# MINUTES OF THE APRIL 25, 1991, QUALITY ASSURANCE MEETING

A meeting of the staff of the U.S. Nuclear Regulatory Commission (NRC) and representatives of the U.S. Department of Energy (DOE), the State of Nevada (NV), and affected units of local governments to discuss items of mutual interest with regard to quality assurance (QA) was held at the NRC Headquarters, Rockville, Maryland on April 25, 1991. An attendance list is included as Attachment 1. At the meeting, DOE presented information on the following seven topics: 1) QA workshops; 2) an update on audit/surveillance schedules; 3) QA grading; 4) root cause determination; 5) Office of Civilian Radioactive Waste Management (OCRWM) QA Program for Monitored Retrievable Storage (MRS) and Transportation; 6) revamping audits; and 7) QA procedure consolidation. The NRC staff presented observation summaries of the DOE/OCRWM Audit No. 90-I-01, the Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) Audit No. 90-08, the Koh Systems, Inc. (KOH) Audit No. HQ-91-001, the Reynolds Electrical and Engineering Company, Inc. (REECo) Audit No. 91-02, the Technical Requirements Document YMP/CM-007, Revision 2 Surveillance (YMP-SR-91-006), the OCRWM Surveillance (HQ-SR-91-002), the Los Alamos National Laboratory (LANL) Surveillance (YMP-SR-91-008), and the Raytheon Services Nevada (RSN) Surveillance (YMP-SR-91-01). In addition, the NRC staff also presented the status of the QA Open Items.

DOE began by providing an update of the QA workshops and discussed the status of action items from the Scientific QA, Software QA, and Data Concerns workshops. These workshops created advisory groups, such as the Quality Integration Group (QIG) and the Software Advisory Group (SAG). The QIG is already functional, and its charter includes, among other things, resolving issues and concerns between the scientific and QA areas, developing guidance on an integrated QA program and eliminating Sections 19 and 20 from the Quality Assurance Requirements Document (QARD). The QIG was scheduled to meet on May 12, 1991, at the Lawrence Livermore National Laboratory in Livermore, CA. The SAG was to meet in Las Vegas, Nevada April 25 and 26, 1991 to develop its charter and a list of action items. DOE indicated that summaries and notes from these workshops and group meetings are sent to the NRC, State of Nevada, and the affected units of local governments.

Next, DOE presented the updated revisions of the DOE/Yucca Mountain Site Characterization Project Office (YMPO) audit and surveillance schedules. The YMPO audit schedule, Revision 3 was dated April 15, 1991, and provided the audit number, dates of the audit, and the name of the audit team leader for each of the organizations on the 1991 audit schedule. DOE also indicated that the DOE audit (HQ-91-002) of DOE's Office of the Environmental Restoration and Waste Management, scheduled for June 3-7, 1991, may be postponed until further notice. The YMPO surveillance schedule, Revision 7, was dated April 4, 1991. DOE stated that the YMPO surveillance schedule is revised and updated on a monthly basis. The DOE/YMPO audit and surveillance schedules are provided as Attachments 2 and 3, respectively.



ENCLOSURE

The next item on the agenda was a presentation by the NRC staff on its observations of the DOE/YMPO audits of DOE/OCRWM, SAIC/T&MSS, KOH and REECo, and DOE/YMPO surveillances of the Technical Requirements Document, Revision 2 (YMP/CM-007), OCRWM, LANL, and RSN (see Attachment 4). The NRC staff did not identify any findings relating to either the DOE/YMPO audit or surveillance process for the above mentioned audits and surveillances. The NRC staff also did not issue any findings relating to the audited organizations' QA programs. The staff reported that all of these audits and surveillances were useful and effective.

The NRC staff then gave a presentation of the status of QA Open Items (See Attachment 5). The status of the QA Open Items was presented in the new format that was agreed upon between NRC, DOE, State of Nevada and the units of affected local governments. The status of Open Item 3-90, "NNWSI Core Handling Procedures," remained unchanged from the January 18, 1991 QA Meeting and the item is still open. For Open Items 4-90, 9-90 and 10-90 (10.d), some progress has been made for closure; however, these items still remain open. The status of Open Items 10-90 (10.a, 10.b, and 10.c), 11-90, and 12-90 remained unchanged from the January 18, 1991 meeting. A new Open Item, 1-91 "Acceptance of OCRWM QARD/QAPD for MRS and Transport of Spent Fuel" has been added to the QA Open Items List. In response to a question regarding Open Item 11-90, DOE stated that the open items regarding the Fenix and Scisson, Nevada and Holmes and Narver QA programs are applicable to the RSN QA program and will be addressed in this program.

Next, DOE provided a discussion about QA grading. DOE stated that the QA grading packages for different quality affecting activities are being received by the YMPO and are being presented to the Quality Review Board (QRB) for its review and acceptance. DOE also stated that a workshop on QA grading was held in Las Vegas, Nevada during the week of April 1, 1991. The grading process was discussed in detail at this workshop. The workshop summary and action items were presented to DOE QA and Project Management. The workshop participants recommended that the current YMP procedure for grading be revised. DOE also stated that a DOE/participants meeting is scheduled for May 13 and 14, 1991, for further discussions about the workshop on QA grading.

DOE then provided a brief update on OCRWM QA programs for MRS and transport of spent fuel. DOE stated that a Management and Operations (M&O) contractor will be dealing with this activity. Many of the M&O personnel have been trained and will work to OCRWM procedures. The M&O is in a process of preparing and implementing procedures especially in the design area. The M&O contract personnel are currently performing support functions in MRS and transport of spent fuel. DOE offered a more detailed presentation by the OCRWM in the areas of MRS and transport at the next QA meeting. The NRC staff distributed copies of a letter the staff received from Lincoln County (see Attachment 6) expressing their interest to stay informed about the transport issues. NRC believes that DOE should make sure that Lincoln County is on distribution for all DOE documents regarding the transport of spent fuel that are sent to NRC.

