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ENCLOSURE 1

OQA

SURVEILLANCE REPORT

HQ-SR-94-02

102.7

OFFICE OF RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

QUALITY ASSURANCE SURVEILLANCE RECORD

SURVEILLANCE DATA

[1]ORGANIZATION/LOCATION:	[2]SUBJECT:	[3]DATE:
M&O/Vienna, VA	Implementation of M&O Quality Administrative Procedures	12/22/93

[4]SURVEILLANCE OBJECTIVE:

To verify satisfactory implementation of M&O Quality Administrative Procedures

[5]SURVEILLANCE SCOPE:
Surveillance evaluation to include:

Flowdown of QARD (DOE/RW-0333P) requirements into the QAPs, the adequacy of the procedure processes to implement the QARD, compliance to these implementing procedures (QAPs), and verification of CAR HQ-93-13.

The surveillance scope does not include QAP-3 series, QAP-2-0, and QAP-2-3 because they are still being developed.

[6]SURVEILLANCE TEAM:
Team Leader:
F. Hugh Lentz
Additional Team Members:
J. George, F. Bearham
R. Peck, C. Coulombe
M. Donovan, ~~D. Hendrix~~ FHL 1/3/94

[7]PREPARED BY:		[8]CONCURRENCE:	
F. H. Lentz F.H. Lentz	12/22/93	Original signed by Bob Clark	1/4/94
Surveillance Team Leader	Date	QA Division Director	Date

SURVEILLANCE RESULTS

[9]BASIS OF EVALUATION / DESCRIPTION OF OBSERVATIONS:

The surveillance team used checklists based on requirements of the following documents:

Quality Assurance Requirements and Description (DOE/RW-0333P), Rev. 0, dated 12/18/92

M&O Quality Assurance Procedures (Table of Contents, Rev. 63)

Corrective Action Request, HQ-93-13, dated 2/17/93.

See pages 2 through 12.

[10] SURVEILLANCE CONCLUSIONS:

See pages 13 through 16

[11] COMPLETED BY:		[12] APPROVED BY:	
F.H. Lentz	3/29/94	R.W. Clark	3/29/94
Surveillance Team Leader	Date	QA Division Director	Date

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

PERSONNEL CONTACTED

The personnel contacted during the surveillance are listed in Attachment 1.

OBJECTIVE EVIDENCE REVIEWED DURING THE SURVEILLANCE

The objective evidence reviewed during the surveillance is listed in Attachment 2.

SURVEILLANCE RESULTS

QAP-1-0, *M&O Organization*

The latest M&O organization chart requires approval before making minor changes to the responsibilities reflected in QAP-1-0. The surveillance team noted a minor inconsistency in the procedure with regard to the wording for some line organization paragraphs - "responsibilities" were listed, but not "authorities". The procedure review indicated that the specific QARD QA Manager authority for stopping work is not listed in this procedure, but the authority is identified in QAP-16-2, *Stop Work* (Recommendation 1).

Review of personnel qualification records (position descriptions and resumes) indicated that the position descriptions were consistent with the responsibilities listed in QAP-1-0 and specific resumes were generally consistent with the position descriptions. Although the procedure, position descriptions, and resumes matched; the surveillance team was not sure the position description met the needs of the task. Refer to specific comments related to QAP-2-2. (Also, see Recommendation 2).

The surveillance team verified that letters delegating authority (sample of 30 letters) are being issued and are being sent to the Local Records Center as QA records (See Recommendation 3).

The surveillance team determined that this procedure meets the requirements of the QARD and defines an adequate implementation process; however, as noted implementation activities should be improved.

QAP-1-1, *Resolution of Quality Disputes*

The M&O organization has not used this procedure to resolve any quality disputes.

The surveillance team determined that this procedure meets the requirements of the QARD and defines an adequate implementation process.

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

QAP-2-1, *Indoctrination and Training*

The surveillance team reviewed activities related to M&O QAP-5-1, *Preparation of Quality Administrative Procedures*, as a basis of determine if indoctrination and training was provided to QAP preparers. CAR HQ-93-013 was issued on 3/18/93 and subsequently QAP-5-1 was revised. A review of training records for QAP procedure preparers (17) revealed that the preparers had completed reading assignments for QAP-5-1; however, classroom training had not been conducted. In light of the many comments made by the surveillance team regarding QAP adequacy, the surveillance team recommends that specific classroom training be conducted to ensure universal understanding of M&O QA Program requirements (See Recommendation 4).

Two "briefings" were conducted in April 1993 for Quality Review Board (QRB) members and QAP preparers; however, the Training Department record files contained insufficient documentation of the activity. The presenters of the briefings provided copies of the briefing content and visual aids. An attendance record classified the briefing as a three hour classroom session; when, in fact, the briefing was a thirty minute presentation given during a three hour QRB meeting. (See Recommendation 5).

Previous OCRWM surveillances have recommended that the Training Department be included on distribution for CARs, audit reports, and surveillance reports to allow a more proactive training role in aiding QA Program implementation. This recommendation is reiterated (See Recommendation 6).

The surveillance team determined that this procedure meets the requirements of the QARD; however, the implementation process is inadequate. Refer to the verification report for CAR HQ-93-013.

QAP-2-2, *Verification of Personnel Qualifications*

Personnel qualifications (18) were examined and found to be in accordance with the QAP except for two QA personnel. The position description for these personnel allowed high school education plus experience as an alternative to a technical degree. The two QA personnel were assigned to quality affecting work prior to verification of their education (See CAR HQ-94-004).

Inconsistencies were noted in qualifications established for several position descriptions in that education and experience requirements varied widely although the work assignments were similar in scope and level of responsibility. Upon further review, it was noted that the education and experience requirements for the positions were apparently based on the actual qualifications of the individuals assigned to the positions rather than an analysis of the qualifications needed to adequately perform the assigned work. For example, education and experience requirements for audit personnel were significantly less

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

with regard to prior QA experience than the qualification requirements for personnel whose work they are evaluating. The approach used in developing position descriptions may result in assignment of quality affecting work to individuals not trained or qualified to perform that work (See Recommendation 2).

The surveillance team determined that this procedure does not meets the requirements of the QARD. Refer to verification report for CAR HQ-93-013.

QAP-2-4, *Quality Assurance Program Status and Trend Reporting*

After reviewing two trend reports and interviewing individuals responsible for the QA program status and trend reporting activities, the surveillance team determined that procedural requirements are being implemented. The procedure was recently revised to change the timing of reporting from quarterly to semi-annually. The team also noted that the Quality Management Information Systems (QMIS) Administrator effectively monitored the system and provided timely input to management on the status of the program.

The surveillance team determined that this procedure meets the requirements of the QARD; however, the implementation process is inadequate. Refer to verification report for CAR HQ-93-013.

QAP-2-5, *QA Surveillance*

A limited number of Vienna-generated surveillance reports were available for review by the surveillance team. However, the team was able to review the training, scheduling, checklist development, reporting, and the processing of surveillance documentation as quality records.

A condition was identified concerning the lack of objective evidence included in audit reports. This condition also exists in surveillance reports. As an example, surveillance report 94-MRS-01 exhibited the same problem that was found in the audit reports. Refer to CAR HQ-94-006.

The surveillance team reviewed the M&O procedure for adequate definition of a process to meet QARD requirements. The surveillance team determined that inconsistencies were discovered in this review and are discussed in the verification report for CAR HQ-93-013.

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

QAP-2-6, *Readiness Review*

The M&O organization has not used this procedure since the previous OCRWM audit.

The surveillance team determined that QAP-2-6 indicates procedural weaknesses. The verification report for CAR HQ-93-013 identifies some of the noted weaknesses. A specific weakness observed was the lack of a documented process for the QA Manager to notify the General Manager when all actions required prior to the start of work have been completed (See Recommendation 7).

