U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT 94-07

OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT HQ-94-02

OF OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

MANAGEMENT AND OPERATING CONTRACTOR

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Enclosure 1

1.0 INTRODUCTION

During June 6-10 and June 20-24, 1994, members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), audit of the quality assurance (QA) program of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The OCRWM audit, HQ-94-02, was conducted at the M&O offices in Vienna, Virginia and Las Vegas, Nevada. M&O offices in Charlotte, North Carolina were not included in this audit since a recent HQ surveillance and an internal audit, observed by OQA, had been conducted. The audit evaluated the adequacy and effectiveness of the M&O QA program in all applicable QA programmatic areas. This represented the "baseline audit" of the M&O in meeting applicable requirements of OCRWM's "Quality Assurance Requirements and Description" document (QARD - DOE/RW-0333P). The State of Nevada and Clark County, Nevada observers participated in the Las Vegas portion of this audit.

This report addresses the effectiveness of the OCRWM OQA audit and the adequacy of implementation of QA controls in the audited areas of the M&O QA program. In the examination of programmatic areas, observations at Vienna and Las Vegas are presented separately, however, conclusions are presented for the audit overall.

2.0 OBJECTIVES

The objectives of the audit by OCRWM OQA were to determine whether the M&O QA program and its implementation meet the applicable requirements and commitments of the QARD and M&O implementing procedures.

The NRC staff's objective was to gain confidence that OCRWM OQA and M&O are properly implementing the requirements of their QA programs in accordance with the OCRWM QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the audit process and the M&O QA program on direct observations of the audit team members; discussions with audit team and M&O personnel; and reviews of the audit plan, audit checklists, and pertinent M&O documents. The NRC staff has determined that OCRWM Audit HQ-94-02 was useful and effective. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team finding that implementation of the M&O QA program overall is marginally effective. Fourteen Corrective Action Requests (CARs) addressing thirty-three individual deficiencies were identified by the OQA audit team. Thirty other potential CARs were acceptably resolved by the M&O organization during the audit. The audit team also presented 17 recommendations. M&O implementing procedures appeared to adequately address the QARD; that is, they form an adequate

baseline. However, implementation was not yet effective, particularly in the critical design control and corrective action areas.

OCRWM should continue to closely monitor implementation of the M&O QA program and corrective actions to ensure that the deficiencies identified during this audit are adequately corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the M&O QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

William L. Belke	Observer	
John G. Spraul	Observer	
Robert D. Brient	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE/OCRWM

Marlin Horseman	Audit Team Leader (ATL)	Headquarters QA Division (HQAD)/ Quality Assurance Technical and Support Services Contractor - (QATSS)
Hugh Lentz	Audit Team Coordinator	HQAD/QATSS
Richard Peck	Auditor	HQAD/QATSS
Walter Coutier	Auditor	HQAD/QATSS
Dennis Threatt	Auditor	HQAD/QATSS
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Don Hendrix*	Auditor	HQAD/QATSS
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Pat Cotter*	Auditor	HQAD/QATSS
Rob Howard	Auditor	Yucca Mountain QA Division (YMQAD)/QATSS
Richard Powe	Auditor	YMQAD/QATSS
John Matras	Auditor	YMQAD/QATSS
Ken Gilkerson**	Auditor	YMQAD/QATSS

4.3 State and Local Governments

Susan Zimmerman**	Observer	State of Nevada
E. Von Tiesenhausen**	Observer	Clark County, Nevada

4.4 Others

Tom Colandrea	Observer	M&O
Wayne Booth**	Observer	DOE RW-40

* Vienna, Virginia, only.
** Las Vegas, Nevada, only.

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 5 plus Interim Change Notice 1) and QAAP 16.1, "Corrective Action" (Revision 4). The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of the Audit and Observations

5.1.1 QA Programmatic Elements

The audit scope included the QA programmatic elements listed below:

1 Organization
2 QA Program
3 Design Control
4 Procurement Document Control
5 Implementing Documents
6 Document Control
7 Control of Purchased Items and Services
12 Control of Measuring and Test Equipment
15 Nonconformances
16 Corrective Action
17 QA Records
18 Audits
Supplement I. Software
Supplement III. Scientific Investigation
Appendix C. Mined Geologic Disposal System

5.1.2 Performance Based Evaluation

In addition to the programmatic audit of the applicable QA program elements, a performance based evaluation of the M&O training process in Vienna, Virginia, was conducted.

