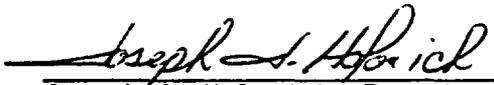
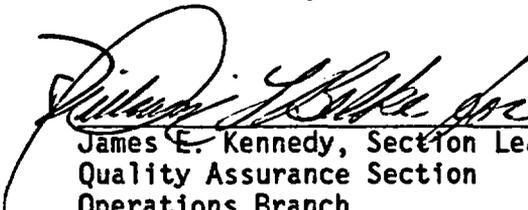
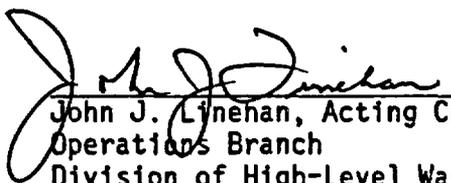


U. S. NUCLEAR REGULATORY COMMISSION
AUDIT OBSERVATION REPORT
FOR THE
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT
AUDIT NO. 88-04 OF THE
U. S. GEOLOGICAL SURVEY

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1.0 Introduction

From June 8, 1988 through June 24, 1988, members of the Nuclear Regulatory Commission (NRC) staff participated as observers in the Department of Energy/Waste Management Project Office (DOE/WMPO) quality assurance (QA) audit of the U. S. Geological Survey (USGS). The USGS is responsible for the Nevada Nuclear Waste Storage Investigations (NNWSI) site characterization activities in the areas of hydrology, geology, geophysics, seismology, and some of the geochemistry investigations. Work in these areas is ongoing at the Nevada Test Site (NTS) and the USGS offices in Denver, Colorado and Menlo Park, California.

The DOE/WMPO audit was conducted at the NTS and in Denver, Colorado and was the second piece of a two-part audit process. The first part of the process was the DOE/WMPO audit of the USGS Menlo Park office conducted in April 1988. The purpose of the NTS and Denver audit, as given in the DOE/WMPO audit plan, was intended to evaluate the effectiveness of the USGS QA Program Plan (QAPP) and to determine if the USGS was acceptably implementing its QA program as it relates to the activities on the NNWSI. The scope of the audit covered all of the criteria from Part 50 of the Code of Federal Regulations, Title 10 (10 CFR 50), Appendix B that were considered applicable by the USGS to its QA program. Criteria 9.0, "Control of Special Processes," and 14.0, "Inspection, Test, and Operating Status" were not audited since the USGS had taken exception to these criteria in its QA plan. During its review of the WMPO QA Plan (88-9), the requirements of which are incorporated into the USGS QAPP, the staff will evaluate these exceptions to determine if they are acceptable.

In addition to the QA aspects of the audit, the technical specialists on the DOE/WMPO team reviewed five scientific investigation plans (SIPs) and their associated procedures. The SIP subjects covered regional surface water hydrology (3310G-01), percolation in the unsaturated zone from surface borehole investigations (3343G-01), boundary conditions and hydraulic gradients within the saturated zone (3331G-01), hydrogenic deposits (3370G-02), and regional studies of seismicity (3233G-03). These SIPs were selected because they represented approved and ongoing work of the USGS.

2.0 Scope and Purpose of NRC Staff Participation

The purpose of the staff observation was to determine if DOE was conducting the audit in a manner such that the NRC staff could gain confidence that the DOE and DOE contractor programs were being properly implemented in accordance with DOE internal QA requirements and 10 CFR 50, Appendix B. These observation audits by the NRC staff will also enable the staff to provide guidance to DOE on its programs as they are being developed. The NRC staff observations on the DOE/WMPO audits and the guidance on DOE QA programs will assist DOE in meeting the NRC QA requirements. This report contains the NRC staff observations on the June 8 through June 24, 1988 audit.

Because the USGS has one QA program that covers all of the locations, NTS, Denver, and Menlo Park, it is the staff position that the DOE/WMPO audit of the USGS Menlo Park office be considered in any findings made on the most recent USGS audit. Therefore, the staff will not only discuss its observations on the June 8-24, 1988 audit in this report, but it will also reference NRC observations on the Menlo Park DOE/WMPO audit that are applicable to the Denver audit.

3.0 Audit Team Members

The NRC observation audit team consisted of a team leader and six observers, including QA and technical specialists.

The DOE/WMPO audit team was comprised of staff from Science Applications International Corporation (SAIC), the DOE contractor for overseeing implementation of the DOE waste management program. The NRC team members, the DOE audit team members, and other observers are listed below.