QAP-2-7, *Management Assessment*

The surveillance team reviewed the 1993 Management Assessment report for the M&O QA Program, which was issued 8/10/93. Currently, M&O responses to the assessment are being coordinated by the QA Manager. The Management Assessment was conducted by a team of independent consultants. The surveillance team determined that the Management Assessment accomplished the intended purpose.

The surveillance team determined that this procedure meets the requirements of the QARD; however, the implementation process is inadequate. Refer to verification report for CAR HQ-93-013.

QAP-2-9, *Development and Conduct of Training*

In order to verify procedural adequacy and implementation, the surveillance team examined lesson plans, instructor certifications, training database reports, and training folders of selected personnel.

Lesson plans for QAP-2-3, Rev. 3; QAP-2-0, Rev. 0; and DOE/RW/0333P (QARD) were reviewed and found to be in compliance with QAP-2-9. Instructor Certifications for two current instructors were reviewed and found to be acceptable. QAP-2-1 allows training to be waived when approved by the Training Manager. Four examples of waived training were reviewed: two because the individuals had authored the QAP, subject of the training, and two others were waived because of documented prior experience. The database reports were acceptable except that "briefing" training was documented as classroom training. The database does not have a field for briefings (See Recommendation 5). No adverse conditions were reported for this procedure.

The surveillance team determined that the procedure meets the requirements of the QARD; however, the implementation process is inadequate. Refer to verification report

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

for CAR HQ-93-013.

QAP-4-1, *Procurement Document Control*
QAP-7-1, *Control of Purchased Items and Services*

There were no active procurements in progress during the surveillance; therefore, the surveillance team reviewed a procurement dealing with Task Orders to Oak Ridge National Laboratories under a Cost Reimbursable Memorandum Purchase Order (MPO).

From interviews, document reviews (selected Task Orders), and procedure reviews, the surveillance team determined that QAP-4-1 meets the requirements of the QARD but was procedurally weak. The weaknesses include inconsistencies: incomplete thought processes (tells to do something, but doesn't tell how to document) and a lack of logical flow. Refer to verification report for CAR HQ-93-013.

QAP 5.1, *Preparation of M&O Quality Administrative Procedures*

After the review of the Requirements Traceability Network (RTN) markups for QAP-5-1 and QAP-5-2 and the record packages for QAP-5-1 and QAP-5-2, the surveillance team has two areas of concern relative to QAP format and updates to the QARD requirements matrix. The format for QAPs as specified in QAP-5-1, Attachment I, Section 5, does not identify the content requirements specified in the QARD Section 5.2.2B, C, E, F, and H.

Also, the objective evidence reviewed by the team to verify adequate compliance with QAP-5-1, Section 5.10, QARD Matrix, does not readily indicate compliance with the process specified in paragraphs 5.10.1 through 5.10.3. The team recommends that this section be reviewed to ensure that the current practice is covered and is being properly implemented (See Recommendation 8).

The surveillance team determined that this procedure does not meet the requirements of the QARD. Refer to the verification report for CAR HQ-93-013.

QAP-6-1, *Document Control*

M&O CAR 93-QL-C-003 was used as a basis for the surveillance evaluation of this procedure. The CAR was generated as a result of surveillances at three locations: Vienna, Charlotte, and Las Vegas. The adverse condition noted in the CAR indicated that a high percentage of manual holders at the three locations had not maintained their QA manuals. Fifty manuals had not been updated. The methodology for updating manuals in accordance with Procedure Change Notices (PCNs) was cumbersome. The Secretariat Department has addressed the problem by issuing a complete QAP with each PCN so that the manual holder replaces a complete procedure rather than individual pages.

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

In addition to this, the Secretariat Department periodically reviews all manuals with the manual holder to ensure that procedures are current. The department has also initiated a "walk in" policy where manual holders may have their manuals checked by LRC staff. It was determined that these policies adequately address the adverse condition noted in CAR 93-QL-C-003 and that the document control process is performed in accordance with QAP-6-1.

The surveillance team determined that this procedure meets the requirements of the QARD and defines an adequate implementation process.

QAP-16-1, *Corrective Action*

M&O CAR 93-QL-C-003 was selected also as the basis for evaluation of this procedure. This CAR was selected because it reported a significant condition adverse to quality and was applicable to the three M&O locations. The following conditions were noted:

> CAR 93-QL-C-003 was prepared as a result of three surveillances: 93-SR5-03 at Vienna; 93-NS5-003 at Las Vegas; and 93-MR5-01 at Charlotte. There was evidence to indicate that corrective action was completed at Vienna, but there was insufficient evidence to conclude that the corrective action had been completed at Las Vegas and Charlotte.
>
> The QA review of the CAR was inadequate because: (a) the root cause was inconsistent with the identified adverse conditions and (b) the Corrective Actions were not recorded in separate fields on the CAR form.
>
> The QA verification of the CAR was inadequate. The verification stated that Corrective Action was complete, when, in fact, several actions were still incomplete (See CAR HQ-93-008).

One minor inconsistency noted during a review of 13 other CARs includes:

> The CAR status log and several CARs had the "Significant" box completed with the designation "N/A"; the correct classification should be "YES" or "NO".

For CARs which are not classified as significant, QAP-16-1, paragraph 5.5.1 requires the Interfacing Manager to investigate the reported conditions and document the results. Of the CARs reviewed, some indicated a separate fully descriptive investigation, some indicated an investigative element as part of the remedial action, and some included no investigative element (See CAR HQ-94-008). In reviewing the selected CARs, the surveillance team noted that the CAR number was not repeated on each page and the audit or surveillance originating the CAR was not identified (See Recommendations 9 and 10).

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

The surveillance team determined that this procedure meets the requirements of the QARD and defines an adequate implementation process.

QAP-16-2, *Stop Work* - There have been no Stop Work conditions identified by the M&O.

The surveillance team determined that this procedure meets the requirements of the QARD and defines an adequate implementation process.

QAP-17-1, *Record Source Responsibilities for QA Records*

After a review of objective evidence (Authentication Lists and Record Package Tables of Contents) and interviews with the individuals having QA record source responsibilities, one deficiency was identified by the team. The deficiency was in the area of making QA record corrections. The QARD and the procedure require that all corrections to QA records be re-authenticated by the Record Source and re-approved, if applicable. The team noted numerous instances, particularly in auditor certification and QA training files, where corrected records were not re-authenticated or re-approved. This condition is addressed in Corrective Action Request (CAR) HQ-94-005.

Interviews with personnel responsible for performing this activity indicated that there was significant confusion regarding who performed the activity and when this activity should take place. Although the QARD clearly states the requirement, which is reiterated in the procedure, and the personnel interviewed in the Local Records Center (LRC) are very clear on implementation of the requirement, some individuals having record source responsibilities were uncertain or interpreted the implementation of this requirement differently.

The surveillance team determined that this procedure meets the requirements of the QARD and defines an adequate implementation process.

QAP-17-2, *Receipt and Handling of QA Records and Records Packages*

The surveillance team reviewed objective evidence, such as record packages, record package logs, the inclusion and exclusion list, and temporary storage facilities for the receipt and handling of QA records. After reviewing the batch control records from the Local Records Center (LRC), the only item of concern noted by the surveillance team was that the process defined in the procedures has missing or out-of-sequence steps. However, this does not appear to affect implementation of the procedural requirements.

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

The surveillance team determined that this procedure meets the requirements of the QARD; however, the implementation process is inadequate. Refer to the verification report for CAR HQ-93-013.

QAP-17-5, *Indexing Quality Assurance Records*

The surveillance team reviewed objective evidence (record package transmittals, records, and logs to control and identify the location of records, the records vault, the fire rating certificate of the vault, the OCRWM Indexing Manual, and the record database reports) for indexing QA records. The main item of concern noted by the surveillance team was that the procedure does not adequately define which M&O Program records are to be indexed. The team determined through interviews with LRC personnel that they use the "inclusion and exclusion" list to determine the records to be indexed; however, this method is not identified in procedures and the inclusion and exclusion list has yet to be approved for use.