5.2 Timing of the Audit

The NRC staff believes the general timing of this audit was appropriate for OCRWM OQA to evaluate the pertinent QA activities of the M&O and for the NRC staff to evaluate the audit process and implementation of the M&O QA program.

5.3 Examination of QA Programmatic Elements

The audit team was composed of five groups of auditors evaluating implementation of procedures relating to different topics. In several cases, one programmatic area was audited by two or more groups which concentrated on specific aspects of the programmatic area. The NRC staff observations regarding the audit and the implementation of each of the QA programmatic elements observed are discussed below.

5.3.1 QA Program (QA Programmatic Element 2)

Vienna

Performance-based Evaluation of Qualification and Training: The audit team evaluated qualification and training activities at Vienna from a performance-based perspective, that is, from the perspective of the effectiveness of programmatic controls in assuring qualified and properly trained staff. The auditors identified five steps in the qualification and training process, along with objectives and measurement methods for each of the steps. Checklists were then developed based on the objectives and measurement methods, rather than being based on procedural requirements. Several of the auditors involved in this evaluation were observed. To evaluate the first two steps of the process, "Recruitment and Hiring" and "Identify Work Tasks," a number of M&O first-line supervisors and managers were interviewed. The M&O managers explained these processes as they understood and implemented them. Responses were consistent between managers and indicated good understanding of the processes. The same approach of interviews with M&O managers was used in the evaluation of the process step, "Establish and Implement Delivery System," with similar results.

The auditors determined that qualification and training efforts of the M&O were effective. This may appear to be at odds with the large number of procedural compliance deficiencies identified during the audit, but much of the improvement in training has been very recent, and the audit findings may reflect activities occurring prior to the improvements.

The application of performance-based evaluation to a single criterion is unusual, but appeared to be effective. The NRC staff feels that performance-based audits are generally more effective than strictly programmatic audits and supports their use in evaluating all criteria applicable to technical activities.

Programmatic Audit: In addition to the performance-based evaluation of portions of this criterion, the audit team performed a conventional programmatic audit of this element. A limited portion of the audit concerning implementation of M&O QA Procedure (QAP)-2-0, "Work Control" was observed. QAP-2-0 describes the process the M&O uses to identify the activities subject to QARD requirements, the portions of the QARD and implementing procedures applicable to an activity, and the personnel training requirements necessary to perform an activity. In the Systems Engineering area, the auditor found that certain QA programmatic requirements (such as position descriptions and training) where considered to be non-quality affecting because these were not directly associated with Q-List items. In addition, QAP-2-0 evaluations were done for organizational units (as opposed to activities), and those with no direct quality affecting products (for example, Contracts) graded themselves as non-quality affecting. These organizations did recognize that they performed quality affecting activities, albeit for other organizations' products, and their personnel had received appropriate training for those activities. This sort of confusion in the implementation of QAP-2-0 led to generation of a CAR for inadequate work control evaluations and a marginally effective status for this program element.

During the interview of supervisors, some of the supervisors appeared to lack the necessary knowledge and familiarity with the contents of the work control procedures and their implementation. The supervisors had to rely on their subordinates for the appropriate details on how to implement the procedural requirements. The lack of familiarity with the procedures may be attributable to numerous revisions to procedures in addition to reorganization and reassignment of management positions.

The NRC staff noted that training methodology differed between the Vienna and Las Vegas M&O offices. At the Vienna M&O office, procedural training is mainly accomplished by the "read and understand" concept. At the Las Vegas M&O office, training has or is planned to be accomplished by formal classroom training whereby students actually practice implementing a product associated with the procedure. The NRC staff believes the Las Vegas M&O office concept is a more effective method of training in comparison to the "read and understand" concept.

