

QA OBSERV AUDIT

OCT 14 1988

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MEMORANDUM FOR: John J. Linehan, Chief
Project Management & Quality Assurance Branch, HLWM

FROM: Ronald L. Ballard, Chief
Geosciences & Systems Performance Branch, HLWM

SUBJECT: HLTR STAFF QA OBSERVATION AUDIT REPORT

Transmitted with this memorandum is the QA Observation Audit Report on the observation audit of LANL in some technical areas of geochemistry. The report was prepared by John Bradbury. This report fulfills HLGP Branch obligations under the TA task control request from the Project Management & Quality Assurance Branch dated 10/11/88 (PPSAS Number 411333, TAC L60095).

Please contact John Bradbury, Ext. 20535, if you have any questions regarding this transmittal.

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[Signature]

Ronald L. Ballard, Chief
Geosciences & Systems Performance Branch, HLWM

Enclosure:
As stated

cc: J. Donnelly, HLPM
J. Gilray, HLPM

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QA Observation Audit Report - Geochemistry
Authored by: John W. Bradbury, HLGP/HLWM
October 14, 1988

This report describes the observations of John Bradbury acting as an NRC technical observer on the YMP 88-08 audit of LANL. The observations relate to the following criteria:

- 1) scope of the audit
- 2) timing of the audit
- 3) review of technical products
- 4) conduct of the audit
- 5) qualifications of the auditors
- 6) audit team preparation
- 7) conduct of meetings
- 8) team coordination

The NRC technical observer witnessed portions of the audit in the following technical areas:

- 1) Hydrothermal Geochemistry 86/4.1.3-HG, Rev. 0
- 2) Biological Sorption Transport 86/4.1.5-MB, Rev.1
- 3) Sorption 86/4.1.5-SP, Rev.0
- 4) Solubility Determination 86/4.1.4, Rev.0
- 5) Dynamic Transport Process 86/4.1.6-DTP, Rev.0
- 6) Retardation Sensitivity Analysis 86/4.1.7, Rev.0
- 7) Reactive Tracer Testing 86/4.1.1/C-Wells, Rev.0.

Due to the scheduling of the audit interviews concurrently, the technical observer was not able to witness all of the technical discussions (checklist questions and responses). However, the purpose of the observer is not to track all of the audit but to see and hear enough to be able to evaluate the quality of the audit and the auditors. Consequently, the technical observer had to select which interviews to observe based on 1) the possible significance of the area to repository performance or site characterization, 2) the familiarity of the observer with the auditor (as from previous audits), and 3) the familiarity of the observer with the technical area. The areas tracked extensively by the NRC observer were Dynamic Transport Process, Solubility Determination, and Sorption. Portions of Reactive Tracer Testing and Biological Sorption Transport interviews were observed. The interviews for Hydrothermal Geochemistry and Retardation Sensitivity Analysis were not observed.

Observations

1. Scope of the Audit

The choice of the technical areas audited was appropriate. These technical areas are key to some of the geochemical aspects of site characterization and performance assessment. The rest of the key geochemical areas were audited in 1987.

Objectives for the technical phase of the quality assurance audit were included as part of the audit notebook. A list of questions (Attachment 1) were provided to serve as a basis for the checklist questions. Not all of the objectives of the audit were met. For example, the question "Were the procedures in place technically adequate for the intended application?" was not addressed. Sorption ratios from batch experiments were not shown in this audit to be adequate for modeling the repository. Another question not addressed was "Were there sufficient technical procedures for the activity under review?" The checklist questions referred to existing procedures, not all of the alternative procedures that might be considered to characterize the site. The types of questions in Attachment 1 are better addressed in a peer review and not a QA Audit. The scope of the audit would be too large if these questions were considered.

2. Timing of the Audit

Audits appear to stimulate activity towards improving QA programs. For example, many detailed procedures were written or revised just prior to this audit. Therefore, the timing of this audit was appropriate.

On the downside, however, the late revisions of the procedures were not included in the audit notebook. Thus, the effectiveness of the audit was reduced because some of the auditors' questions were based on out-of-date information.

3. Review of Technical Products

The review of technical products by the DOE technical auditors was adequate. Questions from the checklist provided a basis for discussion. However, the technical auditors sometimes expanded the questioning when appropriate to determine how the activity fit into the overall site characterization program.