The surveillance team determined that the above deficiency is another example of missing procedural steps as identified in the verification report for CAR HQ-93-013.

QAP-17-6, *Storage and Retrieval of Quality Assurance Records*

The surveillance team reviewed storage cabinet and vault access lists and microfilm and record storage areas for adequate control, storage, and retrieval of QA records. The surveillance team determined that the procedure meets the QARD requirements; however, the implementation process is inadequate. Refer to the verification report for CAR HQ-93-013.

QAP-18-1, *Certification of Audit Personnel*

After the review of QAP-18-1, the review of six lead auditor and auditor qualification files, and interviews with the M&O quality assurance staff, the surveillance team identified inconsistencies in the methodologies used by the M&O Quality Assurance organization for qualifying and certifying personnel assigned to the audit process. Contrary to the QARD, the surveillance team found that a Lead Auditor had been certified based on the requirements detailed in QAP-18-1 paragraph 5.1.4, which allows certification of personnel possessing current Lead Auditor certification equivalent to QARD requirements from recognized sources. This Lead Auditor had been certified without confirmation of education and work experience, including confirmation that five (5) audits in three (3) years, one of which must be a nuclear audit, had been performed. Additionally, the work experience and education of another individual qualified as an auditor had not been verified prior to qualification as an auditor.

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

The balance of the qualification files was determined to be acceptable. Prior to the end of the surveillance all issues stated above had been corrected, presented to the surveillance team for their review, and found to be acceptable. See Section 10 of this report.

CAR HQ-94-004 provides details related to the deficiencies found in the area of verification of work experience and education. It should be noted that this is a similar deficiency to the condition identified in OCRWM CAR HQ-93-019.

The surveillance team determined that this procedure does not meet the requirements of the QARD. Refer to the verification report for CAR HQ-93-013.

QAP-18-2, *Audits*

The surveillance team reviewed a representative sample of audits conducted by the M&O. The review included an examination of the audit schedule, audit notification, audit plan, checklist, and audit report content. Problems were found in the area of checklist development and the recording of the objective evidence reviewed. Recommendations 11 and 12 address the need to improve the checklists.

The condition concerning failure to adequately document objective evidence is related to the fact that audit checklists have not been considered QA records; and therefore, the checklist content must be adequately documented within the audit report. Examples of this condition were found in the sampling of the following audit reports: 93-MRA-01, 93-VIA-01, and 94-VIA-01. In addition, the lack of adequate identification of objective evidence was also observed in Surveillance Reports 94-MRS-01 and 93-SRS-03. The deficiency is reported in CAR HQ-94-006. This adverse condition is similar to the one reported in CAR HQ-93-021.

The surveillance team noted that conditions identified as corrected during the M&O's audits did not provide (in some cases) any explanation as to how they were resolved nor any explanation as to the extent of the indicated conditions. Additionally, it was noted that several appear to be CAR conditions that require further investigation, root cause determination, preventive measures, and recurrence control. This determination is based on the lack of information contained in the written text of the audit report (See Recommendation 13).

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

The M&O audit reports contain standard wording at the end of Section III (DEFICIENCIES CORRECTED DURING THE AUDIT) that read as follows: "Some of these conditions adverse to quality were evaluated against criteria A through I of QAP-16-1, Attachment III and were determined not to be significant." The surveillance team reviewed the subject criteria and determined that it specifically dealt with meeting the requirements of the QARD, section 16.0, paragraph 16.2.4A for the establishment of criteria for determining a significant condition adverse to quality. This statement is somewhat misleading in that it implies that normal conditions adverse to quality are not required to be documented on a CAR. It appears that only the criteria for significant conditions is applied (See Recommendation 14).

The surveillance team determined that this procedure does not meet the requirements of the QARD. Refer to the verification report for CAR HQ-93-013.

QAP-19-1, *Computer Software Verification and Validation*
QAP-19-2, *Software Configuration Management*
QAP-19-3, *Model Validation*
QAP-19-4, *Software Management*

There has been no work performed in accordance with the 10/30/93 (or later) versions of the 19-series procedures. The Characteristics Database (CDB) is the only software package currently subject to QARD controls at the M&O Vienna facility. Version 1.0 of the CDB was approved late in 1992. In response to OCRWM CAR HQ-93-014, changes were incorporated into version 1.1 of the CDB, which was approved for use on 9/30/93 (Vienna only) and 10/11/93 (M&O-wide).

Although the work of changing the CDB software and the subsequent distribution of the changes were accomplished according to the now superseded procedures, ongoing activities related to configuration management were reviewed by the surveillance team. During this review, it was determined that the distribution of the updated version of the CDB did not include instructions on the disposition of the superseded version, nor did the previous or current procedures require such instructions. Review of the media distribution records and interviews with several of the users of the CDB indicated that some had returned the previous version of the software, while others had both versions in their possession. It was noted that approval of the new version of the software by the Software Configuration Control Board (SCCB) resulted in both the old and new versions being approved for use for work subject to QARD controls. The software configuration management staff indicated that it is the responsibility of the user organizations to evaluate any new version issued and determine which version is appropriate for that user. However, none of the user organizations interviewed have established procedures to

9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS (Continued)

provide a process for this evaluation or to otherwise control the use of software, as is required by M&O QAP-19-4 (these procedures were also required by the M&O CSQAP which preceded QAP-19-4). CAR HQ-94-007 was issued to document this lack of procedures.

The surveillance team determined that this procedure does not meet the requirements of the QARD. Refer to the verification report for CAR HQ-93-013.

10 SURVEILLANCE CONCLUSIONS (Continued)

SURVEILLANCE SUMMARY

Surveillance HQ-SR-94-02 was conducted to evaluate the implementation of the M&O Quality Administrative Procedures (QAPs) and to verify the completion of the corrective actions for OCRWM CAR HQ-93-013. The surveillance was conducted at the M&O offices in Vienna, Virginia on January 10-14, 1994. The surveillance team consisted of personnel from Headquarters Division, Office of Quality Assurance (HQAD). It was determined that the implementation of the QAPs and the completion of the corrective action was unsatisfactory. Five Corrective Action Requests (CARs) were issued to identify deficiencies in the implementation of the M&O QAPs. An unsatisfactory verification report was issued identifying inadequate procedural conditions. Thirteen recommendations were made for management consideration.

CORRECTIVE ACTION REQUEST HQ-93-013

The M&O corrective actions were reviewed and found to be unsatisfactory. Except for Condition 8 (QAP-3-9, *Design Analysis*) which was not evaluated during the surveillance, completion of all remedial actions was reviewed. Discussions of the unsatisfactory Investigative Action and Preventive Action to Preclude Recurrence are included in the Verification of Corrective Action report for CAR HQ-93-013.

CORRECTIVE ACTION REQUESTS

HQ-94-004: Adverse condition concerns personnel performing quality affecting work prior to verification of education and experience. Controlling document is QAP-2-2, Rev. 2.

HQ-94-005: Adverse condition concerns QA records being corrected without being re-authenticated and re-approved by the originating organization. Controlling document is QAP-17-1, Rev. 3.

HQ-94-006: Adverse condition concerns audit and surveillance reports not containing all the necessary objective evidence to support the evaluations. Controlling document is QAP-18-2, Rev. 2 and QAP-2-5, Rev. 2.

HQ-94-007: Adverse condition concerns user organizations not establishing procedures for controlling the use of software. Controlling document is QAP-19-4, Rev. 1.

10 SURVEILLANCE CONCLUSIONS (Continued)

HQ-94-008: Adverse condition concerns inadequate root cause determination and inadequate verification of corrective action. Controlling document is QAP-16-1, Rev. 1.