Las Vegas

The portion of the audit observed concerned surveillance, which the M&O places under QA Programmatic Element 2, rather than grouping surveillances with audits (QA Programmatic Element 18). The checklist was based on QAP-2-5, "QA Surveillance," and Nevada Line Procedure (NLP)-2-3, "Overview Surveillance." "QA Surveillance" is performed by the M&O Las Vegas QA Audits group, while "Overview Surveillance" is conducted by a separate construction QA group, looking specifically at field construction activities. The surveillance planning process was reviewed, as well as the 31 field surveillance reports completed to date. With the completion of most of the Exploratory Studies Facility (ESF) starter tunnel, few quality affecting activities were ongoing, and these were subject to surveillance. The audit of this area was effective and the implementation of this aspect of the QA program was adequate.

5.3.2 Design Control (QA Programmatic Element 3)

Vienna

Portions of the audit of QAP-3-9, "Design Analysis," and QAP-3-12, "External Transmission of Design Input Data," were observed. One potential CAR concerning the sequence of sign-off dates for a design analysis was corrected during the audit.

Las Vegas

Audit of QAP-3-5, "Preparation of Technical Documents:" Many of the M&O design activities result in the development of Technical Documents, for example, requirements documents, basis for design documents, design input documents, and design documents. Usually a Technical Document Preparation Plan (TDPP) is prepared as described in QAP-3-5. The TDPP serves both to control the work and to specify the content of the document to be prepared. The auditor reviewed TDPPs and the resulting technical documents from a number of the various M&O design organizations. The auditor identified a deficiency in QAP-3-5 in that it did not address distribution of documents not subject to

baseline control, resulting in the documents not being sent to the Document Control Center. This deficiency required only remedial action, and was corrected during the audit. The auditor also initiated a CAR for a technical document that did not identify input data of indeterminate quality as "To Be Verified (TBV)" as required.

Audit of QAP-3-13, "Document Identifiers:" The M&O uses document identifiers (serial numbers) as an extension of its configuration item identifier (QAP-3-6) system. Documents associated with particular configuration items are assigned document identifiers corresponding to the configuration item. M&O personnel discussed and displayed the system that is used to assign document identifiers and the controls in place to minimize the chance of assigning duplicate identifiers. The M&O personnel appeared knowledgeable of their system, and the system appeared to be effectively implemented.

Audit of NLP-3-15, "To be Verified and To be Determined Monitoring System:" This procedure identifies the methods by which data of indeterminate quality (which includes design assumptions) are identified and tracked for eventual resolution. Much of the TBV data will be verified by field data collected in the ESF, at which time the TBV status would be removed. M&O personnel demonstrated how data identified in upper tier design documents as TBV or "To Be Determined" carry through those designations to lower tier documents, eventually to specifications and drawings. The tracking system was also demonstrated. The controls appeared appropriate and effective, however, other members of the audit team identified several incidents of data lacking the appropriate TBV status identifier (see the discussion above of the audit of QAP-3-5).

The audit of the design control area was effective. The NRC staff agrees with the OCRWM audit team's conclusion that implementation in the area of Design Control was marginally effective to ineffective. The M&O is in the process of addressing CAR-HQ-93-018. This CAR was issued against the design control process as a result of the previous OCRWM audit but has not yet completed corrective action.

5.3.3 Procurement Document Control and Control of Purchased Items and Services (QA Programmatic Elements 4 and 7)

Vienna

The Vienna M&O office controls all procurement for the M&O, which to date, (for quality affecting services) has been primarily for records storage facilities and for research at Sandia and Oak Ridge Laboratories. These contracts had been in existence for some time and were initiated by the DOE or other project participants. A procurement in process was the request for proposal for design of the multi-purpose canister, and this procurement was reviewed by the auditor in depth. The M&O appeared to be adequately communicating quality and technical requirements and was properly evaluating supplier performance. The audit of this element was adequate, and implementation was effective.

