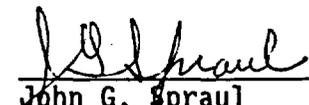
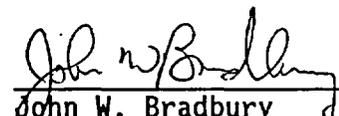


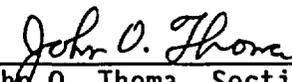
U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT OA-96-04
OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT YM-ARP-96-12
OF THE U. S. GEOLOGICAL SURVEY

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1.0 INTRODUCTION

Members of the Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) and geosciences staff observed the U. S Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) performance-based audit of the U. S. Geological Survey (USGS). The audit, YM-ARP-96-12 was conducted on April 29 through May 2, 1996, of work being performed at the USGS offices and laboratories in Denver, Colorado. The State of Nevada did not participate in this audit.

The objective of this performance-based audit by YMQAD was to evaluate the implementation of the USGS QA program requirements and the technical activities leading to the generation of the Preliminary Site Saturated Zone 3-Dimensional Ground Water Flow Model (Work Breakdown Structure WBS 1.2.3.3.1.3.3) and the Unsaturated Zone Hydrochemistry Data Synthesis Report (WBS 1.2.3.3.1.2.7).

The NRC staff's objective was to gain confidence that YMQAD and the USGS are properly implementing the requirements of their QA programs in accordance with the OCRWM Quality Assurance Requirements and Description (QARD: DOE/RW-0333P) and Title 10 of the Code of Federal Regulations (10CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

This report addresses the effectiveness of the YMQAD audit and the adequacy of implementation of QA controls in the audited areas of the USGS QA program.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that YMQAD Audit YM-ARP-96-12 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA and technical disciplines, and its assignments and checklist items were adequately described in the audit plan.

The audit team determined that the USGS technical performance was satisfactory. The audit team also determined that USGS compliance with ten of the 13 audited QA programmatic elements audited was satisfactory, but compliance with the other three (Procurement Document Control, Control of Purchased Items and Services, and Corrective Action) was determined to be unsatisfactory. One of four deficiencies found by the audit team was corrected during the audit. The corrective actions for the three others are to be addressed with the corrective actions associated with similar findings at an earlier compliance audit (YM-ARC-96-10). In this regard, the NRC staff understands that YMQAD issued an action plan for USGS along with its earlier Corrective Action Request concerning USGS procurements. In light of the procurement nonconformances noted at USGS, the NRC staff believes that such action was warranted and looks forward to hearing of the timeliness and effectiveness of the resultant corrective action. The audit team also made three recommendations.

The NRC staff determined that this audit was effective. Further, the NRC staff agrees with the audit team conclusions, findings, and recommendations.

The Key-Technical Issue (KTI) associated with the audit is Radionuclide Transport. The technical portion of this audit provided insight into DOE's program that will facilitate resolution of this KTI.

4.2 Conduct of Audit

The audit was performed in a professional manner. Audit team personnel were well prepared and demonstrated a sound knowledge of the USGS and DOE QA programs. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The audit plan identified this as a performance-based audit in which the evaluation process and product acceptability would be based on: 1) satisfactory completion of the critical process steps, 2) acceptable results and quality of the end product, 3) documentation that substantiates quality of products, 4) performance of trained and qualified personnel, and 5) implementation of applicable QA program elements. The audit included the technical evaluation of the data selected and input to the model, the authenticity of the data, the completeness of the database, the process of reconciling conflicting data, the documenting of data used and data not used, and the modeling results.

The DOE audit team and observers caucused at the end of each day. Also, meetings of the audit team and USGS management (with an NRC observer present) were held each morning to discuss the then-current audit status and preliminary findings.

4.3 Timing of the Audit

The NRC staff believes the general timing of the audit was appropriate for YMQAD to evaluate the pertinent USGS activities associated with the ongoing modeling process and implementation of the QA program. YMQAD performed this audit while activities leading to the respective reports were still being conducted. Therefore, in the absence of a final (or even a reviewable draft) report, items 2 and 3 in Section 4.2 above could not be verified during this audit.

4.4 Examination of QA Programmatic Elements

The auditing effort was generally divided between the technical aspects of the activities being audited and the related QA programmatic elements. The NRC staff observed that each of the audit team members reviewed pertinent documentation and interviewed a representative sample of USGS personnel to determine their understanding of implementing procedures. Checklists were used effectively, and issues were pursued beyond the checklists when appropriate. NRC observers were provided ample opportunity to provide comments and ask questions. This portion of the report covers only the auditing of QA programmatic activities that were observed by the NRC.

The audit team reviewed the training, education, and experience records of involved USGS personnel to ensure they met their individual position descriptions. Objective evidence was provided and reviewed. The audit team concluded that the personnel were in compliance.

The audit team audited procurement documents for procurements directly related to the work being audited. This portion of the audit revealed several discrepancies that are to be followed-up by DOE as part of following-up on a CAR issued earlier in the area of procurement control.