NRC

Joseph J. Holonich, Team Leader (NRC)
William Belke, Observer, (NRC)
John Bradbury, Observer, (NRC)
Alan B. Duncan, Observer, (NRC)
John W. Gilray, Observer, (NRC)
Abou-Bakr Ibrahim, Observer, (NRC)
Fred W. Ross, Observer, (NRC)

DOE

Henry H. Caldwell, Team Leader, (SAIC)
Daniel A. Klimas, Lead Auditor, (SAIC)
James E. Clark, Auditor Trainee, (SAIC)
Stephen P. Hans, Auditor, (SAIC)
Robert H. Klemens, Auditor, (SAIC)
Wendell B. Mansel, Auditor, (DOE/WMPO)
Steven Nolan, Auditor, (SAIC)
Dave Cummings, Lead Technical Specialist, (SAIC)
S. J. Chern, Technical Specialist, (SAIC)
Keith M. Kersch, Technical Specialist, (SAIC)
Jerry L. King, Technical Specialist, (SAIC)
Steven R. Mattson, Technical Specialist, (SAIC)

OTHER PARTICIPANTS

Robert W. Clark, Observer, (DOE HQ)
Dan E. Haymond, Observer, (DOE HQ)
Karen K. Hatch, Observer, (DOE/WMPO)
Mae D. Cotter, Observer, (SAIC)
Susan Zimmerman, Observer, (State of Nevada)
Jenny Chapman, Observer, (State of Nevada)

4.0 Staff Observations

4.1 Summary of Staff Participation

As observers, the NRC staff evaluated the effectiveness of the audit and audit team. The audit areas that were observed and evaluated included:

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

As a result of its participation, the NRC staff identified several observations on the above areas that should be addressed by DOE/WMPPO in future audits. In addition, the staff has some observations on the USGS program which are contained in Appendix A to this report.

4.2 Observations

4.2.1 Scope of Audit

As stated in Section 1.0 of this report, the audit covered all of the 10 CFR 50, Appendix B criteria that are considered applicable to the USGS QA program. Although the necessary 10 CFR 50, Appendix B criteria were covered, the staff observed that the extent of investigation of each criterion was limited to those portions of the QA program that were in place. In other words, the team only reviewed adherence to those Quality Management Procedures (QMPs) that had been approved and were being used by the USGS. Not included in the audit was an evaluation of whether the USGS program was meeting its stated objectives without QMPs being issued, and an attempt to draw overall conclusions using the issues identified during the Menlo Park and Denver audits. In addition to the examples and findings discussed below, there are also several observations in Appendix A to this report that were made by the NRC staff on the USGS program. Had the DOE/WMPPO team conducted an overall evaluation of the USGS program, the NRC staff would have expected DOE to make similar observations to those given in Appendix A.

In its observation of the DOE/WMPPO team, the NRC staff noted several areas where the auditors should have done an assessment of the overall QA program. One example where the team needed to expand its analysis was in its evaluation of the USGS NNWSI organization. As a result of its review of the DOE/WMPPO checklist questions for this area, the NRC staff observed that the questions covering the USGS NNWSI organization only confirmed that the organization described in the USGS QAPP was in place. The checklist questions did not attempt to make an assessment of the ability of the USGS NNWSI organization to function. Missing from the checklist and subsequent investigations were questions that addressed organizational issues such as the integration of information between USGS organizations or the control of work that crossed organizational boundaries.

Because the USGS NNWSI organization relies upon other divisions within the Survey to perform work, there is a large amount of communication across organizational boundaries. One approach for measuring the effectiveness of an organization is to evaluate a particular work task from start to finish. This review could have covered the entire process including: (1) work initiation by the NNWSI portion of the USGS; (2) the performance of work by the non-NNWSI organizations; (3) an evaluation of how NNWSI QA requirements are followed by non-NNWSI entities; and (4) a comparison of the final work product versus the initial work request to determine if the desired output had been obtained. Several of the steps described above were performed by different parts of the team, and the results from these other audit activities could have been incorporated into the evaluation of the organization. By tracing the entire USGS NNWSI work process, the audit team might have been able to determine if the organization in place was performing acceptably.

Another area where the audit should have been expanded was the need to address issues in the Denver portion of the audit that were identified during the DOE/WMPO audit of the USGS Menlo Park office. As stated in Section 2.0 of this report, there is one QAPP for the USGS that is implemented at all of its locations. Therefore, issues found during an audit of the USGS Menlo Park office need to be considered in an audit of the USGS Denver office. The reason for this is to allow the audit team to determine if there is a problem with implementation of the QA program at a specific location, or whether there is a systematic deficiency in the entire program.

Although there were several areas where the DOE team was aware of findings from the DOE/WMPO audit of the USGS Menlo Park office, there were just as many areas where the DOE Denver team did not include findings from Menlo Park. In one instance, members of the DOE/WMPO Menlo Park audit team noted that certain procurement records needed to be checked during the Denver portion of the audit. This was due to the fact that the records were placed in the USGS record control system which is located in Denver. Hence, they were not available for review in Menlo Park. During the Denver portion of the audit, the staff observed that the DOE/WMPO checklist did not contain any questions concerning these records. Because these records were not available for audit in Menlo Park, they should have been reviewed in Denver to determine if they were complete. If it was found that only the records from Menlo Park were incomplete, this may have indicated that there was a problem with implementation of the QA program at that USGS location. On the other hand, if problems were found with both the Denver and Menlo Park records, this may have indicated that there was a problem with the overall USGS record processing system. Since the records from Menlo Park were not checked, this type of conclusion could not be made.