The NRC staff also gave the status or its review of the OCRWM QARD and Quality Assurance Program Description for MRS and Transport of Spent Fuel and distributed copies of an acceptance letter from NRC, dated April 15, 1991 (see Attachment 7).

DOE then gave a brief presentation of the status of Root Cause Determination (RCD). DOE indicated that this topic was discussed in detail between the YMPO QA management and the YMP participant QA managers at the March 5, 1991, meeting (see Attachment 8). DOE further stated that there are plans to provide training to the participant representatives who will then provide training to the applicable personnel. The training will focus on defining root cause, defining responsibilities and determining when RCD is required.

DOE then discussed its plans and format for "revamping" of audits. The new OCRWM/YMPO audits of their participants will be of reduced scope. Each participant's QA program will be covered in three audits each year and each audit will be limited to a maximum of 7 criteria. Technical areas will only be covered in conjunction with Criteria 3 and 20. DOE stated that they plan to start these new audits in the beginning of FY-92. There is a plan to revise Quality Assurance Administrative Procedure, QAAP 18.2 to accommodate these changes (see Attachment 9).

The last topic for discussion was DOE's update on OCRWM/YMPO procedure consolidation. A DOE group is working on the procedure consolidation effort and a plan has been developed for consolidating different types and levels of procedures into fewer and easier to implement procedures.

Following this, the NRC invited closing remarks from the meeting participants. The Nye County representative expressed an interest in attending a QRB meeting. A tentative date of June 25, 1991, was noted for the next DOE/NRC QA meeting. The meeting was then adjourned.

Tilak R. Verma 6/12/91

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Repository Licensing and Quality
Assurance Project Directorate
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Corinne J. Macaluso

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Repository Licensing Branch
Office of Civilian Radioactive
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QA BI-MONTHLY MEETING
APRIL 25, 1991

| NAME | ORGANIZATION | PHONE NO. |
|---|---|---|
| Teek Verma | NRC | (301)492-3465 |
| Ken Hooks | NRC | (301)492-0447 |
| Bill Belke | NRC | (301)492-0445 |
| Donald G. Horton | DOE | (202)586-7220 |
| Clyde N. Morell | DOE | (703)276-9300 |
| Susan Zimmerman | State of Nevada | (703)687-3744 |
| Ray Wallace | USGS/HQ | (202)586-1244 |
| Stan Echols | Winston & Straw | (202)371-5777 |
| Sharon Skuchko | DOE | (202)586-4590 |
| Tom Colandrea | Edison Electric | (619)487-7510 |
| Pat LaPlante | CNWRA | (703)979-9129 |
| Corinne Macaluso | DOE | (202)586-2837 |
| Jim Blaylock | DOE | (702)794-7913 |
| Philip A. Niedzielski-Eichner | Nye County | (703)818-2434 |
| Carl Gertz | DOE OGD/YMP | (702)794-7520 |
| Steve Rossi | DOE | (202)586-9433 |
| Nello Del Gobbo | DOE | (202)586-5492 |

Attachment 1

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AND

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE
FY-91 AUDIT SCHEDULE* REVISION 3

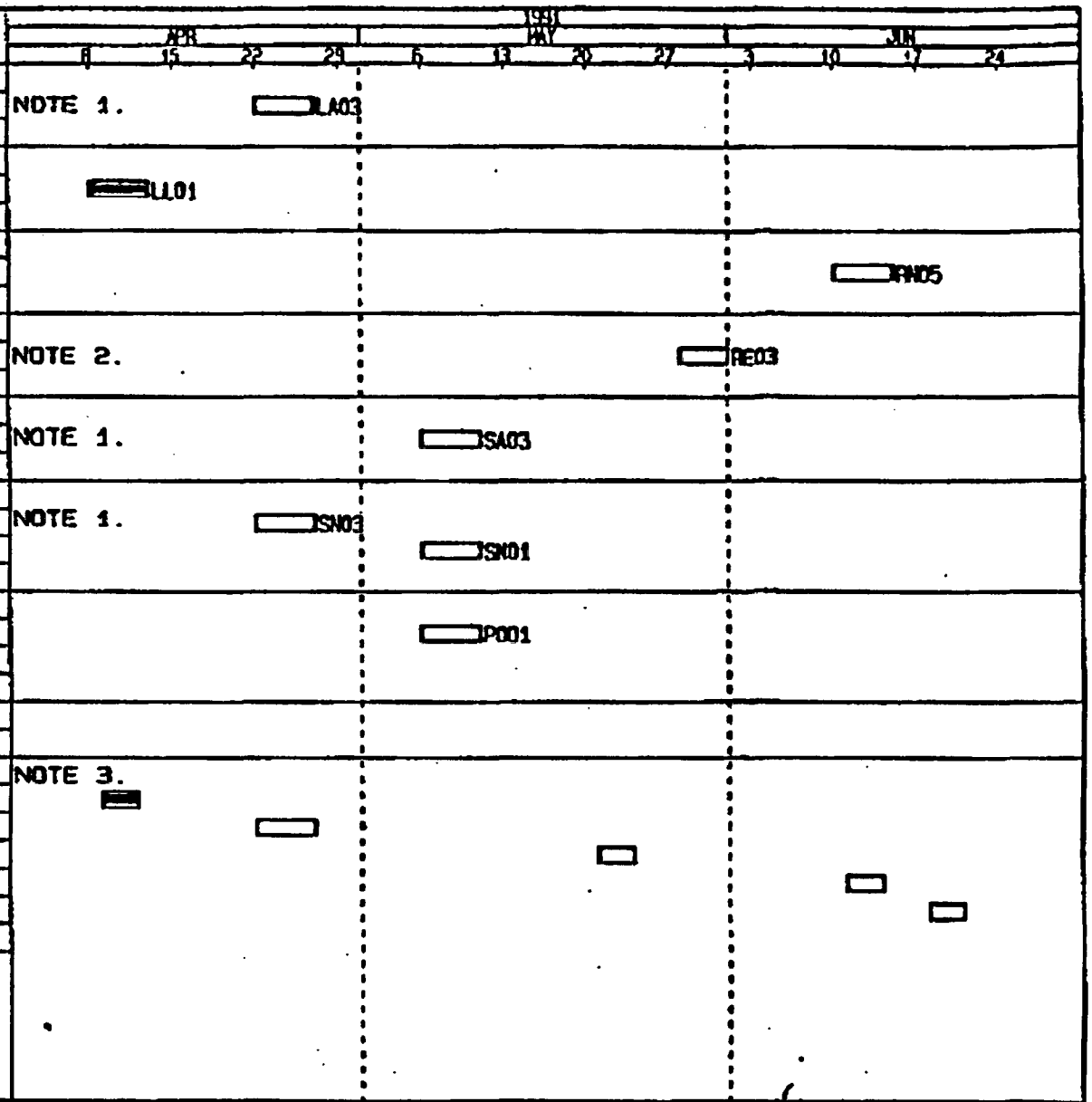
| ORGANIZATION | AUDIT NUMBER | DATE OF AUDIT | AUDIT TEAM LEADER |
|---|---|---|---|
| REECo | YMP-91-02 | Feb. 25-28 | Robert H. Klemens |
| LANL | YMP-91-03 | March 25-29 | Richard E. Powe |
| RTTD | HQ-91-003 | April 29 - May 3 | Norman C. Frank |
| USGS | YMP-91-05 | May 20-24 | Charlie C. Warren |
| EM | HQ-91-002 | June 3-7 (1) | James J. George |
| LLNL | YMP-91-01 | June 3-7 | Frank J. Kratzinger |
| SAIC | YMP-91-06 | June 17-21 | Richard L. Mandlin |
| YMPO | YMP-91-I-01 | July 8-12 (2) | Richard E. Powe |
| Raytheon | YMP-91-04 | July 29 - Aug. 2 | Stephen R. Dana |
| SNL | YMP-91-07 | August 19-23 | Neil D. Cox |
| OCRWM-HQ | HQ-91-004 | Sept. 9-13 | Tom Rodgers |
| PNL-MCC | Delayed Until Further Notice (3) | | |
| EG&G | To Be Determined (3) | | |