ADVERSE CONDITIONS CORRECTED DURING THE SURVEILLANCE

1. M&O Training verified high school education for two M&O QA personnel identified during the surveillance.

2. M&O Audits Manager along with M&O Training verified education and experience, including auditing experience, for lead auditor candidate.

3. Based on item 2, M&O QA Audits Manager submitted a revised Lead Auditor Certification Record.

RECOMMENDATIONS

1. The M&O should consider revising procedure, QAP-1-0, to identify the QA Manager's authority to stop work.

2. After reviewing the position descriptions, the surveillance team recommends that the M&O re-evaluate their position descriptions to strengthen the level required of personnel assigned to QA tasks, such as Auditors and QA Specialists. Also, the M&O process for evaluating position responsibilities for work subject to the QARD needs review to provide consistent position descriptions for similar levels of responsibility.

3. Because QAP-1-0 is a new procedural requirement and the surveillance team reviewed a limited sample, the surveillance team recommends that the M&O verify that all letters delegating authority are being captured as QA records.

4. Due to the identification of repetitive QA Program and procedure problems, the surveillance team recommends that M&O review as part of their root cause investigation if personnel require additional pertinent classroom training.

10 SURVEILLANCE CONCLUSIONS (Continued)

5. Modify the requirements or procedurally delete the requirement for "briefing training" in QAP-2-9, *Development and Conduct of Training,* based on the following observations:

   a) Briefings are less formal (i.e., informal) than classroom and it is unnecessary to proceduralize informal training.

   b) QAP-2-9, Para. 5.6.1 requires a Training Attendance Record to be completed and forwarded to the Training Department. This record is of no value to the Training Department without lesson plans, overheads, or other supporting material.

   c) The Training Department records database has no field for briefings and erroneously records them as classroom training.

   d) The Training Department does not receive all Training Attendance Records for briefings.

6. The Training Department should be included on distribution of CARs and verification reports for the planning of training activities. The planning should factor in quality issues, which would aid QA Program implementation.

7. The surveillance team recommends that instructions for open item disposition, sign-off, and authorization to start work in follow-up to a Readiness Review be added to QAP-2-6.

8. Because of the confusion noted during the surveillance, the surveillance team recommends that the M&O review Paragraph 5.10, QARD Matrix, of QAP-5-1 to ensure the procedure reflects current practices.

9. To make the CAR form more clear and traceable, the M&O might consider the following changes to the CAR form:

   a) Use "yes/no" for "Significance determination"; some indicate "n/a".
   b) Reference origin of CAR - surveillance, audit, etc.
   c) Repeat CAR number on each page.

10 SURVEILLANCE CONCLUSIONS (Continued)

10. The lead auditor and auditor qualification and training packages need organization to improve on retrieveability and to ensure that all applicable documentation isgenerated and filed. The surveillance team recommends the following items be considered:

    a) Develop a checklist that can be used by the training organization, prior to the certifying authority signing off the certification.
    b) Index the files using the above checklist as the basis. This will enable the training personnel to better maintain the files and to retrieve the documents.

11. Improved verification checklists to provide a more thorough evaluation (e.g., refer to specific requirements paragraphs in the checklists) should be considered. Checklists written to specific requirements would assist the team in transferring checklist information to the audit report. Other checklist recommendations include:

    a) Ensure that the use of "canned" checklists are adequate for the verification scope.
    b) Have the audit team member that developed the checklist sign the checklist or at least identify the preparer. Also have the audit team leader approve the checklist prior to the audit.

12. The surveillance team recommends that the explanations be provided in the M&O's audit reports for conditions corrected during the audit to contain detailed information as to the extent of the problem and the actual solution to remedy the situation.

13. The M&O should consider using different words and terminology in describing the actions taken related to conditions corrected during the audit.

NAME	TITLE
Barbara Bernhart	Subcontracts and Purchasing Manager
Dick Boyd	Supervisor, Contract Technical Integration
Jim Cassidy	Manager, Quality Engineering
Pete Chomentowski	Auditor
Gene Chulick	Training Manager
Hubert Dameron	Sr. Specialist, Quality Engineering
Ed Eckfeld	Technical Consultant
William Farmer	Lead Auditor
Doug Franks	QA Audits Manager
Sherrill Gibson	Records Analyst
Kelly Green	Training Specialist
Virginia Harris	Secretary (Vienna QA Manager)
Phil Horsman	Quality Support Specialist
Gary Keener	Lead Auditor
Chris Kelly	Training Specialist
Stephanie Keyser	Information Management Engineer/Indexing Manager
Bob Morgan	Vienna QA Manager
Don Nitti	Project Engineer
Meraj Rahimi	Senior Engineer
Roland Robertson	General Manager, CRWMS M&O
Virginia Sauers	Software Configuration Management
Peter Schlereth	Sr. QA Engineer
Margaret Shepherd	Local Records Center Manager
Vince Skrinak	Manager, Information Management Systems
Warren Standley	Manager, Modeling and Databases

NAME	TITLE
Angela Tayfun	Records Manager
Michelle Telenko	Records Analyst
James Tierney	Vienna Quality Support Manager
Michael Vance	Quality Management Information Systems (QMES) Administrator
George Vaslos	Lead Auditor
Paul Viggiano	QA Specialist
Doug Wiliamson	Senior Technical Associate

QAP-1-0, *M&O Organization*, dated 1/17/94

Computer file for letters of delegation (S. Gibson)
List of authors:

R. Robertson	(12)
A. Kubo	(7)
R. Godman	(6)
V. Skrinak	(3)
J. Blandford	(3)

QA files for letters of delegation (V. Harris)

R. Ruth	(3)
R. Morgan	(1)

Training and Qualification Records - position descriptions and resumes

J. Miller	A. Kubo	J. Clark
V. Skrinak	R. White	J. Coles
J. Cassidy	W. Farmer	D. Franks
G. Keener	M. Vance	P. Chomentowski

Memo to All M&O Employees from R. L. Robertson, Compliance with QA Program Requirements, dated 4-22-93

Notebook for CAR HQ-93-013 verification provided by J. Brackett on 11-23-93

QAP-2-1, *Indoctrination and Training*, dated 12/9/93

VA.QA.HCD 4/93.009, Meeting Notice for Briefing Session

Test of Briefing Session Above

Overheads for Briefing Session for QRB, dated 4/13/93

Personnel Records for 18 M&O Personnel

QAP-2-2, *Verification of Personnel Qualifications*, dated 10/30/93

G. Chulick	J. Evans	A. Mace
P. Viggiano	G. Carruth	V. Sauer
J. Watson	S. Robinson	C. Walters
P. Schlereth	E. Leonard	R. Andrews
A. Tayfun	J. Lim	M. Shepherd
P. Horsman	R. Takamatsu	H. Dameron

QAP-2-4, *Quality Assurance Program Status and Trend Reporting*, 10/30/93

Records Package Tables of Contents Data Track No. 93-09-0170 and 93-09-0172 (QAPs-5-1, R.2/5-1, R.0)

Oct/Nov Trend Analysis (IOC Memo) J. Tierney to B. Morgan, dated 12/3/93

dated 12/3/93 and 1/7/94 (12/93.014 & .1/74)

Quarterly QA Program Status & Trend Report, dated 3/31/93

Quarterly QA Program Status & Trend Report, dated 9/30/93

CAR 93-QV-C-090 (LRC No. 94-01-0006), dated 1/5/94

CAR 94-QV-C-002 (LRC No. 94-01-0010), dated 1/3/94

CARs 92-MR-C-001, 92-HR-C-007, 92-OP-C-016 and 92-QA-C-027 (LRC No. 92-03-0066)