A similar set of circumstances existed in the area of training. Again, the staff is concerned that the audit team failed to evaluate the overall USGS program. In particular, the team not only failed to raise a preliminary finding on training during the Menlo Park portion of the audit, but without this finding being made by the Menlo Park DOE team, the DOE Denver team was unaware that there was a potential problem. Lacking this knowledge, the DOE Denver audit team did not realize that some of the training records of Menlo Park personnel should have been checked.

Even though the DOE/WMPO Menlo Park team did not make the overall finding on training, the NRC staff questioned the effectiveness of the QA training program in its observation report on the Menlo Park audit.¹ The staff concern with training was made as a result of its observation of the DOE/WMPO audit of procurement at Menlo Park. During the Menlo Park audit, it became apparent that the USGS personnel did not know of nor understand the QA requirements for NNWSI procurements. Although the area being audited dealt with procurement, the staff observed in its report that the DOE/WMPO auditors should have made a finding that training appeared to be ineffective. This was a finding that should have been made by the DOE team in Menlo Park so that training records of Menlo Park personnel could have been evaluated in Denver. However, because the DOE/WMPO team only evaluated the program implementation, the DOE auditor only addressed areas where the procedures were not being followed in the Menlo Park procurement process. The auditor did not conclude or indicate that there was a problem in training. Since the broad finding concerning training went unaddressed by the Menlo Park audit team, the Denver team could not have known that the training records for Menlo Park personnel needed to be checked at Denver. Thus, this is another example of where DOE did not conduct an overall evaluation of the USGS program.

A third audit area where the staff observed that the scope needed to be expanded was in the area of standard deficiency report (SDR) reviews. In this area, the staff observed that the team merely ensured that actions were being taken, but did not analyze the impact of the action with respect to the overall implementation of the program. For example, it was noted that SDR #70, which dealt with (WMPO Audit 87-6/87-7) Criterion 12, "Control of Measuring and Testing Equipment," as it relates to the traceability of calibration standards to the National Bureau of Standards, could be closed. However, the same problem was found during both the Menlo Park and Denver audits. This indicates that the implementation of the corrective actions provided in response to SDR #70 was not validated before the SDR was closed. The validation of corrective actions is an important part of confirming that the work is being done correctly. In addition, this further supports the NRC staff observation that corrective actions should have been audited at Menlo Park (i.e., the corrective actions accomplished in Menlo Park cannot be verified by paper in Denver). Even though the NRC staff believes that more effort should have been placed on corrective actions, it did find that the auditors had developed a matrix for this criterion to help them follow the different nonconformance reports and SDRs issued during other audits. This matrix is a useful tool to aid the auditors in future audits, and DOE/WMPO may want to consider having all team members use one. Copies of these matrices are given in Appendix B of this report. Overall corrective actions should have had more emphasis and been more thorough especially since the lifting of the stop-work order.

A final example of where the staff believes that DOE needs to expand its audit is in the area of what is covered by the audit teams. Of particular concern here, is the fact that DOE/WMPO teams only evaluate if an audited organization is following approved procedures. If QA procedures are not issued, they are not included in the audit. This is of concern to the NRC staff since the lack of procedures can have an

¹ Letter from B. J. Youngblood (NRC) to Ralph Stein (DOE), May 31, 1988

adverse impact on the overall quality of ongoing activities. For example, under Criterion 8.0 of the USGS QAPP, only one of the necessary QMPs has been issued. The QMP that is issued is QMP 8.01, "Identification and Control of Samples." Not issued are QMP 8.02, "Control of Data," and QMP 8.03, "Acceptance of Data Not Developed Under the NNWSI QA Plan." During the audit, technical specialists from the DOE/WMPO team and members of the NRC staff noted that there was a lack of control of data by USGS personnel. As a result of this concern, the staff noted that there could be a chance that data could be lost or altered. If the DOE/WMPO team had evaluated the overall QA program, it should have done an evaluation of how well data was controlled without a procedure in place. This evaluation would have allowed the team to determine if the controls were adequate until a procedure was developed. However, because the QMP for data control was unissued, the team did not include this type of evaluation. This issue of inadequate data control, along with several other observations made by the staff, is included in Appendix A of this report. As stated previously, had the team conducted an overall evaluation of the program, the NRC staff would have expected the DOE/WMPO team to make similar conclusions.

Based on the above observations, the staff is concerned that the DOE/WMPO audit teams did not conduct an integrated evaluation of the USGS QA program nor did they attempt to determine if the overall QA program was achieving its desired output, e.g., quality-assured work. The need to evaluate the complete QA program is an important evaluation that rates the overall performance of the program, not just the programmatic areas that are audited. In its procedure for conducting audits, QMP-18-01, "Audit System for the Waste Management Project Office," DOE/WMPO defines an audit as "a planned and documented activity performed to determine... effectiveness of implementation." Since the DOE/WMPO audit team did not address the overall QA program, the NRC staff is not sure that it is properly following its procedures. Therefore, the NRC staff recommends that DOE (1) provide a discussion of what is intended by QMP-18-01 as it relates to determining effective implementation, and (2) include in the scope of future DOE/WMPO audits an evaluation of the overall QA program.