* All applicable 20 criteria plus implementing procedures

(1) Delayed due to conflict with holiday.
(2) Moved up to avoid conflict with TRB meeting.
(3) Equivalent to a Qualification Award Survey.

Attachment 2

| REPT | ACTIVITY DESCRIPTION | EARLY START | EARLY FINISH |
|---|---|---|---|
| LOS ALAMOS NATIONAL LABORATORY | | | |
| | CRITERIA 2 | 22APR91 | 26APR91 |
| LAWRENCE LIVERMORE NATIONAL LABORATORY | | | |
| | CRITERIA 4,7,2,18 | 8APR91 | 12APR91 |
| RAYTHEON | | | |
| | CRITERIA 1,5,16,18 | 10JUN91 | 14JUN91 |
| REYNOLDS ELECTRICAL AND ENGINEERING CO. | | | |
| | CRITERIA 2,5,6 | 28MAY91 | 31MAY91 |
| SAIC/TEMSS | | | |
| | CRITERIA 2 | 6MAY91 | 10MAY91 |
| SANDIA NATIONAL LABORATORY | | | |
| | CRITERIA 2 | 22APR91 | 26APR91 |
| | CRITERIA 2,16,18 | 6MAY91 | 10MAY91 |
| P.G. | | | |
| | CRITERIA 2 | 6MAY91 | 10MAY91 |
| U.S.GEOLOGICAL SURVEY | | | |
| OCRWM/HQ | | | |
| | CRITERIA 18 | 9APR91 | 11APR91 |
| | CRITERIA 16 | 22APR91 | 26APR91 |
| | CAR VERIFICATION | 21MAY91 | 23MAY91 |
| | CRITERIA 5 | 11JUN91 | 13JUN91 |
| | CRITERIA 3 | 18JUN91 | 20JUN91 |




NOTES:
1. TITLE II REVIEW PROCESS ONLY.
2. RESCHEDULED.
3. H.Q.SCHEDULED SURVEILLANCE.

Activity Bar/Early Dates
Critical Activity
Progress Bar
Primavera Systems, Inc.

DEPARTMENT OF ENERGY
SURVEILLANCE SCHEDULE W/ORG
FY-91 STATUS, REV 8

Sheet 1 of 1

Project Start : 1OCT89
Project Finish: 30SEP91A

Data Date: 1APR91
Plot Date: 22APR91

N Voltura for DG Horton 4/22/91
APPROVED DATE

Attachment 3

OBSERVATION AUDIT OF THE U.S. DEPARTMENT OF ENERGY (DOE)
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

From October 15-19 and October 22-26, 1990, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE) Office of Civilian Nuclear Waste Management (OCRWM) Headquarters (HQ)/Yucca Mountain Project Office (YMPO) Quality Assurance (QA) Internal Audit No. 90-I-01 of HQ in Washington, D.C. and YMPO in Las Vegas, Nevada.

The NRC staff based its evaluation of the HQ/YMPO audit process and the OCRWM QA program on direct observations of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., audit plan, checklists, HQ and YMPO documents). The audit was conducted in a professional manner, and the programmatic and technical portions of the audit were generally effective and well integrated. The audit team was well qualified in the QA discipline, and their assignment and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary finding of the audit team that the OCRWM QA program has adequate procedural controls in place for the areas that were audited. However, the number of areas in which the HQ/YMPO audit team identified the OCRWM QA program as ineffective or indeterminate is of concern to the NRC staff, particularly the areas of audits and corrective actions at HQ and the technical baseline documents at both HQ and YMPO. The NRC staff fully supports the audit team's recommendations of actions to be taken to verify the effectiveness of corrective actions prior to the start of any new site characterization activities.