QAP-2-5, *QA Surveillance*, dated 6/18/93

94-MRS-01, Surveillance Report - Charlotte, dated 1/11/94

93-SRS-03, Surveillance Report, dated 2/16/92

94-MRS-01, Surveillance Checklist

93-SRS-03, Surveillance Checklist

QAP-2-6, *Readiness Review*, dated 8/30/93

92-05-0045, M&O - MRS Design Readiness Review, dated 1/4/92

Readiness Review Plan for CRWMS M&O Contractor MRS Design, dated 1/22/92

MRS Design Readiness Review Attributes List, dated 1/28/92

Readiness Review Report (Team Report), dated 2/18/92

Readiness Review Report (Final Report), dated 2/18/92

94-01-001, MRS Readiness Review FY 1992/Supp. Record Pkg, dated 1/3/94

Completed Open Item Reports

QAP-2-7, *Management Assessment*, dated 4/26/93

R.L. Robertson, M&O General Manager Letter to Dr. John Bartlett, dated 3/30/92

QA Management Assessment Report, dated 8/4/93

QA Management Assessment Plan, dated 4/6/93

8193.038, Ltr. - QA M.A. - Report Distribution, dated 8/10/93

QAP-4-1, *Procurement Document Control*, dated 10/30/93
QAP-7-1, *Control of Purchased Items and Services*, dated 10/30/93

ORNL Cost Proposal to Support a Cost Reimbursable Memorandum P.O. (MPO), dated 11/13/92

QAP-5-1, *Preparation of M&O Quality Administrative Procedures*, dated 11/30/93

RTN Mark-up (for QAP-5-1 R.2) per Para. 5.4.3, dated 5/5/93

RTN Mark-up (for QAP-5-2 R.0) per Para. 5.4.3, dated 5/5/93

QAP-6-1, *Document Control*, dated 6/18/93

Controlled Document Instruction, dated 12/2/93

QAP-16-1, *Corrective Action*, dated 7/30/93

CAR 93-QN044
CAR 93-QN045
CAR 93-QN046
CAR YMP-93-045
CAR 93-QV-C-083
CAR 94-QC-C001
CAR 93-QC-012
CAR 93-QV-C-003
CAR 93-QVC-93
CAR 93-QVC-89
CAR 93-QN-052

QAP-17-1, *Record Source Responsibilities for QA Records*, dated 7/12/93
QAP-17-2, *Receipt and Handling of QA Records and Records Packages*, 7/12/93
QAP-17-5, *Indexing Quality Assurance Records*, dated 7/12/93
QAP-17-6, *Storage and Retrieval of Quality Assurance Records*, dated 7/12/93

CRWMS M&O QAP-17-1 (Att. II), Rev. 0319, List of Authenticators (QAP-17-1) Various Organizations, dated 7/12/93

Inclusions into RIS and LSS, dated 3/8/93

CRWMS M&O RPTL, Rev. 0042, Record Packages Tracking Log, dated 11/4/93

Record Signout Log, Rev. 0043, dated 11/4/93

CRWMS M&O QAP-17-1 (Att. IV), Rev. 0002, Transmittal/Receipt Acknowledgement (QAP-17-1), Various, dated 7/12/93

Batch Control Sheets

Batch Control Log

Fire Rating Certificate for Vault by Professional Service Ind., Inc., dated 5/8/92

Auditor Qualification Files (various)

Training files (various)

QAP-18-1, *Certification of Audit Personnel*, dated 12/6/93

Lead Auditor Qual. Package & Training File, Gary L. Keener

Auditor Qual., Peter J. Chomentowski

Lead Auditor Qual., William Farmer

Auditor Qual., James L. Tierney

Auditor Qual., Doug Franks

Auditor Qual., Paul Viggiano

QAP-18-2, *Audits*, dated 6/18/93

94-YMA-01, Audit of M&O Activities at YMS, dated 11/29 - 12/2/93

93-VIA-01, Audit Report of M&O - Vienna, dated 10/15/93

93-VIA-01, Audit Plan, dated 9/20/93

93-VIA-01, Audit Notification, dated 8/31/93

94-VIA-01, Audit Report of M&O - Vienna, dated 1/10/94

94-VIA-01, Audit Plan, dated 12/3/93

93-MRA-01, Audit Report of M&O - Charlotte, dated 8/13/93

94-VIA-01, Audit Notification, dated 11/5/93
93-MRA-01, Audit Plan, dated 7/12/93

93-MRA-01, Audit Notification, dated 6/16/93

Lesson Plan, M&O Auditor Training Program, dated 10/28/91

93-VIA-01, Audit Checklist

94-VIA-01, Audit Checklist

93-MRA-01, Audit Checklist

Audit Schedule (Quarterly), dated 8/3/93
Audit Schedule (Annual), dated 10/18/93

QAP-19-1, *Computer Software Verification and Validation*, dated 10/30/93
QAP-19-2, *Software Configuration Management*, dated 10/30/93
QAP-19-3, *Model Validation*, dated 10/30/93
QAP-19-4, *Software Management*, dated 12/21/93

Configuration Status Accounting Records for the following CDB versions and program elements:

CDB-F	Version 1.0	Approved for quality-affecting use 11/92
CDB-H	Version 1.0	Approved for quality-affecting use 11/92
CDB-N	Version 1.0	Approved for quality-affecting use 11/92
CDB-Q	Version 1.0	Approved for quality-affecting use 11/92
CDB-R	Version 1.0	Approved for quality-affecting use 11/92
CDB-S	Version 1.0	Approved for quality-affecting use 11/92
CDB-F	Version 1.1	Approved for quality-affecting use 9/30/93
CDB-H	Version 1.1	Approved for quality-affecting use 9/30/93
CDB-N	Version 1.1	Approved for quality-affecting use 9/30/93
CDB-Q	Version 1.1	Approved for quality-affecting use 9/30/93
CDB-R	Version 1.1	Approved for quality-affecting use 9/30/93
CDB-S	Version 1.1	Approved for quality-affecting use 9/30/93

Distribution Records for CDB Version 1.1

Copy #2	Issued to: S. Moore	Trans: 10/13/93	Acknowledgment Date: None
Copy #3	Issued to: J. Farrell	Trans: 10/13/93	Acknowledgment Date: 10/18/93
Copy #4	Issued to: D. Nitti	Trans: 10/13/93	Acknowledgment Date: 10/18/93
Copy #5	Issued to: Bentz	Trans: 10/13/93	Acknowledgment Date: 10/15/93
Copy #7	Issued to: M. Rahimi	Trans: 10/13/93	Acknowledgment Date: 10/15/93
Copy #8	Issued to: Williamson	Trans: 10/13/93	Acknowledgment Date: 10/22/93
Copy #9	Issued to: M. Fortsch	Trans: 10/13/93	Acknowledgment Date: None
Copy #10	Issued to: S. Sinnock	Trans: 10/13/93	Acknowledgment Date: 10/13/93
Copy #11	Issued to: C. Rhodes	Trans: 10/13/93	Acknowledgment Date: 10/20/93
Copy #12	Issued to: Sacks	Trans: 10/13/93	Acknowledgment Date: 10/18/93
Copy #13	Issued to: Gottlieb	Trans: 10/13/93	Acknowledgment Date: 12/14/93
Copy #14	Issued to: Smith	Trans: 10/13/93	Acknowledgment Date: 10/14/93
Copy #15	Issued to: D. Anthony	Trans: 10/13/93	Acknowledgment Date: 10/15/93
Copy #16	Issued to: R. Memory	Trans: 10/13/93	Acknowledgment Date: None
Copy #17	Issued to: E. Eckfeld	Trans: 10/13/93	Acknowledgment Date: 10/19/93

DOE Memorandum to Camille Kerrigan from Tien Nguyen, Distribution of Characteristics Databases (CDB), dated 11/30/92

ENCLOSURE 2

VERIFICATION REPORT

CAR HQ-93-013

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. HQ-93-013
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CORRECTIVE ACTION REQUEST (Continuation Page)

CAR HQ-93-013 VERIFICATION OF CORRECTIVE ACTION

VERIFICATION SUMMARY

The completion of required corrective action for CAR HQ-93-013 except for Condition 8 (QAP-3-9, *Design Analysis*, which is still being developed) was evaluated by reviewing the M&O Quality Administrative Procedures and by conducting OCRWM Surveillance HQ-SR-94-02 at the M&O location in Vienna, Va.