4.2.2 Timing of Audit

The schedule of the audit was appropriate since its timing allowed the USGS to implement its QA plan after the lifting of the stop work order, which was in place from April 1986 through December 1987. Because of the number of SDRs found by the DOE/WMPO team and the fact that the USGS work deals with site characterization activities, future audits should be held at more frequent intervals until the QA program is totally in place and acceptably implemented.

4.2.3 Technical Products

Prior to the audit, each technical specialist on the DOE/WMPO team prepared a checklist related to the SIPs and procedures, which were covered in the audit. These checklists served as the initial basis for conducting the technical evaluation portion of the audit. During the audit, the

specialists followed and amended these checklists as the investigations expanded into more detailed areas not thoroughly described in the SIPs or procedures. Through detailed questioning and investigation, the technical specialists were able to ascertain circumstances where the DOE technical program had been changed from that prescribed in the SIPs and procedures. For example, the technical specialist in hydrology reported that due to the experimental nature of unsaturated zone testing technology, particularly regarding equipment calibration, reliability, and placement methods, strict adherence to the current SIP is highly impractical and projections of future work somewhat uncertain. This is because the work done by the USGS often represents the first-of-a-kind experiment, and the SIPs project the type of work the USGS believes is necessary to conduct the investigations. Once the work is performed, it is often found that the experiment as planned could not be done. Hence, the USGS must either revise the SIP, use different instrumentation, or revise procedures. Because of this, past and currently collected unsaturated zone hydrologic data have been downgraded to QA level III. The staff recommends that future audit teams evaluate the documentation of deviations from SIPs and procedures that occur because of prototype testing. This evaluation will ensure that deviations are identified, documented, and appropriately incorporated into revised study plans and procedures. Another example of how the specialist conducted a detailed investigation was in the case of the technical investigations on regional seismology and saturated zone hydrology. Here the technical specialists reported a concern that some of the seismology and the hydrology procedures were revised or new procedures added to cover work already performed.

Although the specialists covered the SIPs in sufficient detail to ensure that they were adequately developed, the NRC staff did observe that, in some cases, the level of review of the procedures was not as detailed as that done on the SIPs. In one case, the questioning concentrated too much on the SIPs, and the specialist did not address procedure limitations or occasional inconsistencies, omissions, or errors that were discovered by the observers. For example, the technical observer representing the State of Nevada questioned the procedure covering the use of the reference steel measuring tape. The observer noted that the procedure called for paste or chalk for marking the tape when salt was actually used. In another case, the specialist was too programmatic and most of his conclusions centered on the control and protection of data rather than the technical aspects of the SIPs and their procedures. In the future, the technical specialists need to include enough questions in the checklist to ensure adequate coverage of both the SIPs and procedures.

Generally, the technical specialists integrated their review activities with other members of the QA audit team. When a potential programmatic problem was uncovered, the lead technical specialist and the audit team leader were notified. The questioning of USGS personnel by the DOE/WMPO audit team on data management and control was one of several cases in which members of the QA audit team assisted in the technical investigation. The particular circumstance arose as a result of a review by one of the technical specialists. Based on this evaluation, the specialist raised a concern with the handling of data. This concern was discussed at the daily caucus and it was decided that a QA auditor should conduct an evaluation to determine if there were any programmatic problems in this area. This indicates that the technical specialists were included

as part of the team. Besides conducting a thorough investigation, the technical specialists were frank and open, and mostly stayed within the scope of the audit. The questioning resulted in findings or observations related to work performed without procedures; management of data including the need for backup files should data be lost or destroyed; clarification of tentative procedures; and auxiliary software and how its output will be treated.

Overall, the NRC staff found the technical portion of the audit of the USGS to be acceptable. The technical specialists on the team were persistent and thorough in questioning the activities described under the SIPs.

4.2.4 Conduct of Audit

The DOE/WMPO QA audit team performed a complete and thorough compliance demonstration audit, which is what they were assigned to do. A compliance demonstration audit determines if the procedures in place are being implemented. However, it does not address the effect on quality of missing or unimplemented parts of the QA program, nor does it draw an overall conclusion based on the specific issues identified. Although the objectives identified in the "Purpose and Scope" section of the audit plan were to evaluate the effectiveness of the QA program, and verify its implementation, the NRC staff did not observe any evidence that the team was evaluating the overall effectiveness of the USGS program. As stated in Section 4.2.1 of this report, the NRC staff believes that not addressing the overall QA program is a major deficiency in the WMPO QA audit.