OCRWM management must closely monitor HQ and YMPO implementation of the OCRWM program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own audits of HQ and YMPO at a later date to independently determine the adequacy and effectiveness of the QA program.

(a) Observations

The NRC staff did not identify any observations relating to deficiences in either the audit process or the other elements of OCRWM QA program implementation.

(b) Weaknesses

Some auditors appeared to spend a disproportionate time conducting interviews rather than evaluating objective evidence, especially during the HQ portion of the audit (Refer to Section 5.3(a)).

The NRC staff believes that the timing of the audit was less than optimal. In some cases, audit checklists were revised up to and after the start of the audit to incorporate requirements from procedures issued just prior to the start of the audit. Further, due to the recent reorganization within HQ, the auditors in several instances were obligated to interview both the personnel currently assigned and those formerly assigned to various functions (Refer to Sections 5.2 and 5.3(c)).

Several of the auditors were OCRWM HQ (or HQ contractor) personnel, and on more than one occasion they appeared more knowledgeable of the activity being audited than the individual being interviewed. These auditors may have been of greater value as auditees. Otherwise, OCRWM and contractor personnel appeared to be competent and generally familiar with QA requirements and their respective responsibilities (Refer to Section 5.3(c)).

A preliminary effectiveness conclusion concerning Criteria 4 and 7 presented by an auditor during a status meeting did not appear to be well supported by the available objective evidence (Refer to Section 5.3(e)).

No annual management assessment of the HQ QA program was performed (Refer to Section 5.3(a)). This is similar to findings from previous audits of High Level Waste (HLW) repository program participants.

The HQ QA Division was not completely staffed prior to and at the time of the audit (Refer to Section 5.3(a)).

There were indications that training was inadequate in some areas (Refer To Sections 5.3(b) and (c)).

No trending analyses had been performed (Refer to Section 5.3(g)). This is similar to findings from previous audits of HLW repository participants.

The HQ CA program did not result in timely and effective closure of conditions adverse to quality (Refer to Section 5.3(g)). This is similar to findings from previous audits of HLW repository participants.

There appeared to be inadequate review of DRs and CARs for root cause and generic implications (Refer to Section 5.3(g)). This is similar to findings from previous audits of the HLW repository program.

The HQ program for internal audits/surveillances was inadequate and ineffective (Refer to Section 5.3(i)). This is similar to findings from previous audits of the HLW repository program.

The problems identified by the audit team with the WMSR Vol. IV and the YMP/CM-0007, Rev. 1 indicates additional management attention is needed in these technical activities (Refer to Section 5.3(c)).

Based on the above, the NRC observers determined that OCRWM management had not adequately evaluated the results of prior audits of the HLW repository program and applied the lessons learned from these audits to the OCRWM QA program.

(c) Good Practices

In general, the auditors and technical specialists used well researched and detailed checklists and extended their investigations beyond the checklists when appropriate. Integration of programmatic and technical portions of the audit was effective due to the simultaneous conduction of the programmatic audits of Criteria 3 and 20 with the technical evaluations.

Daily caucuses were held between auditors and observers, and daily meetings were held between OCRWM management and the Audit Team Leader to discuss potential findings. Auditors identifying potential findings were included in these status meetings to more clearly explain deficient conditions and allow for resolution during the audit as much as possible. Findings were well substantiated and reflected significant rather than trivial issues. The audit team also did a good job of answering observer questions as they were raised.

OBSERVATION AUDIT OF SCIENCE APPLICATIONS INTERNATIONAL CORPORATION/ TECHNICAL & MANAGEMENT SUPPORT SERVICES

From November 13 through 16, 1990, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE)/Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit NO. 90-08 of Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) contractors in Las Vegas, Nevada, and at the Nevada Test Site (NTS). SAIC/T&MSS, a participant in the Yucca Mountain Project (YMP), is responsible for the environmental and radiological monitoring activities for the YMP. This report addresses the NRC staff's assessment of the effectiveness of the OCRWM audit and, to a lesser extent, the adequacy and effectiveness of the SAIC/T&MSS QA program.

The NRC staff based its evaluation of the OCRWM audit process and the SAIC/T&MSS QA program on direct observations of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., audit plan, checklists, and SAIC/T&MSS documents). Although there was a limited amount of work being conducted by SAIC/T&MSS under the QA program and the SAIC/T&MSS has been a YMP participant for a limited period of time, the NRC staff has determined that, overall, OCRWM Audit No. 90-08 of SAIC/T&MSS was of appropriate scope and achieved its purpose of determining the adequacy and effectiveness of the SAIC/T&MSS QA program. The audit of the criteria observed was conducted in a professional manner, and the programmatic and technical portions of the audit were generally effective and well integrated. The audit team was well qualified in the QA discipline, and their assignment and checklist items were adequately described in the audit plan.

The audit was well organized and was run with minimal logistic delays. The only difficulty encountered was at NTS where there were more auditors and observers than the SAIC/T&MSS personnel to answer questions and to act as escorts to various areas at the site. This caused some audit delays and frustration. The team leader kept the caucuses brief, but did allow sufficient time for the auditors to express concerns or seek clarification from other auditors. Concerns and questions raised by the observers were addressed during the caucus when possible, or during the following day.

The NRC staff agrees with the audit team's preliminary findings that SAIC/T&MSS has an adequate QA program for most of the areas that were audited, and the SAIC/T&MSS QA program, for the most part, has sufficient controls in place to perform work related to the radiation and environmental monitoring for the YMP. The acceptability of the technical products reviewed by the OCRWM audit team were not evaluated by the NRC staff since technical specialists were not a part of the NRC observation team. The NRC staff also agrees with the OCRWM audit team's conclusion that there was an effective implementation of the SAIC/T&MSS QA program in most areas audited by the audit team. However, in other areas audited, there has been minimal activity since May 1990, therefore, adequacy of implementation in these areas was indeterminate.