Audit team personnel audited several of the USGS laboratories where work was ongoing on borehole samples. The auditor reviewed pertinent documents and questioned the laboratory personnel regarding their knowledge of the work and the calibration status of the instruments. No QA programmatic discrepancies were found in the laboratories by the audit team while observed by the NRC staff.

This portion of the audit resulted in the four deficiencies noted in Section 4.8 of this report as well as the finding that USGS compliance with ten of the 13 audited QA programmatic elements audited was satisfactory, but compliance with the other three (Procurement Document Control, Control of Purchased Items and Services, and Corrective Action) was unsatisfactory.

4.5 Examination of Technical Activities

Prior to the audit, the Technical Specialist developed a list of questions to be asked of the Principle Investigators. The questions were developed in such a way as to determine the level of understanding of the Principle Investigators of the systems they were attempting to characterize. The NRC staff review of the questions led them to the conclusion that the Technical Specialist had worked long hours and put considerable thought into the areas of scientific investigation he was auditing. As a result, the questions led to intense and provocative discussions on the objectives of the studies and the interpretations of the physical evidence collected.

The Audit Plan listed the specific products to be audited as:

"Preliminary Site Saturated Zone 3-Dimensional Ground Water Flow Model" Work Breakdown Structure (WBS) 1.2.3.3.1.3.3 and

"Unsaturated Zone Hydrochemistry Data Synthesis Report" WBS 1.2.3.3.1.2.7

However, these reports either did not exist yet or were in such a preliminary stage as not to be auditable. Therefore, two other draft documents generated in the same areas of study were used in place of those identified in the Audit Plan. For the Saturated Zone Hydrologic System Synthesis and Modeling WBS 1.2.3.3.1.3.3, the document audited was:

"Status of Understanding of the Saturated-Zone Ground-Water Flow System at Yucca Mountain, Nevada as of 1995," USGS, Richard R. Luckey *et al*, (Water Resources Investigations Report 96-XXXX) - DRAFT

For the Unsaturated Zone Hydrochemistry WBS 1.2.3.3.1.2.7, the document audited was:

"Interpretations of Chemical and Isotopic Data from Boreholes in the Unsaturated-Zone at Yucca Mountain, Nevada," USGS, In C. Yang et al, (Water Resources Investigations Report 96-4058) - DRAFT

These documents are forerunners of the products listed in the Audit Plan.

The Audit Plan states: "A performance based audit evaluates products and activities to determine the degree to which they meet program requirements and management commitments and expectations. This evaluation of process effectiveness and product acceptability will be based upon:

- 1) Satisfactory completion of the critical process steps;
- 2) Acceptable results and quality of the end products;
- 3) Documentation that substantiates quality of products;
- 4) Performance of trained and qualified personnel; and
- 5) Implementation of applicable QA Program Elements"

The Technical Specialist focused his efforts on the first 4 items, and the rest of the audit team focused on item 5. With regard to item 1, the Technical Specialist noted that to meet all the objectives described in the study plan, the investigators would have to expend considerable more effort and time than has been funded. Given the current level of USGS funding and consequently, manpower, he suggested many of those objectives would not be met by the Milestone due date. It was recognized that this problem was not the fault of the USGS. As funding decreases, the objectives to be obtained also must decrease. The last revisions of the study plans 8.3.1.2.3.3, "Site Saturated Zone Hydrologic System Synthesis and Modelings," and 8.3.1.2.2.7, "Hydrochemical Characterization of the Unsaturated Zone," were submitted in January 1993 and September 1993, respectively. In comparison, Project-Planning & Control System (PACS) sheets describe the work to be done in the current fiscal year. The study plans call for more USGS work and product than is contained in the PACS. The study plans, which served as a starting point from which to derive the audit checklists, are no longer being revised. As a result, they were not used as a measure of the quality and productivity of the USGS. (The NRC technical staff has reviewed many of the study plans. A result of these reviews was the concurrence that the plans describe work adequate for characterizing the site. However, as the work scope changes, the staff has not make a comprehensive comparison of the revised work scope with the old plans to determine what had been eliminated and what had been retained. That effort would require the expenditure of considerable staff time but may be required for licensing decisions. Review of the synthesis reports will provide some of the information needed, but the comparison to the old study plans may still be prudent.)

One of the audit team questions related to geochemical models used in the Unsaturated Zone Hydrochemistry Study. This question led to a discussion of computer codes used in the study. Although no codes have been used to support information in the products, it is likely that future products will contain information derived from geochemical modeling using computer codes. At USGS, there are a number of geochemical codes which have been used for years but have not been qualified. USGS indicated that these codes would be qualified prior to use in licensing documents.

The audit team asked a number of questions dealing with the usefulness of the products given the changes in direction of the characterization program and the knowledge gained from previous work. This type of question highlights how priorities change with regard to the importance of parameters as the high-level waste program evolves. In particular, statements like "the water that contacts the waste packages is likely to have a composition similar to that of perched zone water," provide insights into the conceptual models currently being considered. If the water sampled from the boreholes, that is, fracture water, has a composition different from that from squeezed rock, that is, matrix water, it is the fracture water that should be used in corrosion tests. The difference between fracture and matrix water relates to the coupling between fracture and matrix. This information is important to transport.