Even though the staff is not satisfied with the scope of the audit, its observation of the conduct of the audit is favorable. There were several positive attributes that the staff observed, one of which was a visit to the NTS. Prior to the audit in the USGS Denver office, the team visited the NTS to become familiar with the actual USGS field activities that were covered by the audit. This visit was beneficial in providing a "hands-on" look at the ongoing site characterization activities, and allowed the team to have a better understanding of the uniqueness of how QA applies to them.

With respect to the overall conduct of the audit, the staff observed that during the audit, the team asked sufficient questions to be able to complete the checklist and obtained objective evidence on which to base the SDRs. The deficiencies found represented problems with the implementation of the QA program, and significant issues requiring prompt corrective action were reported to USGS management. When it was decided that there was not enough time to complete the audit, it was extended.

In addition to evaluating the audit process, the NRC staff reviewed the background of the QA auditors, and concluded that the qualifications and backgrounds of the mix of QA auditors were both programmatic and technical. In addition, QA personnel who had technical backgrounds were trained as either engineers or geologists and both disciplines were equally represented and thereby provided a balanced team.

4.2.5 Team Qualifications

As part of its evaluation of the audit process, the NRC staff reviewed the qualifications of those individuals who are part of the QA portion of the team for each audit the NRC has observed. This review was done to

ensure that the auditors on the team were qualified. In order to expedite this review, on this audit, the NRC staff chose to evaluate not only the team members, but also the qualifications of all of the available DOE QA auditors. In addition, the staff reviewed the DOE/WMPPO procedure used to qualify auditors, QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel." In reviewing the qualifications of the DOE auditors, the NRC staff gained assurance that those individuals who were part of the June 8-24, 1988 audit team, or available for future audits were qualified. The purpose of reviewing QMP-02-02 was to allow the NRC staff to gain confidence that auditors who were not reviewed but qualified in accordance with QMP-02-02 would also be acceptable.

The NRC staff reviewed the qualifications of the following SAIC audit team members for the June 8-24, 1988 audit of USGS:

Henry H. Caldwell - audit team leader
Daniel A. Klimas - lead auditor
James E. Clark - auditor trainee
Stephen P. Hans - auditor
Wendell B. Mansel - auditor
Steven P. Nolan - auditor - (also certified as lead auditor)
Robert H. Klemens - auditor - (also certified as lead auditor)

The NRC staff also reviewed the qualifications of the remaining SAIC auditors and surveillance staff. This review covered the following individuals:

William H. Camp - auditor
Everett P. Bryant - auditor
James A. Ulseth - auditor
John E. Therian - auditor and lead auditor
Richard A. Kettell - auditor and lead auditor
Gerald Heaney - auditor and lead auditor
Catherine M. Thompson - auditor and lead auditor
Frederick J. Ruth - auditor and lead auditor

The results of the NRC staff review of the auditor qualifications substantiate that the auditors selected for the June 8-24, 1988 USGS audit and the remainder of the SAIC audit staff are acceptable. The basis for this evaluation was the review of the auditor experience and education against NQA-1-1986 Supplement 2S-3 and NQA-1-1986 Non-Mandatory Appendix 2A-3. In all cases, the qualifications of the auditors met both the requirements of NQA-1-1986 Supplement 2S-3 and the non-mandatory Appendix 2A-3. Based on this information, the staff considers those individuals identified as auditors to be qualified. Similarly, those individuals identified as lead auditors also meet the requirements for lead auditor given in NQA-1-1986 Supplement 2S-3 and Appendix 2A-3. Therefore, the NRC staff considered these individuals qualified to be lead auditors.

Also, NQA-1-1986 Appendix 2S-3 and Non-Mandatory Appendix 2A-3 have been incorporated into QMP-02-02. The NRC staff review of QMP-02-02 indicates it meets, and in several instances, exceeds the guidance for auditors provided in NQA-1-1986. Based on this review, the NRC staff has concluded

that any auditor who is qualified using QMP-02-02 would be acceptable for use on future audit teams. For future observation audits, the NRC staff will not review the qualifications of the individual auditors. However, as new audit personnel are added to the SAIC audit staff, the NRC staff may choose to review their qualifications on a random basis to assure that auditors or lead auditors are appropriately qualified. The NRC staff intends to review all of the qualifications of the auditors on an annual basis.

Based on its review of the qualifications of the technical specialists, the NRC staff has concluded that each technical specialist had sufficient educational and technical experience to be knowledgeable in the areas relevant to the SIPs and procedures they were responsible for examining during the audit. In general, this was further demonstrated by the nature and quality of the questions asked by the technical specialists during the audit. The qualifications ranged from a B.S. degree with more than 20 years relevant experience, to a Ph.D degree in an appropriate field with about three years related experience.

4.2.6 Audit Team Preparation

Basically, the DOE/WMPO audit team was prepared to perform the audit. Members of the DOE/WMPO team were familiar with the USGS QAPP, Administrative Management Procedures (AMPs), and QMPs, as well as the other governing documents. The audit plan detailed the work to be performed and identified the assignments of each team member. Binders, prepared for the team, contained copies of the documents that were the subject of the audit. This included the applicable SIPs, their implementing procedures, the USGS QAPP, QMPs, and the checklist that would be used by the team.

