

U. S. NUCLEAR REGULATORY COMMISSION
AUDIT OBSERVATION REPORT
FOR THE
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT
AUDIT NO. 88-03 OF THE
U.S. GEOLOGICAL SURVEY

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Executive Summary

During the week of April 25, 1988, members of the Nuclear Regulatory Commission staff observed a Department of Energy/Waste Management Project Office (DOE/WMPO) quality assurance (QA) audit of the U.S. Geological Survey (USGS) at Menlo Park, California. Based on the information contained in this report, the staff has concluded that the effectiveness and completeness of the audit were insufficient to ensure that the USGS QA program is being properly implemented. At present, the NRC staff does not have the confidence needed to assure that this DOE/WMPO audit accomplished the degree of understanding needed to ensure that all applicable QA requirements are being implemented. In addition, the staff believes that DOE/WMPO should evaluate the process of this audit in order to determine how more effective and complete audits can be performed.

The main concerns identified by the staff include the need to: (1) expand the scope of the audit; (2) increase the amount of audit time; (3) better coordinate the audit and team activities; (4) be better prepared for the audit itself; and (5) perform sufficient investigations to support the audit findings.

In future audits, the WMPO audit team should include all of the applicable QA criteria and schedule sufficient time to conduct a complete and thorough investigation. Also, the team should be better prepared for and coordinated during the audit.

1.0 INTRODUCTION

From April 27 through April 29, 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) in Menlo Park, California. The purpose of the WMPO audit was to verify the implementation of the USGS QA plan as it relates to the activities on the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. This report contains the results of the NRC staff observations on that audit.

The USGS is responsible for the NNWSI site characterization activities in the areas of hydrology, geophysics and geology. The Menlo Park office of the USGS is responsible for several studies in these areas. Two scientific investigation plans (SIPS) that were recently completed by the Menlo Park office and served as the center of the DOE/WMPO audit dealt with seismic reflection and refraction, and gravity and magnetic surveys.

2.0 SCOPE AND PURPOSE

As stated above the purpose of the DOE/WMPO audit was to determine if the USGS was acceptably implementing its QA program at Menlo Park. The scope of the audit covered several criteria from Appendix B to Part 50 of the Code of Federal Regulations, Title 10 (10 CFR 50). The Appendix B criteria that were considered by the audit team to be applicable to the USGS Menlo Park office are given in Table 1.

Table 1: Appendix B Criteria audited in Menlo Park

<u>Criterion</u>	<u>Title</u>
3.0	Design Control
4.0	Procurement Document Control
5.0	Instructions, Procedures, and Drawings
6.0	Document Control
7.0	Control of Purchased Material, Equipment, and Services
8.0	Identification and Control of Materials, Parts and Components
11.0	Test Control
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage, and Shipping

Since it did not consider them applicable to its work, the USGS had taken exception to Criteria 9.0, "Control of Special Processes;" 10.0, "Inspection;" and 14.0, "Inspection, Test and Operating Status." During its review of the USGS QA plan, the staff will evaluate these exceptions and determine if they are acceptable. Table 2 contains the criteria that the DOE/WMPO audit team felt could be better evaluated as part of a future audit of the USGS in Denver, Colorado. The reason for the DOE/WMPO conclusion was that the USGS QA organization is headquartered in Denver and the audit team believed that the remaining applicable criteria were more "headquarters" related.

Table 2: Appendix B Criteria which will be evaluated at the USGS in Denver, Colorado

<u>Criterion</u>	<u>Title</u>
1.0	Organization
2.0	Quality Assurance Program
15.0	Nonconforming Materials, Parts, or Components
16.0	Corrective Actions
17.0	Quality Assurance Records
18.0	Audits

The DOE/WMPO audit team also reviewed the implementation of the audited QA criteria in SIP 3221G-01, "Gravity and Magnetic Methods," and SIP 3222G-01, "Seismic Reflection and Refraction Surveys" and their implementing procedures. The purpose of this evaluation was to determine if the SIPs and associated procedures were developed and performed using the appropriate QA requirements. Additionally, the technical specialist reviewed the SIPs and procedures to determine if they were complete and adequate for their intended application.

