor skills of T. K. Subramanian in the areas of planning, organizing or directing audits.

CONCERN 6

Assuring that DOE program documents (i.e., audit procedures) are subject to appropriate document control measures.

Response: DOE does assure that QA program documents are subject to appropriate document control measures.

As described to NRC staff, the audit was "planned" using BP 18.6 procedure while it was controlled. The BWIP termination and the subsequent memorandum that rendered all BWIP procedures including BP 18.6 audits "quasi uncontrolled", two weeks before the start of the audit, were "one time" unprecedented events.

This is an explanation and not a justification. DOE will continue to ensure appropriate document control measures are applied to the DOE program documents.

CONCERN 7

Ensuring that approved QA program documents describe the audit process, the roles and responsibilities of audit team members and any audit program criteria or definitions, which are to be implemented in conducting and documenting the audit activity.

Response: DOE agrees with the concern. The issue that prompted this concern is that the audit procedure BP 18.6 used for the Audit 8801 did not: 1) describe the term "subteam lead" (i.e., an auditor who coordinates a group of auditors during an audit, under ATL for the audit); and 2) describe or define the terms "findings", "concerns", and "observations" used during the Audit 8801.

By way of explanation, NRC should be aware that the subteam lead concept is described in BWIP audit handbook and has been used on almost all previous BWIP Audits.

The definitions of findings, concerns, observations used during the audit were those derived from the BWIP contractor task force consensus definitions. Definitions did not violate any of the BP 18.6 audit procedure requirements. These definitions were being processed for incorporation in higher tier project wide documents (e.g., the Project Glossary) at the time the project was terminated.

INFORMAL MEMO

March 16, 1988

TO: R. P. Saget

FROM: W. S. Gibbons *W.S. Gibbons*

SUBJECT: ACCEPTANCE OF A PREVIOUS LEAD AUDITOR EXAMINATION

REFERENCE: NQA-1, Supplement 2S-3, Paragraph 3.4 and 5.2

It has been accepted industry practice to accept a lead auditor's examination based on a previous employer's examination.

The objective evidence used for this purpose has been a copy of the previous employer's lead auditor certification form, which documents passing an examination and the date.

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WSG:c1j

cc: A. M. Sastry
MACTEC QA Rdg. File