It was noted by the DOE technical auditors that the technical products (milestones) from certain activities are not so detailed as to allow one to track results back to specific experiments on specific samples. These details are contained in laboratory notebooks. However, the laboratory notebooks are not submitted to document control until they are full, which may be long after the milestone is met. The auditors were thorough in their review of laboratory notebooks. They spent considerable time tracing results back through the notebooks. They noted that, in some isolated cases, portions of some laboratory notebooks were illegible. However, for the most part, laboratory notebooks were immaculate.

4. Conduct of the Audit

The first day of the audit was very disorganized as people tried to schedule interviews with the various principle investigators. However, a system of scheduling was developed quickly such that the rest of the audit ran smoothly.

A problem arose concerning a particular technical area to be covered in the audit. The DOE audit team thought they were going to audit all sorption work at LANL. However, their letter to LANL described the technical area to be audited as Activity 8.3.1.3.4.3 Sorption. From the CDSCP, the number 8.3.1.3.4.3 actually refers to a study: Development of Sorption Models (Isotherms). The LANL people were surprised at the change in the scope of the audit. As a result, the first afternoon was spent with only some of the principle investigators of this technical area and certain checklist questions could not be addressed. However, the next day the other PIs were made available and the questions were addressed. This problem points out the necessity of using terminology consistent with the system to describe technical areas to be audited.

5. Qualification of the Auditors

The qualifications of the technical auditors were reviewed by the NRC technical observer. Those qualifications were found to be adequate for the technical areas audited. All technical auditors had PhDs in related fields and experience ranging from 3 to 30 years.

6. DOE Audit Team Preparation

The DOE technical audit team members were generally prepared as indicated by the substance of some of the checklist questions and the discussions they held with the principle investigators. One exception, however, was their failure to consider the information from the NRC "mini" audit in June 1987. The "mini" audit reviewed some of the same detailed procedures as contained in this audit. It was found in the "mini" audit that the detailed procedures did not contain a section on acceptance criteria as required in the LANL QA Program. The NRC technical observer did not hear any discussion of this finding by the technical auditors at this DOE audit.

7. Conduct of Meetings

The preaudit/entrance and postaudit/exit meetings ran smoothly but contained no technical information.

The daily audit caucuses were both productive and informative. Inasmuch as there were a number of technical areas being audited concurrently, the discussions held during these meetings provided the NRC technical observer with information to evaluate the quality of the technical audit in areas he had not been able to attend. For example, although the NRC technical observer had not observed the interview with the PI of the Retardation Sensitivity Analysis activity, the discussions by the technical auditor at the caucuses indicated he was capable of auditing that activity.

8. Team Coordination

The audit team appeared well-coordinated and improved through the course of the audit. For example, it was noted by the DOE programmatic auditors that J-13 groundwater had been supplied over a number of years to LANL in 55 gallon drums. Five drums had been used since the beginning of the sorption/solubility work. However, the information in the laboratory notebooks did not specify from which drum water was taken. The technical auditors looked into this possible area of concern. Discussion in the caucus concerned the effect on quality if the drums were not differentiated. Various points of view were presented and a decision was made concerning the action to be taken by the audit team.

Attachment 1

AUDIT PLAN 88 - 4

Rev.1,13May8

OBJECTIVES FOR THE TECHNICAL PHASE OF THE QUALITY ASSURANCE AUDIT

In order to provide a unified approach to the conduct of the technical phase of a Quality Assurance audit the following questions are provided. The intention is to have these questions serve as the basis for the questions developed in the technical checklist (XX-2).

- o Were there sufficient technical procedures for the activity under review
- o Were the procedures in place technically adequate for the intended application
- o Did the prime or critical methodologies employed consider existing/accepted approaches and technologies
- o Where controversial methodologies were employed was an adequate peer review performed
- o Was the background/credentials of those individuals engaged in the task/activity appropriate to the desired/intended outcome of the activity
- o Was the level of effort/rigor employed commensurate with the stated objectives of the task/activity
- o Where concerns exist as to the efficacy of an activity is a further technical review indicated
- o Where the interim analysis or interpretation of data supports reported results is the analysis/interpretation appropriate for the proposed activity/task
- o Were the design calculations, design methods, and design analyses employed for an activity appropriate to the maturity of the design

ENCLOSURE 3