(a) Observations

The NRC staff did not identify any observations relating to deficiencies in either DOE/OCRWM audit process or the SAIC/T&MSS QA program.

(b) Weaknesses

The NRC staff did not identify any weaknesses relating to either the OCRWM audit process or the SAIC QA program.

(c) Good Practices

The audit team was well prepared and conducted a thorough audit in a professional manner.

Improved coordination of the QA programmatic and technical reviews and evaluations simultaneously to allow the integration of these two aspects of the audit.

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-4
FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. OCRWM HQ-91-001 OF KOH SYSTEMS, INC.

From January 7 through 11, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. OCRWM HQ-91-001 of Koh Systems, Inc. (KOH), conducted in Washington, D.C.

The NRC staff based its evaluation of the OCRWM audit process and the KOH QA program on direct observation of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., the audit plan, checklists, and KOH documents). The NRC staff has determined that, overall, Audit No. OCRWM HQ-91-001 of KOH achieved its purpose of determining the adequacy of the KOH QA program implementation. The audit was conducted in a professional manner. The audit team was well prepared and their checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary OCRWM audit team findings that KOH generally has an adequate QA program; however, the NRC staff is concerned about the lack of OCRWM and KOH management attention given to identified training deficiencies and filling the KOH QA Manager position.

OCRWM should monitor the KOH program to ensure that deficiencies identified during this audit are corrected and future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to assess the adequacy and effectiveness of the KOH QA program.

(a) Observations

The NRC observer did not identify any observations relating to deficiencies in either the OCRWM audit process or the KOH QA Program.

(b) Weaknesses

(1) The NRC staff believes it is important for the senior management of the audited organization to be present during the daily audit team briefing for the audited organizations' management. It is particularly important for the senior management to attend the entrance and exit meetings, even if it requires rescheduling the audit. The KOH Project Manager was absent from the entire audit with the exception of the exit meeting. Further, although the KOH Division Director was available he did not attend the entrance meeting and one of the audit team/KOH management briefings. The OCRWM Technical Project Officer (TPO) was not present at any of the audit team/KOH management briefings.

(2) During the audit it was determined that from July 19 through August 20, 1990 and September 20 through December 1, 1990 KOH had no QA Manager nor acting QA Manager (see Section 5.3(a)). The NRC staff understands that KOH was actively trying to fill the QA Manager's position during this time period. However, the staff is concerned that KOH upper management did not recognize the need to appoint an acting QA Manager to oversee the QA program.

(3) The inability of KOH upper management to complete required QA reading assignments in a timely manner was recognized and documented in at least three Training and Indoctrination Status Reports, and yet management took no action to resolve the deficiency (see Section 5.10, CAR HQ-91-014). This deficiency was not acted upon by the OCRWM TPO in charge of the KOH contract.

(4) The exit meeting presentations could have been improved. A summary of the audit scope, visual presentation of criteria evaluated and associated findings, and effectiveness summaries for each criteria would have enhanced the level of understanding between the audit team and KOH management (see Section 5.5).

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 91-4

FOR THE OFFICE OF CIVILIAN

RADIOACTIVE WASTE MANAGEMENT

AUDIT NO 91-02 OF

REYNOLDS ELECTRICAL AND ENGINEERING COMPANY, INC.

From February 24-28, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. 91-02 of Reynolds Electrical and Engineering Company, Inc. (REECo), conducted in Las Vegas, Nevada and at the Nevada Test Site.

The NRC staff based its evaluation of the OCRWM audit process and the REECo QA program on direct observation of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., the audit plan, checklists, and REECo documents). The NRC staff has determined that, overall, Audit No. 91-02 of REECo achieved its purpose of determining the adequacy of the REECo QA program implementation. The audit was conducted in a professional manner. The audit team was well prepared and their checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary OCRWM audit team findings that REECo generally has an adequate QA program in the areas of Instructions, Procedures, Plans and Drawings (Criterion 5), and Document Control (Criterion 6). The NRC staff also agrees with the audit team findings that the REECo QA program is marginally adequate in the area of Quality Assurance Program (Criterion 2) and inadequate in the areas of Organization (Criterion 1), Control of Measuring and Test Equipment (Criterion 12), Quality Assurance Records (Criterion 17), and Audits (Criterion 18).

OCRWM should monitor the REECo program to ensure that deficiencies identified during this audit are corrected and future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to assess the adequacy and effectiveness of the REECo QA program.

(a) Observations

The NRC observers did not identify any observations relating to deficiencies in either the OCRWM audit process or the REECo QA program.

(b) Weaknesses

There appears to be a lack of understanding of the QA procedures on the part of the REECo calibration laboratory staff. It was apparent on several occasions during the audit of Criterion 12 that the calibration laboratory staff were not as familiar with the calibration procedures as they should have been. However, there is no indication that this unfamiliarity has in any way jeopardized the quality of the data being collected. Although the NRC staff believes that the calibration laboratory is competent in performing calibrations, we are concerned because current calibration activities are inconsistent with the procedures in affect. (See Section 5.3(g)).

(c) Good Practices

The NRC observers believe the use of worksheets is a good practice. In reviewing several documents against the same checklist requirements, auditors evaluating Criteria 5, 6, 17 and 18 utilized worksheets to more efficiently record their results. Thus, the auditors were able to maximize the amount of time actually spent reviewing objective evidence.