The audit team did not look at technical procedures or scientific notebooks in this audit. This type of auditing activity would have been appropriate, especially in an area where the technical procedures are unique. This is the case for the Unsaturated Zone Hydrochemistry Study where core from bore holes is exposed to extreme conditions to extract water and gas. The reason the Technical Specialist gave for not auditing technical procedures was that he was familiar with the specific techniques; and, consequently, audited areas he considered more important. Thus he focused more on the products which resulted from implementation of the procedures than on the procedures themselves. However, there was one point in the audit when the Principle Investigator described a PhD thesis which determined the effect of extraction techniques on the isotopic composition of the pore fluid. This discussion was significant because it indicated that the extraction technique affects the results. Both techniques studied are listed as Technical Procedures (HP-126, R1, "Extraction of Residual Water from Tuff Samples by Vacuum Distillation," and HP-223, R0, "Method for Pore-Water Extraction Using One-Dimensional Compression") used in this study. The thesis showed the squeezed rock gave the "better" result. The point of this discussion is to illustrate that just following a technical procedure is insufficient to demonstrate product quality. Considerable time and effort must be directed at validating the techniques. Without the PhD thesis, there was no evidence pointing to the correct technique.

The draft document, "Interpretations of Chemical and Isotopic Data from Boreholes in the Unsaturated Zone at Yucca Mountain, Nevada," described the site specific information used to characterize flow of liquid and gas in the unsaturated zone. There were several instances in this document where the parenthetical phrase: "(This comparison is based on saturated zone chemical composition data that were collected prior to implementation of the approved U.S. Geological Survey Yucca Mountain quality-assurance program, and therefore, the data are not qualified.)" was included. It was not determined whether these data would be (or could be) qualified at a later date based on the methods for qualifying preexisting data described by the NRC in NUREG-1298.

The draft document entitled: "Status of Understanding of the Saturated-Zone Ground-Water Flow System at Yucca Mountain, Nevada as of 1995" describes the information that is used to characterize the site, sub-regional, and regional

hydrologic systems. This document also describes the areas of site characterization that do not have technically defensible evidence. The technical portion of the audit was very informative to the staff. By being flexible with regard to the range of questions asked, the audit team ascertained the level of understanding and training of the investigators.

No nonconformances were found during this portion of the audit, and the audit team found the USGS investigators to be competent and dedicated to the work. The NRC staff concurs.

4.6 Audit Team Qualification and Independence

The qualifications of the ATL and audit team members were found to be acceptable in that they each met the requirements of QAP 18.1, "Auditor Qualification."

The audit team members were prepared in the areas they were assigned to audit and were knowledgeable of applicable procedures. The checklist was adequately formulated and covered the subject matter well.

4.7 NRC Staff Findings

The QA programmatic and technical portions of the audit were conducted in a professional manner and the audit team adequately evaluated activities and objective evidence. The ATL was effective in his daily presentations to the management of the audited organizations and in providing guidance to the audit team members.

The checklist questions provided a sound basis from which to conduct the audit and reach an accurate conclusion on the data, processes, and products audited. The audit team personnel and audited personnel were all knowledgeable in their respective disciplines.

The NRC staff understands that YMQAD issued an action plan for USGS along with its earlier Corrective Action Request concerning USGS procurements. In light of the procurement nonconformances noted at USGS, the NRC staff believes that such action was warranted and looks forward to hearing of the timeliness and effectiveness of the resultant corrective action. The NRC staff agrees with the YMQAD audit team findings summarized below.

4.8 Summary of YMQAD Findings

The audit team determined that the USGS technical performance was satisfactory. The audit team also determined that USGS compliance with ten of the 13 audited QA programmatic elements audited was satisfactory, but compliance with the other three (Procurement Document Control, Control of Purchased Items and Services, and Corrective Action) was determined to be unsatisfactory. At the post audit meeting, the audit team reported on the four QA deficiencies that it found during the audit, one of which had been corrected during the audit. The corrective actions for the three others are to be addressed with the corrective actions associated with similar findings

at an earlier compliance audit (YM-ARC-96-10). The audit team also made three recommendations.

The following four deficiencies were reported at the post audit meeting:

1. One USGS supplier did not have a documented QA program, the appropriate QA requirements were not imposed, there was no supplier evaluation report available, and the supplier was not on the OCRWM Qualified Supplier List.
2. Two Quality Deficiency Reports related to unsaturated zone hydrochemistry activities initiated in May and June of 1994 had not been closed.
3. USGS has not submitted lists of cited references for each study plan and published administrative, technical, and scientific report as required.
4. Core preparation for pore water extraction was not done in accordance with the procedure. This was corrected during the audit by revising the procedure to reflect the actual practice.