OCRWM Headquarters OQA has concluded, based upon the above evaluations, that the required corrective action has not been effectively completed. There continues to be examples of the QAPs not meeting the requirements of the QARD (DOE/RW-0333P) and the lack of definition for an adequate process for implementing the requirements.

Although specific examples are listed, the M&O must investigate to determine if there are similar problems that also require resolution.

ROOT CAUSE

QAP-5-1, previously identified as the root cause, was revised to provide the basis for improvement of the M&O QAPs. The results of the surveillance indicates that QAP-5-1 should be revisited in terms of the requirements to address the interface between procedures and the need for defining a sequential description of process steps within the procedure (flowcharting). Specific classroom training for procedure preparers should be considered in order to implement QAP-5-1 for preparing other procedures. Also, there is a need to determine why the Quality Review Board (QRB) did not identify these QAP inadequacies.

REMEDIAL ACTION

Except for orginal CAR HQ-93-013 Condition 8 (QAP-3-9, *Design Analysis*), which was not evaluated during the surveillance, all CAR HQ-93-013 Remedial Actions were verified as being complete. However, the following inadequate procedural conditions, found during the verification process, require further remedial action:

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Surveillance Condition 1

QARD Section 2.0, Paragraph 2.2.11D states:

Establish minimum education and experience requirements for each position commensurate with the scope, complexity, and nature of work.

QAP-2-2 implementing process for developing a position description for work subject to the QARD is unclear because the process starts with the generic M&O position description.

Surveillance Condition 2

QARD Section 2.0, Paragraph 2.2.11F states:

Ensure minimum education and experience are verified, ...

QAP-2-2 verification of education begins at the college or university level. The procedure does not address the verification of high school education (or lower) when that level of education is used as a basis for qualification to the position description.

Surveillance Condition 3

QARD Section 5.0, Paragraph 5.2.2 states:

Implementing documents shall include the following information as appropriate to the work performed:

- **B. Technical and regulatory requirements.**
- **E. Prerequisites, limits, precautions, process parameters, and environmental conditions.**
- **F. Quality verification points and hold points.**
- **H. Identification of lifetime or nonpermanent quality assurance records generated by the implementing documents.**

QAP-5-1 has not included the above requirements. The method of implementing requirement "H" is not clearly defined for each implementing document.

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CORRECTIVE ACTION REQUEST (Continuation Page)

Surveillance Condition 4

QARD Section 18.0, Paragraph 18.2.14B states:

A lead auditor shall be certified as meeting the requirements for education and experience, communication skills, training, audit participation, and passing the examination as provided in this Section.

QAP-18-1 permits Lead Auditor Certification for personnel possessing current Lead Auditor Certification without verifying the above QARD requirements and it also waives the requirements for additional auditor training.

Surveillance Condition 5

QARD Section 18.0, Paragraph 18.2.2 specifies requirements for scheduling external audits.

QAP-18-2 does not address the process for scheduling and auditing external organizations.

Surveillance Condition 6

QARD Supplement I, Paragraph I2.7.B.2. states:

Changes to baseline elements, including retirement and withdrawal, shall be formally controlled and documented.

QAP procedures for establishing controls for the retirement of software have not been addressed.

Surveillance Condition 7

QARD Section 5.0, Paragraph 5.2.2 states:

Implementing documents shall include the following information as appropriate to the work to be performed:

C. A sequential description of the work to be performed....

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CORRECTIVE ACTION REQUEST (Continuation Page)

The implementing procedure inadequately describes the sequential steps for meeting the QARD requirements as in the following examples (other procedures may have similar problems):

QAP-2-1		Some steps do not indicate "who" is responsible or do not provide enough information to determine "how" steps are to be accomplished.
	Para. 5.2.2	Procedure does not identify what to do if additional training is needed.
	Para. 5.2.5	Procedure does not identify what to do with Training Attendance Record.
	Para. 5.4.1	Responsibility for filling out Reading/Self Study record is not stated.
QAP-2-4		Some steps do not indicate "who" is responsible.
	Para. 5.2	Responsibility for preparing the report is not clear.
	Para. 5.1.6	Responsibility for selecting "CAR Groupings" is not stated.
QAP-2-5		Some steps do not indicate "who" is responsible or do not provide enough information to determine "how" steps are to be accomplished.
	Para. 5.1	Responsibility for validating qualifications of surveillance team leader is not stated.
	Para. 5.3	Responsibility for checklist approval is not stated.
	Para. 5.4.1	Method for notification is not stated.
	Para. 5.5	Responsibility for chairing the meeting is not stated.
	General	Responsibility and method for establishing the surveillance is not stated.
QAP-2-6		Some steps do not indicate "who" is responsible or do not provide enough information to determine "how" steps are to be accomplished.
	Para. 5.6.5	Process does not identify how QA Manager is to notify the General Manager.

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CORRECTIVE ACTION REQUEST (Continuation Page)

QAP-2-7		Some steps do not indicate "who" is responsible or do not provide enough information to determine "how" steps are to be accomplished.
	Para. 5.5	The procedure does not address verification of response to the recommendations.
	Sec. 6	The Follow-up Report identified in this section is not discussed in the process part of the procedure.
QAP-2-9		Some steps do not indicate "who" is responsible or do not provide enough information to determine "how" steps are to be accomplished.
	Para. 5.3.1	Procedure does not specify method of nominating personnel to be Certified Instructors.
	Para. 5.3.2	Responsibility for completing the Instructor Certification form is not identified.
	Para. 5.4.3	Procedure does not address what the Training Manager does with the "approved" lesson plans.
QAP-4-1		Some steps do not indicate "who" is responsible and the process is not sequentially described.
	Para. 5.1.3	Responsibility for determining what constitutes the procurement document package is unclear.
	Para. 5.3.1	Paragraph refers to two different review processes.
	General	Overall procedure steps are not all sequential.
QAP-5-1		Some steps do not indicate "who" has the action.
	Para. 5.3.8&9	Responsibility for resolving mandatory comments is unclear.
	Para. 5.4.2	Responsibility for authorizing release is not stated.
	Para. 5.10.1-.3	The process for marking a copy of the RTN, having it signed by the QA Manager, and providing the information to the RTN data input specialist is not followed.

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QAP-16-1		Redundant instructions in Paragraphs 5.5 and 5.6.
	Para. 5.5.2/5.6.6	Redundant actions for "significant" and "nonsignificant" adverse conditions.
	Para. 5.5.1/5.6.5	Both paragraphs say almost the same thing regarding "intent" and "extent" of investigation.
QAP-17 series		Some steps do not indicate "who" has action and the interface between element 17 procedures is not identified.
	17.2,P3.5	Responsibility for the Fire Protection Specialist is not addressed.
	17.5 General	Subject of "Indexing" is not cross-referenced into other 17 series procedures (for example, QAP-17-2).
	17.6 General	QARD requirement for procedures to define QA records as "lifetime or nonpermanent" is not addressed until this procedure.
QAP-19 series		The interface between QAP 19 procedures is inadequate and terminology between procedures is inconsistent.
	General	Inconsistencies in terminology and position titles that confuse the interfaces between these procedures.
	General	The interface between QAPs-19-1 and -19-3 are not sufficiently defined to ensure that model validation will occur. The problem could be in the inconsistency of position titles.
	19-4,P5.5	List of criteria for determining whether acquired software is categorized as "approved" or "non-approved" is not clear as to whether only one or all the criteria must be met.

INVESTIGATIVE ACTION

The original M&O CAR HQ-93-013 response did not address "Investigation" because all QAPs were to be revised to meet the new QARD (DOE/RW-0333P). Based on the results of the verification, investigative action into all QAPs is needed to discover inadequate QARD requirement flowdown and inadequate process definition for meeting QARD requirements.