# SURVEILLANCE OBSERVATION REPORT NO. 91-S1

The YMPO quality assurance (QA) organization conducted a QA surveillance (YMP-SR-91-006) of Technical Requirements Document YMP/CM-0007, Revision 2 at Las Vegas, Nevada, on November 28, 1990, and at SNL, Albuquerque, New Mexico, on December 3 and 4, 1990. The surveillance activities were followed by an exit meeting in Las Vegas, on December 5, 1990, to discuss the results of this surveillance.

Detailed check lists identifying the characteristics and processes to be reviewed at YMPO and SNL were prepared and used throughout this surveillance. Particular attention was devoted by the surveillance team to a thorough review of the documented comments of reviewers and the resolutions to these comments. Technical Requirements Document YMP/CM-0007, Revision 2 was also reviewed to determine that the resolutions to the comments were adequately incorporated in the document.

In addition, the surveillance team traced the requirements in YMP/CM-0007, Revision 2 back to the higher level hierarchy requirements documents to assure proper accountability and traceability.

Overall, the DOE/YMPO surveillance team determined that "Technical Requirements for the Yucca Mountain Project (Midway Valley Trenching and Calcite/Silica Activities)," YMP/CM-0007, Revision 2 was prepared and reviewed in accordance with YMP QA procedures and controls; no deficiencies were identified. Therefore, it was concluded by the surveillance team that the QA program was being adequately implemented throughout the rereview process.

The NRC staff determined this limited surveillance to be useful, productive, and effective in evaluating the adequacy of the QA program controls applicable to the preparation and review of YMP/CM-0007, Revision 2. The DOE/YMPO surveillance team was familiar with the QA programs and relevant QA procedures. The checklists used by the surveillance team were well prepared and used throughout the surveillance process. The surveillance team exhibited thoroughness in its review of the comments and resolutions and in its check to assure that the resolutions were properly incorporated in the Technical Requirements Document. The NRC staff is in general agreement with the surveillance team preliminary conclusion that Revision 2 of the Technical Requirements Document was properly prepared and reviewed in accordance with the YMP QA program procedures and controls.

Additional surveillances by DOE/YMPO will be necessary in order to verify acceptable implementation of corrective actions for other deficiencies relating to the Midway Valley Trenching and Calcite/Silica Activities which were identified in Audit 90-I-01 of the Office of Civilian Radioactive Waste Management QA program.

## SURVEILLANCE OBSERVATION REPORT NO.91-S2

HQ-SR-91-002

From February 4-6, 1991, OCRWM conducted a surveillance to evaluate the procedural implementation of OCRWM procedure, "DOE/RW-0223", Program Change Control Procedure (PCCP). This procedure governs the initial issue of program-level type documents, their revision, replacement, identification, distribution, and control. The NRC staff observed this surveillance to gain confidence that OCRWM is properly implementing QA program requirements in the area of procedural implementation under 10 CFR Part 50, Appendix B Criteria 3 and 6.

The surveillance team conducted a detailed examination and review of the OCRWM records to assess compliance with procedural requirements. Responsible OCRWM and contractor personnel were interviewed in depth to assess their knowledge of the document change control process. Also, training records were examined to verify appropriate training was assigned and completed by responsible personnel involved in the document change control process.

The surveillance team identified two recommendations and one potential Corrective Action Request (CAR). The first recommendation concerned the amount of detail required for the DCP Impact Analysis portion of the DCP package. The surveillance team recommended that the Impact Analysis should contain, where appropriate, more in-depth detailed documentation to address the impact of the analysis and be readily understood by all interested personnel. It was also recommended that the individual(s) performing the actual Impact Analysis be clearly identified. The second recommendation pertained to the training forms associated with the DCP procedure. It appeared that from the interviews of the various personnel involved in the DCP process, and the completeness of the DCP documentation and accuracy of the tracking system, that personnel were familiar with its implementation. However, a sample of the personnel training records indicated that certain personnel had not formally initialed the reading and understanding of the PCCP. The potential CAR will be considered for the PCCP not clearly defining which documents are to be controlled by the PCCP.

The NRC observer found the surveillance of the OCRWM document issuance and change control process useful and effective. The surveillance team was well qualified in the QA discipline and familiar with the requirements of the PCCP. The surveillance team was also thorough and professional in interviewing the OCRWM and contractor personnel and in conducting the surveillance. The surveillance checklists were well prepared and utilized in determining the effectiveness of implementation of the document change process.

The NRC staff believes that the procedure in place for controlling the document issuance and change control process is adequate. The NRC staff is in agreement with the surveillance team's preliminary evaluation that there were no deficiencies identified which would make the document issuance and change control process unacceptable. Consequently, the NRC staff agrees with the surveillance team's conclusion that the implementation of the document issuance and change control process is adequate.

OBSERVATION REPORT NO. 91-S3 ON QUALITY ASSURANCE SURVEILLANCE YMP-SR-91-008 OF THE LOS ALAMOS NATIONAL LABORATORY PROGRAM

From February 25-28, 1991, the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) conducted a quality assurance (QA) surveillance (YMP-SR-91-008) of the LANL YMP QA program at Los Alamos, New Mexico. This surveillance was conducted in accordance with the YMPO Quality Management Procedure (QMP)-18-02, Revision 2, "Surveillance. A member of the U. S. Nuclear Regulatory Commission (NRC) staff participated in the surveillance as an observer.

The scope of this surveillance was limited to procedural implementation. No assessment of technical adequacy and qualification of any of the technical documents (technical procedures and laboratory and/or field data) was made during the surveillance.

The NRC staff observed and evaluated the DOE/YMPO QA surveillance to gain confidence that DOE and LANL are properly implementing the requirements of their QA program by assessing the effectiveness of the DOE/YMPO surveillance and determining the adequacy of the LANL QA program in the areas surveilled. The staff's evaluation is based on direct observations of the surveillance team members, discussions with the surveillance team and LANL staff, and reviews of pertinent QA and technical records relating to corrective actions and procedural implementation.