The main reason for members of the staff to attend such DOE/WMPO audits is to allow the staff to evaluate the DOE audit program. 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 the DOE internal QA requirement and 10 CFR 50, Appendix B. These internal DOE requirements will be formally reviewed by the NRC staff once they are submitted by DOE. These observation audits by the NRC will also enable the staff to provide guidance to DOE on the QA programs as they are being developed. The staff observations on the DOE/WMPO audits and the guidance on DOE QA programs will assist DOE in meeting the staff QA requirements.

3.0 AUDIT TEAM MEMBERS

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 team members from SAIC are given below along with the observers who were present during the audit.

Catherine M. Thompson, Team Leader, (SAIC)
 Frederick J. Ruth, Auditor, (SAIC)
 Daniel A. Klimas, Auditor, (SAIC)
 Steven Nolan, Auditor, (SAIC)
 Keith Schwartztrauber, Technical Specialist, (SAIC)
 Forrest D. Peters, Technical Specialist, (SAIC)
 Royce E. Monks, Observer, (DOE/WMPO)
 Robert W. Clark, Observer, (DOE HQ)
 Dan E. Haymond, Observer, (DOE HQ)
 Susan Zimmerman, Observer, (State of Nevada)
 Alan B. Duncan, Observer, (NRC)
 Abou-Bakr Ibrahim, Observer, (NRC)
 Joseph J. Holonich, Observer, (NRC)

4.0 STAFF OBSERVATIONS

As part of its participation as observers, the staff evaluated all of the applicable areas that should comprise a good audit and audit team. The areas that were evaluated and observed included:

- (1) auditor qualifications;
- (2) team preparation;
- (3) audited areas;
- (4) conduct of meetings;
- (5) coverage and conduct of the audit;
- (6) technical products; and
- (7) team coordination.

Although several of the areas may at first appear to be subjective in nature, the staff is interested in these areas in order to determine if they affect the depth or coverage of the audit. For example, how someone conducts a meeting is dictated by personal preference. However, if the team meetings are not conducted in a manner that allows the team members to follow up on issues or identify root causes of problems, then the conduct of the meeting affects the effectiveness of the audit.

Within these areas, the staff identified several concerns that it felt should be addressed by DOE/WMPO in future audits. The staff findings and concerns are discussed below.

Based on its review of the auditor qualifications, the staff has concluded that the auditors meet the education and experience requirements of NQA-1 for auditors. The lead auditor had a A.S. degree in Mathematics/Physics and 19 years of experience in the nuclear industry in quality control and quality assurance. She has developed and managed QA programs and has been an auditor for the past five years. The remaining auditors had a range of ten to 14 years of experience in reviewing, developing and auditing QA programs, as well as having the education and experience to qualify as lead auditors. Even though the audit team was well qualified to conduct the audit, the staff is concerned that all of the QA auditors have a programmatic background. While it is necessary to have some team members with a programmatic background, the staff believes that a QA organization, and, therefore, a QA audit team, should have a mix of programmatic and technical background personnel trained in QA. While it is important to check the programmatic areas of QA, it is also equally important to verify that the work itself is a quality product, as reported in the Ford Study, NUREG-1055. Although this type of review is partially covered by the use of a technical specialist, the specialists do not cover all areas audited and are not trained in QA or auditing. In future audits, the staff recommends that the DOE/WMPO team have a better mix of QA auditors with programmatic and technical backgrounds.

In the area of team preparation, the staff felt that overall, the team members were knowledgeable of the USGS organization, the USGS QA plan, and its implementing procedures. This knowledge was demonstrated by the checklists that were prepared by the team and the ability of the team members to go to specific requirements within the QA plan or procedures. However, there was an area where additional team preparation was needed. This area dealt with the

availability of equipment and personnel identified by the auditors as part of the original scope of the audit. The equipment that was needed was instrumentation that will be used in future seismic refraction tests to be run by the USGS. This instrumentation was to be audited to determine if proper calibration requirements for it had been followed. The auditor responsible for this area was unable to perform this check since the instrumentation was not at Menlo Park. Rather, it was being used to record data from a large test explosion. The USGS had planned to have the trucks available but was informed of the blast on short notice.