Although the DOE/WMPO team was adequately prepared to do the audit, the NRC staff did observe several areas where better preparation could have been exercised by the team to ensure that the scope of the audit was complete. For example, in the first week of the audit, QMP-3.03, "Scientific and Engineering Software," was excluded from the audit. The audit team was not aware that the Denver office of the USGS was using any software. This DOE/WMPO conclusion was based on the results of the DOE/WMPO audit of the Menlo Park office. As a result of the evaluation conducted by the DOE/WMPO technical specialists, it was determined that software was being used in Denver. Had the team adequately prepared for the audit, it should have confirmed its assumption that no software was in use at Denver. The DOE audit team did correct this deficiency by bringing in a software QA (SQA) technical specialist for the second week of the audit, and several SDRs were identified in the this area.

Another area where the staff believed that better preparation could have been done was at the NTS visit. At the start of the first day, there was a great deal of confusion because the team had not informed the USGS exactly what it wanted to see. Because of this, the USGS had to assemble the responsible individuals while the 25-member team had to wait for their escorts. Once the escorts arrived, trying to match team members with USGS personnel caused more confusion. If the team had better prepared for the visit by discussing what areas it wanted to visit with the USGS before the audit began, this confusion may have been eliminated.

4.2.7 Conduct of Meetings

Prior to the NTS visit, the team leader held an "informal" entrance meeting to introduce the participants and review the purpose of the visit. As noted in Section 4.2.6, the entrance meeting at NTS did not clearly describe what was to be examined at the site, and, therefore, caused some confusion as to which activities needed to be covered. Although the staff does not consider this a major deficiency, since it only caused some inconvenience but left the overall audit unaffected, it is recommended that for future audits, better preparation and coordination of activities be undertaken.

The official entrance meeting for the audit was held at the USGS office in Denver. At this meeting, the team leader accurately presented the purpose of the audit, identified the areas to be audited, and covered the proposed schedule.

The daily caucuses were well managed and increased the team interaction. This interaction assisted the team leader in directing the team to other potential areas that needed to be audited. An example of this is given in Section 4.2.6. As noted there, the team had determined, as a result of the daily meetings, that computer software was being used in Denver. In response to this finding, the team leader adjusted the scope of the audit to include computer software. Similarly, one of the technical specialists noted that there was a lack of procedures in the area of data control. This issue was raised at the daily caucus, and as a result, the team leader assigned a QA auditor to evaluate the problem.

The exit meeting was well conducted and presented the audit team findings in a chart that provided the QA criteria, the number of SDRs issued for each criteria, and the severity level of the SDRs. However, the details of the SDRs were presented to USGS in a closed-door session; therefore, the NRC staff was unable to observe this part of the audit. A summary of the SDRs, team observations, and recommendations was presented to the USGS at the exit meeting. Although this summary presentation identified the subjects of the SDRs to the NRC staff, it is important that the staff understand the details of the SDRs. Hence, the NRC staff recommends that it be allowed to observe all DOE/WMPPO audit-related meetings.

4.2.8 Audit Team Coordination

The audit team leader ensured that the activities of the team were well coordinated. This was a difficult job, considering the size of the audit team and the large number of observers. Several examples of effective coordination include:

- (1) adjusting the team assignments whenever it was apparent that an auditor could not complete the audit;
- (2) expanding the QA scope of the audit to include computer software once it was determined by the technical specialist that software was in use at Denver; and

- (3) assigning QA personnel to evaluate a concern raised by the technical specialists on data control.

Based on its observation of the team, the NRC staff believes that the audit team was well coordinated such that it had sufficient coverage in all of the audited areas.

4.3 Summary of Recommendations

Based on the information contained in the previous sections the NRC staff has the following recommendations. For each recommendation provided below, the staff has identified the report section where the recommendation is discussed in detail. DOE/WMPPO should review the staff recommendations and provide a response describing how these will be considered in future audits.

Recommendation 1

Describe what is intended in QMP-18-01 as it relates to determining the effectiveness of implementation of QA programs (Section 4.2.1).

Recommendation 2

Include an evaluation of the overall QA program in future audits (Section 4.2.1).

Recommendation 3

Increase the frequency of audits of the USGS until its QA program is totally in place (Section 4.2.2).

Recommendation 4

In the area of technical investigations, ensure that adequate coverage of SIPs and procedures is included in the checklist (Section 4.2.3).

Recommendation 5

Include the evaluation of the documentation of deviations from SIPs and procedures that occur because of prototype testing (Section 4.2.3).

Recommendation 6

Conduct better preparatory activities to ensure that all necessary areas are audited to minimize confusion during entrance activities (Section 4.2.6).

Recommendation 7

Allow observation by the NRC staff of all DOE/WMPPO audit-related meetings (Section 4.2.7).

5.0 Preliminary Results/Findings of the DOE/WMPO Audit Team

As a result of the audit, the DOE/WMPO team had several preliminary findings that it reported to the USGS. These are listed in the following sections.