The staff observer found the DOE/YMPO surveillance of the LANL QA program useful and effective. The surveillance team seemed well prepared and was familiar with the LANL QA Plan and the relevant QA procedures being implemented. Their checklists for this surveillance were well prepared and utilized in determining the adequacy of procedural controls and status of procedural implementation of the LANL QA program under the Code of Federal Regulations Title 10 Part 50, Appendix B, Criteria 2, 6, 16, and 17.

The NRC staff agrees with the DOE/YMPO surveillance team's preliminary conclusion that the LANL QA program provides adequate procedural controls and procedural implementation under the criteria surveilled. In addition, the staff agrees with the surveillance team's evaluation that LANL is closing out deficiencies identified during previous audits and surveillances in a satisfactory manner.

SURVEILLANCE OBSERVATION REPORT NO. 91-S4 ON SURVEILLANCE YMP-SR-91-011 OF THE RAYTHEON SERVICES NEVADA QUALITY ASSURANCE PROGRAM

From March 4-6, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Surveillance No. YMP-SR-91-011 of Raytheon Services Nevada (RSN) conducted at Las Vegas, Nevada.

The scope of the DOE/YMPO surveillance of RSN was limited to a review of training and qualification records for RSN personnel for compliance with procedural requirements.

The NRC staff evaluated the DOE/YMPO surveillance to gain confidence that RSN personnel are appropriately trained and qualified to satisfy QA program requirements. The staff's evaluation is based on direct observations of the surveillance team members, discussions with the surveillance team and RSN staff, and reviews of pertinent QA records related to training.

The NRC observer found the DOE/YMPO surveillance of RSN to be satisfactory in evaluating the adequacy of training and qualification records of personnel working for RSN. The records reviewed were generally adequate and complied with QA program requirements. It was noted that the merger of the QA programs of Fenix & Scisson of Nevada and Holmes & Narver into the RSN QA program was not complete as of the week of March 4, 1991. Accordingly, the staff believes that the surveillance would have been more productive if it had been performed at a later date. This would have enabled the surveillance team to review the development and implementation of additional RSN procedures based on the requirements of the RSN Quality Assurance Program Description (QAPD-002, Revision 0) document which was approved by the YMPO Quality Assurance Division on February 22, 1991.

*** BRACKETED PORTIONS INDICATE CHANGES RESULTING FROM 1/18/91 QA MEETING OR ADDED AS A RESULT OF NRC REVIEW ACTIONS.

SUBJECT: STATUS OF NRC/DOE OPEN ITEMS - APRIL 25, 1991

| ITEM | DESCRIPTION | STATUS | RECOMMENDATION FOR CLOSURE/REMARKS |
|---|---|---|---|
| 3-90 | NNWSI Core Handling Procedures | Open | DOE submitted the Core Handling procedures to the NRC staff in a 8/11/89 transmittal (Gertz to Stein). The issues raised in the YMP Surveillance Report (YMP-SR-89-134) will need to be resolved before this item can be closed. NRC will determine acceptability of implementation and adequacy of procedures when they are issued in final form and subsequently implemented. At the 11/8/90 QA meeting, DOE indicated that based on the prototype drilling at Apache Leap, the procedures have been revised and should be submitted for NRC review and comment before the end of 1990. |

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|---|---|---|---|
| 4-90 | Qualified QA Program before start of new site characterization activities. | Open | DOE has made a commitment to having a qualified QA program before the start of new site characterization activities. However, this item remains open up until the the NRC staff accepts the DOE QA program as qualified for the start of new site characterization activities. At the 11/8/90 QA meeting, NRC provided a letter (Linehan to Shelor dated 10/24/90) which addresses the acceptance of (6) participant QA programs with the exception of LANL. The NRC accepted the QARD/QAPD 12/3/90(see open item 12-90). Subsequent NRC letters of 1/18/91 & 3/11/91 state that the OCRWM QA program is acceptable only for new site characterization activities associated with Midway Trenching and Calcite-Silica Activities. NRC will also need clarification from DOE on the review and acceptance status of the Raytheon participant QA program. The 1/22/91 letter from L. Desell provides the Transition QA Program for Raytheon until the Raytheon QA program is established. NRC is waiting for the DOE response to comments transmitted 2/13/91 for T&MSS (SAIC) QA Program. |
| 8-90 | SCA comments | Open | Response provided to NRC-12/14/90. NRC staff presently evaluating these responses with a target completion date of 5/31/91. |
| 10-90 | Responses to NRC Observation Audits | | DOE should respond within 30 days after NRC Observation Audit Report transmittal. The DOE responses are to be reviewed and considered by NRC staff in accepting DOE QA programs. DOE should respond to the following NRC staff Obeervation Audit Reports: |
| 10.d | Sandia Ntl. Lab. | Open | (2) Observations:<br>* Resolution of allegations concerning inadequate quality per AP-5.8Q.<br>* Retention of audit and surveillance checklists as QA records.<br>The 3/4/91 DOE response will be discussed at the 4/25/91 meeting. |

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|---|---|---|---|
| 11-90 | DOE QA Participants Acceptance Letter Dated 10/24/90 | Open | DOE should provide a response to the open items for the following DOE participant QA programs:<br>FSN - Procurement<br>Software<br>H&N - Procurement<br>Software<br>REECo - Privacy Act<br>USGS - Privacy Act |
| 12-90 | DOE QARD/QAPD Acceptance Letter Dated 12/3/90 | Open | DOE should provide a response to the (6) open items listed for the NRC review of the QARD/QAPD. |
| 1-91 | NRC 4/15/91 letter accepting QARD/QAPD for MRS & Transport of Spent Fuel | Open | DOE should provide a response to the (5) comments listed for the NRC review of the QARD/QAPD pertaining to MRS & transport of spent fuel. |

Intertech Consultants
PLANNING - ECONOMICS - PROGRAM MANAGEMENT

April 10, 1991

Nuclear Regulatory Commission
Quality Assurance Section
Repository Licensing and Quality
Assurance Project Directorate
Washington, D.C. 20555
Attn: Tilak R. Verma

Dear Tilak:

Lincoln County, Nevada will not have a representative present at the April 25th scheduled NRC/DOE meeting on quality assurance. Although scheduling conflicts prevent participation by the County at the meeting, we remain interested in quality assurance aspects of the federal radioactive waste management program, particularly those pertaining to the transportation operations system. I would appreciate being kept informed of the results of the April 25th meeting and being notified of any subsequent meetings concerning QA aspects of transportation systems.