With respect to the availability of personnel from the USGS, a similar set of circumstances to the instrumentation problem existed where the principal investigator (PI) responsible for the seismic reflection and refraction SIP was unavailable during the audit. USGS personnel informed the staff that the PI was scheduled to be available based on what it believed to be the scheduled time for the audit. However, once the USGS was told the actual dates of the audit, it was too late to arrange for the needed PI to be available.

In both of these situations, DOE/WMPO needed to exercise more effort in preparatory activities. These two circumstances seem to indicate a lack of communication on the part of DOE/WMPO in preparing for the audit.

With respect to the scope of the audit, the staff expressed a concern to the audit team leader that all of the applicable Appendix B criteria were not being covered. In response to this concern, the team leader stated that these criteria could be better covered in the Denver office of the USGS. The reason for this, as previously discussed in Section 2.0 of this report, was the fact that these criteria were more "headquarters" type functions and since the headquarters for the USGS QA program was Denver, these criteria would be evaluated when DOE/WMPO audits the USGS Denver office.

As the audit progressed, it became apparent to the staff that the other applicable criteria of Appendix B needed to be covered. This conclusion was based on several situations observed by the staff during the audit. In one circumstance, procurement documents and purchase orders (POs) did not contain markings that indicated that the documents were part of the NNWSI program. These markings are needed so that the procurement personnel can identify those documents that must be forwarded to the QA organization for review and to Denver to be made part of the lifetime QA record system. In addition, even if the documents had been appropriately marked, the USGS procurement staff did not realize that NNWSI documents needed to be sent to Denver to be made permanent lifetime records. Finally, when the NNWSI related procurement documents were located from amongst all of the procurement documents, none contained any indication of the appropriate QA level. Because it had no QA level on it, the USGS representative present noted that it probably was a QA Level III. The audit team member requested that this be confirmed. After asking the responsible PI, it was determined that all of the services procured by these POs were purchased as Level III activities; however, the PI responsible for issuing the POs indicated that the data collection activities for Amargosa

Valley requisitioned under one of the POs was actually a Level I activity. This determination was made after the service had been purchased and completed.

The confusion over procurement documentation, the lack of knowledge of NNWSI related requirements, and the exclusion of QA level assignments on procurement documents may be indicative of problems in the USGS program in areas not audited by the team. For example, the lack of understanding on how to handle NNWSI procurement records may be the result of inadequate indoctrination and training of personnel who will work in areas covered by the program. The fact that the procurement documents were not sent to the Denver QA office could be from inadequate training or poor record processing procedures. Furthermore, missing QA level assignments on procurement documents should have been found in the required review by the QA manager, if procurement procedures were followed, or in a USGS audit. Based on this, the staff concluded that it was necessary to cover criteria 2.0, 17.0, and 18.0 of Appendix B during this audit. Since these criteria were not audited, neither the team nor the staff could make a finding as to whether these deficiencies were isolated instances or deficiencies in the program. Because of the information provided above, the staff has concluded that the audit should have been expanded to include all of the applicable Appendix B criteria. This conclusion is also based on the fact that although much of the effort associated with the excluded criteria may be handled in Denver, the Menlo Park office must still implement the criteria.

Another area where the staff concluded that the scope of the audit was insufficient was in the area of SIP development. The only two SIPs that were considered in the audit were those two SIPs which covered part of the ongoing work. Most of the other SIPs that will be implemented by the Menlo Park office had not received WMPO approval and, therefore, work had not begun. A few remaining SIPs were still undergoing USGS development.

Although field work had not started for most of the SIPs, the audit still should have considered all of the SIPs being developed or implemented by Menlo Park personnel. Those SIPs that were not approved by WMPO were still complete with respect to the developmental activities of the USGS. Hence, the team could have audited these SIPs and, if available, any implementing procedures to determine if these would accomplish their intended purpose and if their development was appropriately controlled under the QA program. Also, a review of the development of the SIPs could have been performed. This audit area could have covered such activities as the developmental process, the SIP review process, the methods for ensuring proper QA for the process, the QA level assignments within the SIPs, and the availability of appropriate documentation for all parts of the SIP process. None of this type of evaluation was done on any of the SIP being developed, and it was limited in the two active SIPs that were part of the audit.