5.3.4 Implementing Documents (QA Programmatic Element 5)

Both Locations

The OCRWM audit team and NRC staff observers recognized that the M&O appeared to have a large number of implementing procedures, particularly in the design control area. The procedures included QAPs and Line Procedures (LPs) for each of the locations, Vienna (VLPs), Charlotte (CLPs), and NLPs. The relationships between these procedures, and the reasons for such a large number was not clear, so the M&O discussed its strategy for procedure development, as follows: QAPs apply to all locations. The M&O has chosen to divide procedures into the portions of an activity that an individual work group may be performing; that is, one of the records control procedures applies only to records generators, others only to records processors. LPs are developed when one of the sites has a unique function, so an LP applicable to all locations would not be appropriate. An LP may supplement one or more QAPs, or may describe the entire process, including that portion that may already be addressed in a QAP. In any case, LPs should not conflict with QAPs or the QARD.

The M&O explanation seemed logical, but the number of procedures applicable to a single activity still appeared to be excessive. For example, an M&O training manual for the design process identifies the procedures applicable to each step of the process. For most steps three or more procedures apply, and at the extreme, 4 QAPs, 3 NLPs, and 1 CLP could be applied to the preparation and checking of drawings and specifications. Implementation difficulties, as evident from the 10 CARs and 4 deficiencies corrected during the audit concerning design control, might be caused to some degree by the large number of procedures. The NRC staff agrees with the audit team's conclusion that implementation of the QA program in the area of Implementing Documents is marginally effective. The audit of this program element was adequate.

5.3.5 Nonconformances (QA Programmatic Element 15)

Las Vegas

The M&O in Las Vegas operates in direct support to the DOE in administering the nonconformance control system for all Yucca Mountain participants operating at the Nevada Test Site. Personnel operate to DOE procedure YAP-15.1Q, "Control of Nonconformances," and are functioning within the Yucca Mountain Site Characterization Office QA program for this activity. Since the M&O does not perform any fabrication or construction activities, there is little chance of the M&O initiating a Nonconformance Report (NCR) for M&O nonconforming items. However, the M&O processes and tracks NCRs; and, as Architect/Engineer for the Yucca Mountain activities, M&O design groups usually specify the disposition of nonconforming items. The audit of this area was adequate and implementation was effective.

5.3.6 Corrective Action (QA Programmatic Element 16)

Vienna

The portion of the audit of this criterion involved reviewing in detail three CARs which were classified as non-significant to determine whether these classifications were appropriate. For background, the QARD requires that conditions adverse to quality be evaluated for significance, and if significant, root cause determinations and corrective action to prevent recurrence are required. If non-significant, only remedial action is necessary. The M&O has initiated a large number of CARs addressing its start-up difficulties, and the vast majority of these, including some CARs identifying adverse trends, were classified as non-significant. This appears contrary to common practices. An additional concern is that QAP-16-1 did not require an investigation of the extent of a condition prior to classification as significant or not, and it does not require any justification for the classification decision. The M&O had recognized these and other deficiencies in its corrective action program through an internal CAR and appears to be taking appropriate action.

The results of the evaluation of the three CARs classified as non-significant revealed that, in spite of their classification, the extent of the deficiency was investigated and corrective action to preclude recurrence was proposed. Since an M&O CAR had already been initiated, the audit team felt no need to initiate another. The audit of this area was adequate, and the audit team appropriately determined the corrective action system to be marginally effective.

Las Vegas

Six CARs initiated in Las Vegas during 1994 were reviewed, with essentially the same findings as in Vienna. Most were classified as non-significant, but appropriate investigations and action to preclude recurrence were proposed as necessary. The audit in Las Vegas confirmed the initial conclusions that had been reached during the Vienna portion of the audit.

5.3.7 Audits (QA Programmatic Element 18)

Vienna

The portion of the audit observed concerned auditor qualification, as described by QAP-18-2. The M&O has two Lead Auditors in Vienna and two in Las Vegas. The auditor reviewed qualification documentation to address the checklist for this element, and no deficiencies were identified. The audit was adequate and implementation appeared effective.