The County would be interested to learn the status of DOE's QA program concerning transportation systems. Of particular interest are near term plans for activities concerning the Cask Maintenance Facility (CMF). It is our understanding that this facility will be an early requirement of DOE's transportation system. Any information which can be provided concerning planning for the CMF and related QA program applications would be appreciated.

Sincerely,

Mike L. Baughman
Principal

cc: Geri Ann Stanton-Turner, Lincoln County
Judy Foremaster, City of Caliente

35 Clark Road • Fiskdale, Massachusetts 01518 • (508) 347-5040 • FAX (508) 347-5445

Attachment 6

APR 1 5 1991

Mr. Dwight E. Shelor, Acting Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U. S. Department of Energy, RW 30
Washington, D.C. 20585

Dear Mr. Shelor:

SUBJECT: ACCEPTANCE OF THE U.S. DEPARTMENT OF ENERGY (DOE) QUALITY ASSURANCE REQUIREMENTS DOCUMENT (QARD) AND QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD) FOR TRANSPORT OF SPENT FUEL AND HIGH-LEVEL NUCLEAR WASTE AND MONITORED RETRIEVABLE STORAGE SYSTEM

The purpose of this letter is to provide a response to the February 1, 1991, telephone call made by D. Horton and R. Clark of the DOE Office of Civilian Radioactive Waste Management to K. Hooks of the U. S. Nuclear Regulatory Commission (NRC). In this telephone call, D. Horton requested that the NRC review and accept the QARD and QAPD for the transport of spent fuel and high-level nuclear waste and the monitored retrievable storage (MRS) system.

In a December 3, 1990, letter (J. Linehan to D. Shelor), the NRC accepted the QARD and QAPD subject to the satisfactory resolution of six open items. This letter also stated that the NRC staff did not perform a review of the QARD and QAPD pertaining to transport of nuclear fuel and high-level nuclear waste and MRS system. As a result of the February 1, 1991, DOE telephone call, the QARD and QAPD were reviewed by the NRC personnel having responsibility for transport of nuclear fuel and high-level waste and the MRS system. The results of this review are as follows:

A. Transport of Nuclear Fuel and High-Level Waste

(1) The QARD and QAPD are acceptable as meeting the requirements of Appendix H of 10 CFR Part 71, provided the six open issues identified in the NRC letter of December 3, 1990, are satisfactorily resolved.

(2) Section 1.0 a. of Appendix B of the QAPD should read, "Transportation operations planning, scheduling ..." (instead of "shielding").

(3) Section 1.0 of Appendix B in the next to last paragraph should read, " ...Systems and Compliance..." (instead of "Systems Compliance").

B. MRS System

(1) Sections 1 through 19 of the QARD appear generally acceptable. Appendix D of the QARD should be modified similar to the way Appendices A and B amplify the QARD for the mined geologic disposal system and

waste acceptance process. Examples of such modifications would include, but not be limited to, considerations in the areas of QA program scope, readiness reviews, graded QA, peer reviews, etc.

(2) Similarly, for the QAPD, the NRC staff also finds it to be generally acceptable. However, as in the aforementioned comment (1) for the QARD, consideration should also be given to modifying Appendix C of the QAPD similar to the way Appendices A and B amplify the QAPD.

Should you have any questions concerning our review, please contact William Belke of my staff on (301) 492-0445.

Sincerely,

ORIGINAL SIGNED BY Joe Holonich

for John J. Linehan, Acting Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

cc: R. Loux, State of Nevada
C. Gertz, DOE/NV
S. Bradhurst, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV

# ROOT CAUSE DETERMINATION (RCD) STATUS

PRESENTATION ON RCD GIVEN TO PARTICIPANT QUALITY ASSURANCE (QA) MANAGERS ON 3/5/91.

PLANS ARE TO PROVIDE RCD TRAINING TO PARTICIPANT REPRESENTATIVES WHO WILL THEN PROVIDE TRAINING TO APPLICABLE PERSONNEL.

- FIRST RCD TRAINING TO PARTICIPANT REPRESENTATIVES - APRIL 10, 1991
- SECOND RCD TRAINING SESSION TO PARTICIPANT REPRESENTATIVES (MAKE-UP) - MAY 1, 1991

OBJECTIVES OF RCD TRAINING.

- DEFINE ROOT CAUSE
- DEFINE RESPONSIBILITIES
- DETERMINE WHEN RCD IS REQUIRED
- UNDERSTAND THE DEFINED CAUSES AND HOW TO APPLY THE CAUSES TO A RCD APPLICATION

SOURCES OF RCD INFORMATION.

(1) SAVANNAH RIVER FAULT TREE

(2) TVA APPLICATION

Attachment 8

# AUDIT FORMAT

- Cover QA Program Criteria on an Annual Basis
- Visit Paticipants 3 Times Per Year
- Limit Scope of Audit to Maximum of 7 Criteria Per Audit

Attachment 9

- Audits Will Have 3 or 4 Programmatic Auditors
- Audits Will Have 2 - 3 Auditing Days
- Technical Areas Will Only Be Done in Conjunction with Criteria 3 and 20

- Change to QAAP 18.2 to Accomodate Changes

- Implement with Start of FY-92