A final concern raised by the staff in the area of the audit scope dealt with the strict adherence of the QA auditors to the checklist. The staff noted several instances where the audit team members did not pursue an issue because the checklist requirement had been fulfilled. One example in this area dealt with the audit of handling, shipping, and storage of samples. In response to questions asked during the audit, the team member determined that the only NNWSI samples at the USGS were taken without using appropriate controls and,

therefore, were not considered valid. Because these were not "quality" samples, they were not handled following QA requirements. Therefore, the checklist requirements had been fulfilled since none of the samples were "quality" samples and did not have to be handled in accordance with QA requirements. The staff concern with this situation is that the auditor did not ask the USGS if, in the future, it planned to attempt to qualify any of these samples. If the USGS had any such plans, the samples should have been handled in accordance with the appropriate procedures until a final determination was made.

Another observation raised by the staff and conveyed to the audit team leader dealt with the conduct of the meetings that were held during the audit. At the first daily caucus, there was little if any team interaction. The reason for this was the fact that at this meeting, a representative of the USGS was present and often rebutted the team members. Basically, the members reported their preliminary findings and then had to defend these findings to the USGS. This resulted in a lack of questions of the team findings by other team members and thus did not allow members to determine if common issues were present in other audit areas. Interactions between the team members did occur at the second day team meeting; however, by then there was insufficient time to explore new areas. At neither team meeting did the team leader question the findings. In addition, the significance of the findings were not discussed nor were there any attempts to determine if the findings represented systematic deficiencies in the program and its implementation or just isolated occurrences. As discussed in Appendix A to this report, the staff believes that these may be indications of some systematic deficiencies with the USGS program. As it stands now, the staff is unable to make a final determination on whether problems exist in the USGS program until a more solid foundation is built. The type of findings reported by the staff in Appendix A should have been reached by the audit team. This was not the case since the team did not perform any root cause analysis as part of its audit.

Because team interactions were generally not effective, the team leader could not adjust the scope of the audit or the depth of investigation. This may have left several areas that required more investigation unaddressed. For example, at the second team meeting held on Wednesday, the team member responsible for procurement noted that there was no traceability of procurement documents to the appropriate SIPs and thus the QA level. The auditor for calibration activities stated that the lack of traceability to SIPs probably existed for instrument calibration also. However, because this interaction took place at the final daily caucus, no time was available for the calibration auditor to follow this issue.

This lack of time to pursue issues appeared to result from the short amount of time allowed for the audit and may be one of the reasons that the auditors adhered so rigorously to the checklists. The actual amount of time available to audit was about 10 hours (1:00-3:30 p.m., April 26; 8:30-11:30 and 1:00-3:30 p.m., April 27; and 8:00 a.m.-10:00 a.m., April 28). Based on this information as well as its observation of the depth of the audit, the staff has concluded that the time allotted for the audit was insufficient to accomplish the required activities.

Not only did the lack of time limit the ability for further or additional investigations but it also constrained the amount of supporting documentation and facts that could be used to justify team findings. This was observed at the exit meeting or post-audit conference when the USGS cited several objections to Standard Deficiency Reports (SDRs) to which the team could not respond. One example was when the team member reported an SDR concerning the requirement to prepare a materials receiving and inspection report (MRIR). The MRIR for Disco computer software had not been completed. The USGS responded that the software was purchased in 1982 before the QA program requirements were in place. If the auditor had more time, this fact may have been found and a determination made if the requirement needed to be retrofit to the software. Rather, the auditor was unable to respond to the USGS rebuttal. This does not mean that an SDR is not warranted, rather additional work is needed before a final conclusion can be reached. A summary of all of the proposed SDRs and audit team findings is given in Section 5.0 of this report.

This discussion of issues and potential SDRs should have occurred before the exit meeting. By doing this, the audit team could have reported those SDRs that were nearly final. However, no time to review the proposed SDRs with the USGS was available.