5.3.8 Computer Software Control (QARD Supplement 1)

Both Locations

The checklist for auditing the M&O's computer software controls was developed by the auditor of this programmatic element from the four QAPs that specify

the controls: "Computer Software Verification and Validation" (QAP-19-1), "Software Configuration Management" (QAP-19-2), "Model Validation" (QAP-19-3), and "Software Management" (QAP-19-4). These procedures were being revised by the M&O to more clearly specify its current practices in the area of computer software control.

At the M&O offices in Vienna, Virginia, the only "quality-related" computer software is the "Characteristics Data Base," or CDB. This software was acquired from the Oak Ridge National Laboratory after it had undergone peer review. The CDB is being maintained by the M&O, and it is used by many users other than the M&O.

At the M&O offices in Las Vegas, Nevada, there are six computer software programs within the scope of computer software control program: ANSYS, VNET, UDEC, FLAC, MCNP, and LYNX. None of this computer software was developed by the M&O. Like the CDB, each of these computer software programs was acquired. And like the CDB, these programs are cited as being certified for quality-affecting work.

The auditor interviewed M&O personnel involved with the control and use of these computer software programs, including the Managers of Software Configuration Management (Vienna and Las Vegas), the users, the qualifying analysts, and their managers. The auditor also reviewed applicable documentation and ran at least one test case of each of the computer software programs noted above.

Except for one of the programs noted, the test cases used to "validate" each of the programs were the test cases supplied by the computer software developer. That is, the M&O did not develop its own test cases, and the "validation" was primarily an installation test that showed that the computer software functioned the same on the user's computer hardware as it did on the developer's computer hardware. This puts more reliance on the software developer than would be required if the users developed their own test cases. The vintage of the programs varies, and most were not developed under the controls of a 10 CFR Part 50, Appendix B, QA program. On the other hand, most of the programs have been used for a number of years and are generally accepted by knowledgeable personnel as being the best available for their intended use. The NRC staff recommends that acquired computer software (not developed under an Appendix B QA program) be "validated" by more than rerunning the developer's test cases.

The auditor identified one condition adverse to quality that resulted in a potential CAR, in that problem reports received from the vendor of one of the computer software programs were not being integrated into the configuration management system. Several other deficiencies were found by the auditor that required only remedial action which was taken during the audit. In addition, the auditor made several recommendations that should improve the M&O's program for computer software control.

The audit of computer software was adequate. The NRC staff agrees with the audit team's preliminary finding that the M&O's computer software control should be classified as marginal.

5.3.9 Conclusions

The NRC staff observed that each of the auditors reviewed related documentation and interviewed at least a representative sample of M&O personnel to determine their understanding and degree of implementation of the procedures. Within the scope of the audit, the audit team concluded that the M&O QA procedures were adequate but that implementation was marginally effective.

5.4 Conduct Of Audit

The audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the M&O QA program. The auditors used their checklists effectively and pursued issues beyond the checklists when appropriate. They solicited comments and questions from the NRC observers in an appropriate manner.

The interview method of auditing, combined with periodic checking of objective evidence, allowed for thorough responses to the questions and permitted many additional questions to be answered. In general the audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. A caucus of auditors and observers was held at the close of each work day, and a meeting of the ATL and M&O management (with an NRC observer present) was held each morning to discuss the audit status and preliminary findings.

At the daily meetings and during the daily interfaces between the audit team and M&O staff, potential audit findings appeared to be viewed as a means of improving the program rather than as a measurement of job performance or punitive action. The NRC staff indicated to the auditors and M&O staff on two occasions that this was a positive attitude and healthy for the program.

5.4.1 Conclusions

The auditors adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the M&O QA program.

5.5 Qualification Of Auditors

The qualifications of the ATL and auditors were found to be acceptable in that each auditor and the ATL met the requirements of QAAP 18.1, "Qualification of Audit Personnel."

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The Audit Plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, a list of the activities to be audited, and audit checklist references.