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CORRECTIVE ACTION REQUEST (Continuation Page)

The investigation should include an analysis of the relationships between all of the implementing procedures required to make the M&O Quality Assurance Program work effectively to meet the QARD requirements.

CORRECTIVE ACTION TO PREVENT RECURRENCE

The Corrective Action To Prevent Recurrence has been determined to be inadequate based on the review of the flowdown of QARD requirements and the surveillance of QAP implementation.

One primary inadequacy is in the lack of implementation and training to QAP-5-1. Another inadequacy concerns the audit and surveillance program, which has not identified the above problems. Aspects of the audit process (qualification of auditors, planning, audit reporting, and records) were found to be inadequate (Reference the above remedial action examples and the CARs issued during HQAD Surveillance HQ-SR-94-02).

The corrective action to prevent recurrence should address a plan to ensure that the procedures adequately identify requirements, interface effectively, and are adequately implemented.

CONCLUSIONS

The Headquarters Quality Assurance Division (HQAD) has reviewed the completion of corrective actions to CAR HQ-93-013 and has determined the results to be unsatisfactory for the above reasons.

In accordance with QAP 16.1, Paragraph 5.3.1e), an amended response is requested addressing those items found unsatisfactory. Please submit your response by ~~03/31/94.~~ 4/15/94 Rec 3/31/94

VERIFIED BY F. H. Lentz DATE 3/29/94

F. H. Lentz, Surveillance Team Leader

REV. 08/91

ENCLOSURE 3

HQ CARS

94-004

94-005

94-006

94-007

94-008

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[6] CAR NO. HQ-94-004
DATE: 1/21/94
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QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
M&O QAP-2-2, Rev. 2, *Verification of Personnel Qualifications*	HQ-SR-94-02
[3] Responsible Organization	**[4] Discussed With**
M&O	R. Morgan

[5] Requirement:

a. QAP-2-2, Verification of Personnel Qualifications Para 1, (Purpose) states:

"This procedure provides a method to ensure that individuals performing work subject to QARD requirements have position descriptions and that the employee's level of education and experience is verified and documented."

b. DOE/RW/0333P, Para. 2.2.11 F requires:

"Minimum education and experience to be verified."

[6] Adverse Condition:

a. The M&O did not verify education and experience prior to two QA auditors (G. Keener and P. Chomentowski) performing quality affecting work.

b. The verification of highest applicable level of education (High School) for two QA personnel was not performed.

Note: Remedial Actions were taken during the surveillance. CARs HQ-93-016 and HQ-93-019 reflect similar conditions. The response to this CAR should not only address the identified condition, but also the repetitive situation including a re-evaluation of the previously identified root cause.

[9] Does a significant condition adverse to quality exist? Yes_x_ No__ If Yes, Circle One: (A) B C	[10] Does a stop work condition exist? Yes__ No_x_ ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 4/15/94

[12] Required Actions: ☐Remedial ☒Extent of Deficiency ☒Preclude Recurrence ☒Root Cause Determination

[13] Recommended Actions:

Conduct classroom training for all affected personnel on procedure QAP-2-2.

[7] Initiator F. Bearham J. Bearham Date 1/21/94	[14] Issuance Approved by: QADD R.W. Cl... Date 3/21/94
[15] Response Accepted QAR Date	[16] Response Accepted QADD Date
[17] Amended Response Accepted QAR Date	[18] Amended Response Accepted QADD Date
[19] Corrective Actions Verified QAR Date	[20] Closure Approved by: QADD Date

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[8] CAR NO. HQ-94-005
DATE: 1/21/94
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QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
QAP 17-1, Rev. 3, *Record Source Responsibilities for QA Records*	HQ-SR-94-02
[3] Responsible Organization: M&O	[4] Discussed With: W. Farmer, C. Kelly, M. Shephard

[5] Requirement:

1. Quality Assurance Requirements & Description (QARD), DOE/RW-0333P, Rev. 0, Section 17.2.4.B., states: "Corrections to quality assurance records shall be approved by the originating organization."

2. CRWMS M&O QAP-17-1, Rev. 3, Section 5.6, states in part, "All corrected QA records shall be re-authenticated by the Record Source and shall be re-approved if applicable."

[6] Adverse Condition:

Contrary to the stated requirements, completed, authenticated, approved QA Records are being corrected and are not being re-authenticated or re-approved by the originating organization or Record Sources. In one instance, corrections were made to records by an individual other than the record source two years after they were originally completed. Examples of this condition were noted in the M&O lead auditor certification records and in numerous M&O QA training records.

[9] Does a significant condition adverse to quality exist? Yes__ No_x_ If Yes, Circle One: A B C	[10] Does a stop work condition exist? Yes__ No__ ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 4/15/94

[12] Required Actions: ☒Remedial ☒Extent of Deficiency ☒Preclude Recurrence ☐Root Cause Determination

[13] Recommended Actions:

1. Revise QAP-17-1 to more clearly define the correction, re-authentication, and approval process.
2. Conduct classroom training for all affected personnel on procedure QAP-17-1.

[7] Initiator	[14] Issuance Approved by:
J. George Date 1/21/94	QADD R.W. Clark Date 3/29/94
[15] Response Accepted	[16] Response Accepted
QAR Date	QADD Date
[17] Amended Response Accepted	[18] Amended Response Accepted
QAR Date	QADD Date
[19] Corrective Actions Verified	[20] Closure Approved by:
QAR Date	QADD Date

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[8] CAR NO. HQ-94-008
DATE: 1/21/94
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CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
QAP-18-2, Audits, Rev. 2, QAP-2-5, Rev. 2, QA Surveillance	HQ-SR-94-02
[3] Responsible Organization: M&O Quality Assurance	[4] Discussed With: R. Morgan, W. Farmer

[5] Requirement:

1. QAP-18-2, Para. 5.5.3 requires that objective evidence be examined to the depth necessary in order to determine if the elements are being implemented effectively. Also, Attachment I, Item IV (Summary of Audit Results) requires that the audit report summarize the documents reviewed and the specific results of the reviews and interviews. The summary should make the reader aware of the activities of the audit team and support the findings (i.e. a summary of the checklist contents).

2. QAP-2-5, Attachment I, Item IV (Summary of Surveillance Results) requires that the report provide a detailed summary of the activities surveyed, processes monitored, and documentation of records reviewed.

[6] Adverse Condition:

Contrary to the above, a sample of M&O audit and surveillance reports do not contain all the necessary objective evidence to support the reviews and interviews conducted during the audit. The following are examples of audit and surveillance reports reviewed and how objective evidence is not stated in those reports.

a. In audit report 93-VIA-01 for Element 2 no objective evidence is listed for review of training. A review of the checklist revealed that the Training List was reviewed. For Element 16, it was noted in the checklist that the Corrective Action Request (CAR) status logs for both Vienna (VA. QA. JLT.09/93.008) and Las Vegas (LV. QA. BRJ.09/93.239) were reviewed. This was not documented in the report as objective evidence reviewed. Additionally, other examples which were reviewed in the area of qualifications and not documented in the report were thirty (30) position descriptions, thirty (30) reading/self-study records (M&O and DOE OCRWM and five (5) certifications. Other similar examples exist in this section. (Continued on Page 2)

[9] Does a significant condition adverse to quality exist? Yes_x_ No__ If Yes, Circle One: (A) B C	[10] Does a stop work condition exist? Yes__ No_x_ ; If Yes-Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 4/15/94

[12] Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

[13] Recommended Actions:

1. Retrain all affected personnel in audit and surveillance report preparation.
2. Retain the completed checklists as non permanent QA records.
3. For subsequent audits, review checklists as well as the audit report for follow-up action to ensure that adequate information is in the audit report.