The audit team attempted to followup previously reported SDRs and observations only in the area of Criterion 12. This criterion was reviewed under a surveillance performed in October 1987, and reported to the USGS. Although the USGS Denver office responded to the observation report for this surveillance, the Menlo Park office QA representative indicated that a copy of this response had not been received by Menlo Park. Therefore, the audit team did not further pursue the issue. The staff did not observe any indications of followup on the remaining SDRs or observations from previous audits. Due to the number of previous SDRs and observations, the staff believes that Criterion 16 on corrective actions should also have been covered by this audit to assure that the USGS is following through with its responses to the SDR and observations.

In the audit area that dealt with the examination of technical products, the staff believes that the technical specialist did not integrate the technical and QA portions of the audit as he should have done. During the audit process, the QA auditor was not involved in the discussions nor is there any evidence that either the QA or technical checklists were used by the appropriate individual on the subteam. This is indicated by the fact that one of the checklist items in the technical area included verification that the procedures used to implement the SIPs contain a discussion of the procedure limitations. As a result of this review, the staff found that NWM-USGS-SP-08, Revision 0 and NWM-USGS-GPP-01, Revision 1 do not discuss any limitations of these procedures. If the checklist were followed, this could have been identified by the auditor.

Based on a review of the technical specialist qualifications, the staff believes that the specialist is well qualified and knowledgeable in the technical areas being audited. This was further demonstrated by the questions asked by the specialist during the audit. The questions were relevant and of significance to the audit.

With respect to the technical team members complementing the QA auditors, it was noted by the observers that the specialist discussed the technical aspects of the program in detail. One of the jobs of the technical specialist is to advise the QA auditor on what type of technical issues or activities should be covered under the different QA levels. In addition, the specialist was supposed to determine if the SIP and its accompanying procedures accomplished their intended function. Although this may have been done, there is no indication that the specialist completed the checklist.

Several examples of poor team coordination were identified by the staff. These included the lack of a well planned and executed exit meeting as well as daily caucuses. This may indicate that at future audits, the team leaders need to concentrate on team coordination.

In closing, the staff has concluded that in other areas the audit team members did an adequate audit of the USGS QA program. With respect to completing the checklist, most of the QA auditors asked sufficient questions to make a determination. Team members were aware of the regulatory requirements as well as industry standards. This was demonstrated by their ability to easily cite specific requirements. In addition, the team was knowledgeable of controlling documents such as WMPO requirements. For example, one auditor noted that the USGS procedure permitted the use of loose-leaf notebooks. This was inconsistent with the governing WMPO requirement which prohibited the use of loose-leaf notebooks.

As a final point, it should be noted that when the staff observations were presented to the audit team leader, the question of being able to address these issues in a future audit of the USGS Denver office was raised. Although the USGS QA organization is centered in Denver, documents such as SIPs are originated in Menlo Park plus requirements and actions must still be implemented by the Menlo Park office. Too much of a reliance on the Denver portion of the audit may have actually reduced the effectiveness of the Menlo Park audit. Once the staff observes the Denver audit, it will report any findings it may have on the order of the audits as well as the reliance on the Denver audit to address staff observations on the Menlo Park audit.

5.0 PRELIMINARY RESULTS/FINDINGS OF AUDIT TEAM

As a result of the audit, the SAIC team has several preliminary findings that it reported to USGS. These are listed below:

- There was no list of software as required by the configuration management program.
- Coding errors were not reported according to procedures.
- A unique identification code is not assigned to each Software Summary Form and Software Checklist and Indexing Form.
- Computer codes were used and results published before the codes were verified and validated.