5.1 Preliminary SDRs

- Minimum education and experience requirements are not established for some QA staff positions. Not all positions on the QA organization chart have position descriptions.
- There is no documented basis for the certification of receiving personnel who conduct QA-related inspections.
- There is a lack of documentation of an annual assessment of continued indoctrination and training needs.
- There is a lack of a trend analysis to support the 1988 USGS Annual QA Assessment.
- Quality assurance levels assignments (QALAs) assigned to computer codes were not consistent with the QALAs in the SIPs.
- Data was published without the computer codes used in the analysis having been verified and validated, and the software checklist and index form being updated.
- The documentation requirements for auxiliary software are not consistent with the USGS QAPP.
- The certification of technical reviewers of publications could not be demonstrated.
- No criteria letter was available to define the scope of a subcontractor's responsibilities.
- SIP-33316-01, Rev. 0 did not include two procedures that are required to perform activities within the scope of the SIP.
- Comments generated for the technical review of publications are not available in the QA record.
- Field notebooks and sample collection forms are inadequate to provide the necessary sample traceability.
- Procurement documents did not have the QALA or SIP number.
- The required signature of a peer or supervisor was not demonstrated for the computer code CALIBRATE.FOR.
- Procedures have not been developed and updated to fully prescribe quality activities.
- Four of the six procedures for SIP-33316-01, Rev. 0 were not controlled.

- The USGS is not in compliance with its requirement that the QA office be notified when equipment is ready for calibration.
- There was no evidence that the USGS has a deficiency document trending program.
- Nonconformance reports, corrective actions reports, and audit findings were not evaluated as required.
- The USGS has not been forwarding processed records to the Project Records Center
- Only one subtier contractor was audited in fiscal years 87 and 88.
- Data reduction software is not documented and controlled as required.

5.2 Preliminary DOE Audit Team Observations

- Certification for individuals is not being renewed annually as required.
- SIP activities are being initiated prior to development and approval of the SIP.
- For the calcite and opaline silica (hydrogenic) deposit activities, there is no procedure for thin section preparation that would ensure sample traceability.
- For the strontium (SR) isotope analysis, it was observed that individuals not involved on the NNWSI project were handling samples. Sample traceability could be jeopardized. Additionally, entries made in the daily log book revealed anomalies.
- Analytical balances and other instruments for the study of ostracods and microfossils did not include appropriate calibration stickers.
- USGS is developing real time data acquisition software through a contract with Martin Marietta. The contractor has prepared system and subsystem specifications that are being implemented without formal review and approval. No established requirement exists to cover this activity.
- Key references cited by the technical procedures need to be attached to the procedure when it is providing instructions for related activities.
- Activities for SIP 3310G-01, data sheets for the crest-stage measurement, are incomplete.
- There is no data management procedure in place. The concern exists regarding loss or damage to existing data. There is no log or index of data collected.
- Many SIPs specify activities that are not covered by technical procedures.

- Copies of Level I procurements are not being transmitted to DOE/WMPO.
- Review comments for technical procedures are required to be treated as QA records. Contrary to this, some comments are not controlled as such.
- Distribution lists for controlled documents are not maintained and controlled as required.
- The requirement that the QA organization review all technical documents compliance in accordance with the checklists in QMP 3.07, "Technical Review Procedures," could not be verified.
- No bid evaluations have been performed and documented for contracts at USGS Denver.
- There is no evidence of compliance with QMP 12.01, "Instrumentation Calibration," regarding tracking of instruments to be calibrated.
- Records are required to be sent to the USGS Records Processing Center (RPC). This was identified by USGS Audit Finding 87-01-01 and the proposed corrective action to revise QMP 17.01, "Quality Assurance Records Management," has not been issued.

5.3 Preliminary DOE Audit Team Recommendations

- It was recommended that field notebooks and laboratory notebooks be reproduced and submitted to the NNWSI Project file approximately every six months to prevent inadvertent loss of information.
- It was recommended that slides and photographs, data used for sample location and identifications, and in some cases to back up the trench log maps, be stored in a limited access, fireproof area or placed in an NNWSI project file.
- It was recommended that the sample procedures for tracking sample -identify the physical location of the sample on the sample or sub-sample form.
- An internal standard is being used for the calibration of the mass spectrometer for the SR isotope studies. Although the use of an internal standard is normal for this type of work, it is recommended that the rationale and justification for using this standard and other standards involving non-NBS traceable standards, be placed in the Project files.
- It was recommended that notes and request forms be included in the documentation of the sample preparation processes for the isotopic analysis. The notes should include the process being performed and the sample identification number.
- It was recommended that individual seismic monitoring stations be uniquely identified on the exterior for traceability for maps, logs, etc.