[7] Initiator R. G. Peck [signature] Date 1/21/94	[14] Issuance Approved by: QADD R.W. Cl[illegible] Date 3/29/94
[15] Response Accepted QAR Date	[16] Response Accepted QADD Date
[17] Amended Response Accepted QAR Date	[18] Amended Response Accepted QADD Date
[19] Corrective Actions Verified QAR Date	[20] Closure Approved by: QADD Date

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[8] CAR NO. HQ-94-006
DATE: 1/21/94
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[6] Adverse Condition (continued):

a. (continued)

For Element 19, objective evidence is stated as seven (7) Software Baseline Forms, three (3) Document Change Notifications, seven (7) Open Software Problem Reports and thirteen (13) Closed Software Problem Reports. No specifics (numbers, identifications, etc.) were stated to clearly identify what was reviewed.

b. In Audit Report 93-MRA-01 for Element 2, objective evidence refers to position description, verification of education and experience, indoctrination and training (M&O and DOE OCRWM) and certifications. There are no specifics as to who and what was reviewed. For Element 6 the report refers to "controlled documents including QAP Manuals (8,100% sample)." No details are provided as to which manuals were reviewed. For Element 17 the report refers to the review of 12 records packages and the interview of 5 individuals. No specifics are provided.

c. In Audit Report 94-VIA-01 for Element 1, the report refers to the selection of five (5) management positions for analysis versus position descriptions and verification of education and work experience. For Element 17 the summary refers to ten QA records packages, one audit report and two CARs as objective evidence reviewed. No specifics are provided for the above. Other examples exist in the report.

d. In Surveillance Report 94-MRS-01 for Section IV (Summary of Surveillance Results) some objective evidence is stated as follows.

1. CDR, Volume IIA MPC and 20 related DRRs
2. CDR, Volume IIB, Transportation Cask CDR, and 7 related DRRs
3. 47 DRRs were selected

No reference is made to which DRRs were specifically reviewed.

e. In Surveillance Report 93-SRS-03, the specific QAPs reviewed are not identified (refers to the QAP Manual only).

Note: CAR HQ-93-021 reflects similar conditions. The response to this CAR should not only address the identified condition, but also the repetitive situation including a re-evaluation of the previously identified root cause.

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CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
QAP 19-4, Rev. 1 - PCN 1 - Rev. 1, Software Management	HQ-SR-94-02
[3] Responsible Organization	**[4] Discussed With**
M&O	V. Sauers/R. Morgan

[5] Requirement:

Para. 5.4.3.4 of QAP-19-4 requires user organizations to establish procedures for controlling the use of software. These controls include reviews to ensure that the software is applicable to the problem being solved.

[6] Adverse Condition:

3 of 3 user organizations interviewed did not have procedures in place as required, even through this requirement was also included in the M&O CSQAP which preceded QAP-19-4. These organizations (and others) have multiple versions of a configuration-managed computer program in their possession. The procedure and the documented evaluation to select the applicable version is needed.

[9] Does a significant condition adverse to quality exist? Yes__ No_X_ If Yes, Circle One: A B C	[10] Does a stop work condition exist? Yes__ No__ ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 4/15/94

[12] Required Actions: ☒Remedial ☒Extent of Deficiency ☐Preclude Recurrence ☐Root Cause Determination

[13] Recommended Actions:

Consider proceduralizing whether certain circumstances warrant dispositions of previously issued software by the M&O issuing organization, rather than by the M&O or outside M&O user organizations.

[7] Initiator M. Donovan F. H. Hentz for Date 1/21/94	[14] Issuance Approved by: QADD R.W. Clap Date 3/29/94
[15] Response Accepted QAR Date	[16] Response Accepted QADD Date
[17] Amended Response Accepted QAR Date	[18] Amended Response Accepted QADD Date
[19] Corrective Actions Verified QAR Date	[20] Closure Approved by: QADD Date

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[5] CAR NO. HQ-94-008
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CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
M&O QAP-16-1, Rev. 1, *Corrective Action*	HQ-SR-94-02
[3] Responsible Organization: M&O QA Department	[4] Discussed With: J.L. Tierney

[6] Requirement:

A) M&O QAP-16-1, Para. 5.6.2 requires the QA Representative (QAR) to concur with proposed corrective action including remedial action. Para. 5.6.5 requires verification of corrective actions.

B) M&O QAP-16-1, Para. 5.6.7 requires the QAR to ensure that all action to prevent recurrence and remedial actions have been completed and that all documentation is satisfactory.

C) M&O QAP 16-1 Para. 5.5.1 requires interfacing managers to investigate and document the results of the investigation for CARs not classified as "significant".

[6] Adverse Condition:

A. The M&O QAR concurred with the response to M&O CAR 93-QL-C-003, designated as a significant condition adverse to quality, without considering the following:

A1. The root cause was identified as a procedural inadequacy when, in fact, the adverse condition was attributable to manual holders failing to maintain their manuals in a current condition.

A.2 Planned Remedial and Corrective Actions were not presented in separate fields as required by QAP-16-1, paragraph 5.6.3, and they included two recommendations. Paragraph 5.6.3 requires a statement of Corrective Action rather than recommendations. (Continued on Page 2)

[8] Does a significant condition adverse to quality exist? Yes_x_ No__ If Yes, Circle One: A (B) C	[10] Does a stop work condition exist? Yes__ No_x_ ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 4/15/94

[12] Required Actions: ☒Remedial ☒Extent of Deficiency ☒Preclude Recurrence ☒Root Cause Determination

[13] Recommended Actions:

a) Conduct classroom training for all affected personnel on procedure QAP-16-1.
b) Provide additional direction to Quality Assurance Representatives (QARs) regarding the format and degree of detail required for verifying completion of corrective action for adverse conditions identified in CARs.
c) Provide additional direction to Interfacing Managers regarding requirement of QAP-16-1, paragraph 5.5.1.

[7] Initiator F. Bearham F.H. Bearham for Date 1/21/94	[14] Issuance Approved by: QADD R.W. Cle Date 3/29/94
[15] Response Accepted QAR Date	[16] Response Accepted QADD Date
[17] Amended Response Accepted QAR Date	[18] Amended Response Accepted QADD Date
[19] Corrective Actions Verified QAR Date	[20] Closure Approved by: QADD Date

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[6] Adverse Condition (continued):

B. The verification of the Corrective Action was inadequate. The verification stated that the Corrective Action was complete, however:

1) Classroom training was committed to, but not conducted;
2) Examples of PCNs were not included in the next revision of QAP-5-1 as committed by the CAR response;
3) A surveillance at the M&O Vienna office was committed to, but not conducted; and
4) CAR 93-QN-C-052, verified as tracking the Las Vegas deficiency, was not available in its complete form at the time of CAR 93-QL-C003 verification. The continuation sheet for CAR 93-QN-C-052 describing the adverse condition, was received at the Vienna office during the OCRWM surveillance.

C. M&O CARs 93-QN-C-027 and 048 did not address any investigative action.

Note: Subsequent to the Surveillance HQ-SR-94-02, which generated this CAR, M&O CAR-94-QV-C-008 was issued concerning this adverse condition. Three additional CARs lacking investigative action were identified.

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ATTACHMENT III

Format for Corrective Action Response

The CAR response shall include the following information:

1. Corrective Action Response for CAR # _____

   A. Remedial Action - Actions taken to correct specific deficiencies noted.

   (Required for all CARs)

   B. Investigative Action - Actions taken to determine the extent of the condition.

   (Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)

   C. Root Cause Determination - Identification of the root cause of the condition.

   (Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)

   D. Corrective Action to Preclude Recurrence - Actions taken to address the root cause and preclude recurrence of the condition.

   (Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)

2. For each action above, identify the name of the individual assigned responsibility for completion and the anticipated (or actual, if complete) completion date.

3. Response Approved: _____ Date: _____
   Responsible Manager