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

5.8 Review of Previous Audit Findings

Implementation of corrective actions for CARs issued as a result of the last OCRWM OQA audit of M&O was verified. In addition, the audit checklist included specific follow-up of CAR HQ-93-013, which covered deficiencies in the M&O design control process at both audit locations.

5.9 Summary of NRC Staff Findings

The NRC staff agrees with the preliminary OCRWM audit team finding that implementation of the M&O QA program is marginally effective overall. The NRC staff did not observe any deficiencies in the audit process.

5.9.1 Observations

The NRC staff did not identify any Observations relating to deficiencies in either the audit process or the M&O QA program.

5.9.2 Good Practices

The NRC staff identified a good practice in the use of status sheets which identified potential findings and concerns, and which were presented in each of the daily meetings with M&O management. These were very helpful in tracking potentially adverse conditions.

5.9.3 Weaknesses

1. Training methodology is inconsistent between the Vienna, Virginia, and the Las Vegas, Nevada M&O offices (See Section 5.3.1).

2. There seems to be a complex document hierarchy and excessive number of procedures which may lead or contribute to QA program implementation problems. When a changes is initiated, numerous documents and procedures need to be checked and revised to accommodate the change. It may be prudent for the M&O to check this document hierarchy and eliminate redundancy where possible (See Section 5.3.4).

3. In the area of software, most test cases used by the M&O to "validate" computer programs were the test cases supplied by the computer software developer. Thus, the "validation" was primarily a check that showed that the computer software functioned the same on the M&O computer as it did on the developer's computer (see Section 5.3.8). The NRC staff recommends that acquired computer software (not developed under an Appendix B QA program) be "validated" by more than rerunning the developer's test cases.

5.10 Summary of OCRWM Audit Findings

Within the scope of this audit, the audit team concluded that the M&O QA procedures are adequate, but that implementation of the M&O QA program is marginally effective. The NRC staff agrees with these conclusions. At the post-audit meeting, the audit team provided observations of the M&O QA program and discussed the preliminary CARs resulting from the audit. The CARs are summarized below.

1. Inadequate QAP-2-0 work control evaluations.

2. No objective evidence that the QA classification of multi-purpose canisters was forwarded to the Yucca Mountain Site Characterization Office for inclusion in the YMP Q-List.

3. Trend program ineffective in obtaining correction of identified trends.

4. No objective evidence that QA program is being adequately applied to advanced conceptual design activities.

5. Incomplete information on document review records for design package 1B.

6. Design verification documentation was not generated or was not available.

7. Technical document was approved and issued without identifying a "TBV."

8. Various design control deficiencies, including inadequate identification of design inputs, missing signatures on classification analyses, and inconsistent rounding and truncating.

9. Omission of information on design input data transmittal; transmittal input not marked "verification pending."

10. Inadequate implementation of QAP-5-2 for the preparation of LPs.

11. Inadequate integration of problem reports into the configuration management system.

12. Attachments to QAP-3-8 are no longer consistent with the specification cover sheet descriptions in MGP-3-9.

13. QAP-3-5 did not address control of approved technical documents that were not baselined.

14. No objective evidence was identified that indicates that the ESF Basis for Design, revision 2 preparation complies with NLP-3-20.

Thirty other potential CARs were acceptably resolved by the M&O organization prior to the post-audit meeting.

OPEN ITEM

COMMENT

In the area of software, most of the test cases used by the M&O to "validate" each of the programs were the test cases supplied by the computer software developer. That is, the M&O users of the software did not develop their own test cases, and the "validation" was primarily an installation test that showed that the computer software functioned the same on the user's computer as it did on the developer's computer.

Basis

By not developing its own test cases, the M&O puts more reliance on the software developer than would be required if the M&O users of the software developed their own test cases. The vintage of the software programs varies, and most were not developed under the controls of a 10 CFR Part 50, Appendix B, QA program. On the other hand, most of the software programs have been used for a number of years and are generally accepted by knowledgeable personnel as being the best available for their intended use.

Recommendation

The NRC staff recommends that acquired computer software (not developed under an Appendix B QA program) be "validated" by more than rerunning the developer's test cases.