- For SIP 3310G-01, it was recommended that the implementing procedure be revised for only continuous measurements, rather than containing the option to monitor during and after peak flows or continuously.
- In SIP-3310G-01, for the crest-stage gage, it was recommended that the results be measured from two different sources to improve the quality of data. in addition, a standard rain gage should be used for calibration of and comparison to the plastic pipe gage presently in use.
- It was recommended that activities that state no calibration necessary in technical procedure be evaluated for accuracy.
- It was recommended that USGS QMP 4.01, Rev. 1, "Procurement Document Controls," be modified to eliminate the requirement that all QA Level I and II procurements require non-conformances related to the procurement requirements to be documented by the supplier. It is not intended to apply to off-the-shelf items.
- It was recommended that a log book of surveillances be maintained and updated for tracking surveillance results.
- It was recommended that the USGS eliminate the surveillance activities from the inspection function in Criterion 10.0, "Inspection," and place them under Criterion 18.0, "Audits." Additionally, the USGS should refrain from using non-conformance reports for non-engineered items.
- It was recommended that the technical staff assist in the preparation of the fiscal-year, internal audit schedule.

APPENDIX A

As part of its observation of the DOE/WMPO QA audit, the NRC staff has identified several items concerning the implementation of the USGS QA program. The preliminary staff findings are given below. The NRC staff will consider these observations in its review of the USGS program and recommends that future DOE/WMPO audits investigate these observations and determine if SDRs should be issued.

A. Observation

Many of the technical procedures covering SIP activities were written in the early 1980's and do not reflect current thinking. Some data collection was conducted without written procedures, and many of the QA procedures are out of date or have not been developed.

Recommendation

The USGS should undertake a program to update its QA and technical procedures. Also, in the next revision of its QAPP, the USGS should include a requirement to review and update procedures annually. This should not preclude the fact that both QA and technical procedures should be reissued everytime a procedure is revised.

B. Observation

In most instances, no procedures are in place for data management and control. Records reside with the principal investigator (PI) until investigations are completed and reports published. No backup files or master indices of data are maintained. The USGS system of data management may not lend itself readily to the "timely" release of data.

Recommendation

The USGS should develop procedures to control data until it becomes part of its record system. In addition, the USGS should process and release all data on a schedule consistent with the NRC-DOE Site-Specific Procedural Agreement for Geologic Repository Site Investigation and Characterization Program.

C. Observation

One of the NRC staff technical members indicated during the daily caucus meetings that certain of the technical records and data were left in an unsuitable condition whereby they could be misplaced, lost, or open to the possibility of being altered. It may take up to three years to make some of those records final. There is no requirement to control such records until they become final. Once a record is finalized, the USGS will place it in the record control system. A DOE audit team member commented

that at the Basalt Waste Isolation Project, Battelle had a "record monitor" assigned to, on a periodic basis, copy incomplete records as records in process. Such records would be filed until completed, and the copy would then be discarded and the original processed for permanent storage. This system would assist in maintaining a better control over in-process records to prevent them from being lost or damaged.

Recommendation

The NRC staff suggests that a record monitor be assigned to the USGS portion of the project and that a record control system be considered for and worked into the USGS QA program. In addition, DOE/WMPO should evaluate the other QAPPs to determine if a similar initiative is necessary.

D. Observation

During the June 9-10, 1988 visit at the NTS, the NRC staff observed that there was no QA individual at the site to perform routine QA activities such as surveillances and audits, and to monitor ongoing Level I or II work. The only person involved in QA activities, which appeared to be minimal, was the PI, who has the responsibility to assure that all technical and QA requirements were met. However, the NRC staff observed that the PI did not appear to be physically involved in observing quality activities and documenting the results. The NRC staff questioned the USGS in this matter and it was our understanding that the USGS will be seeking a QA individual in the near future for the NTS.

Recommendation

The USGS should place a QA individual at the NTS as soon as possible.

E. Observation

At the audit status briefing on June 17, 1988, the NRC staff noted that USGS may need additional information on the NRC QA requirements covering documentation for the licensing process. Additionally, there may be some misunderstanding on the value of QA on the part of certain USGS scientific personnel.

Recommendation

The USGS should include a description of the NRC licensing process and the importance of QA in a regulated area. By doing this, the USGS personnel assigned to NNWSI activities may better appreciate the need for QA.

APPENDIX B
AUDITOR MATRIX

USGS NCR'S

PROGRAM
ELEMENTS

NCR'S 5 12 15

	5	12	15
88-01		X	
88-03	X		
88-04	X		
88-07	X		
88-08	X		
88-10	X		
88-11	X		
88-13			X
88-24	X		
88-25	X		

USGS

AUDIT FINDING REA

PROGRAM ELEMENTS

NO'S	3	4	5	6	10	12	15	17
83-4-1			X					
83-15-2			X					
83-15-5						X		
83-15-6							X	
83-15-4					X			
84-8-2		X						
84-8-3							X	
84-8-6						X		
84-8-7						X		
84-8-8			X					
84-8-9						X		
84-14-1								X
84-14-2						X		
84-14-3				X				
84-14-6						X		
84-14-8				X				
85-1-2			X					
85-7-1		X						
85-7-4			X					
85-7-5	X							