- The Quality Management Procedure for computer software QA places too much reliance on individual technical contacts who are not qualified in all areas of software QA.
- Software cannot be traced to the SIP that assigns the QA level of the software.
- Commercial software may not be adequately documented for QA Level I work.
- Procurement documentation does not indicate quality level; a QA review was not performed; the documents are not stored as quality document.
- All procurement documentation was not processed on the proper requisition form.
- No vendor evaluation was completed prior to awarding of contracts, nor is there an approved vendors list.
- The USGS has not established a Material Receiving Inspection Report file or log.
- The USGS has not followed procedures in accepting procured services.
- Calibration equipment is not traceable to the National Bureau of Standards; equipment calibration has expired; there is no calibration tracking system as required.
- There was no system to segregate equipment under repair from calibrated serviceable equipment.
- Computer software was being used and the USGS personnel were not following the appropriate procedures for the use of software.
- Technical procedures have insufficient detail to provide guidance on necessary QA records.
- The SIP for gravity and magnetic methods does not provide the quality level for reducing and interpreting data.
- Technical procedures do not identify QA record requirements.
- Technical procedures should be more specific about evaluation accuracy requirements.

APPENDIX A

As part of its observation of the DOE/WMPO QA audit, the NRC staff has identified several concerns with the implementation of the USGS QA program. At present, these concerns are preliminary because additional investigations are needed to confirm that the findings are systematic and not isolated deficiencies. Because the DOE/WMPO QA audit of the USGS Menlo Park office did not provide the necessary details to support a final set of staff findings, the staff will report its final conclusions following the audit of the USGS Denver office. The preliminary staff findings are given below. The 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

Through observations of the USGS personnel during the audit, it appeared to the staff that there was a certain amount of unfamiliarity with the requirements of the QA program. Several examples dealing with the processing of procurement documents, the exclusion of QA level assignments, and the lack of knowledge of NNWSI related requirements are discussed in Section 4.0 of this report. These concerns may be indicative of problems with the lack of or effectiveness of the USGS QA indoctrination and training program.

Recommendations

In future audits, the DOE/WMPO team should cover all of the applicable 10 CFR 50, Appendix B criteria. Also, the depth of the audits should be sufficiently detailed to determine if these types of problems are isolated incidents or systematic deficiencies. Further, the staff recommends that DOE/WMPO take these actions immediately so that future audits are more complete and thorough.

B. Observations

As part of its function as observers of the audit, the staff reviewed some of the records available to the audit team. During this review, the staff found several records that were outdated or completed after the work was done. One area where this was the case was the seismic reflection test performed in January 1988 in Amargosa Valley. Several of the certification forms for personnel responsible for the test were completed and signed after the test was performed. A similar concern was the fact that calibration stickers for instrumentation had expired.

Not only do these situations support the staff findings that the DOE/WMPO audit should have been expanded to cover all of the applicable criteria but they may also indicate the need for more frequent internal audits by the USGS QA organization.

Recommendation

It is the finding of the staff that DOE/WMPO should evaluate its audit program to determine how more effective and complete audits can be performed. In addition, the staff believes that the USGS should evaluate the QA workload for its Menlo Park office and determine if additional QA resources are needed. Also, the USGS should review its audit schedule and procedures in order to determine if the audits are accomplishing their intended purpose and are being conducted on the frequency that they should be.

C. Observation

During the course of the audit, the NRC observers questioned the USGS Menlo Park QA representative on the corrective actions being taken in response to previous SDRs. In response to this question, the USGS Menlo Park QA representative stated that he had not seen the USGS response to the SDR. Because the Menlo Park office had not seen the response, it was not possible to implement the corrective actions.

This situation further supports the staff finding that the DOE/WMPO audit should have included all applicable criteria. The criterion applicable in this instance is 16.0, "Corrective Actions."

Recommendation

Based on the above information, the staff has concluded that the USGS review its program for corrective actions and determine if sufficient procedures are in place to ensure that the necessary corrective actions are being followed and implemented. In addition, the USGS should evaluate its audit program to determine if sufficient and timely audits are being conducted such that these types of problems are identified.

In addition, the staff has concluded that more complete audits need to be performed by DOE/WMPO in order to cover the applicable program elements.

D. Observation

The USGS technical staff assigned to the project are well qualified and provided all the technical assistance required during the audit. They were very cooperative in providing all available material requested and responded to all questions in a professional manner. The staff noticed that the USGS technical staff is not getting appropriate and sufficient QA guidance.

Recommendation

Effective guidance to the USGS technical staff regarding QA program requirements should be clearly provided.