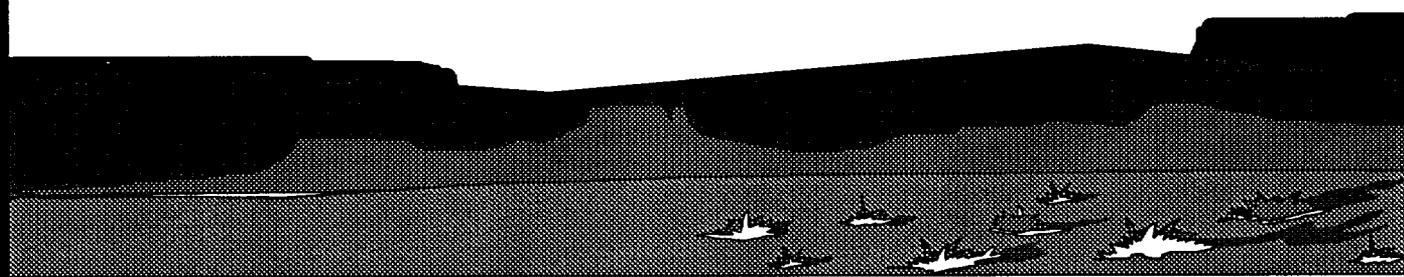


YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE



OQA AUDIT NO. YMP-91-I-01

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PDR WASTE PDR
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*ADD: John Buckley Encl.
1*

ATTACHMENT

N 100504

Revision 1
Non-Prop

~~ISOMETRIC DRAWINGS~~

BINDER/VOLUME #: 1

ATTACHMENT

AUDIT 91-I-01 Daily Schedule

SUBJECT	Auditors	Observers	Mon	Tue	Wed	Thur	Fri
			AM PM				
1.0 Organization	J. Martin		X XX	XX XX	XX		
2.0 QA Program	J. Martin				XX XX	XX XX	XX
Readiness Review	C. Warren		X XX	XX			
QA Grading	N. Cox				XX XX		
3.0 Design Control	N. Cox		XX	XX XX	XX		
	C. Warren			XX	XX		
4.0 Procurement Document Control	R. Maudlin		X XX	XX XX			
5.0 Instructions, Procedures, Plans, and Drawings	K. McFall		X XX	XX XX			
6.0 Document Control	K. McFall					XX XX	XX
7.0 Control of Purchased Items and Services	R. Maudlin					XX XX	XX
8.0 Identification and Control of Items (Samples and Data)	R. Maudlin				XX XX		
	K. McFall				XX XX		
13.0 Handling, Shipping and Storage	R. Maudlin				XX XX		
15.0 Control of Nonconforming Items	A. Arceo / S. Bates		X X				
16.0 Corrective Action	A. Arceo / S. Bates			X XX			
17.0 QA Records	A. Arceo / S. Bates			XX	XX XX	XX XX	XX
20.0 Scientific Investigation Control	N. Cox				XX	XX XX	XX
	C. Warren				XX	XX XX	XX

Audit Team/Observer Meeting: 8:00 a.m. on 10/28/91 in the Valley National Bank Building (VBB), Room 660 (DOE YMQAD Library)
 Pre-Audit Conference: 9:00 a.m. on 10/28/91 in the VBB, Room 450
 Audit Team/Observer Caucus: 4:15 p.m. Daily 10/28 - 10/31/91 in VBB, Room 660
 Audit Team/YMPO Liason: 8:00 a.m. Daily 10/29 - 11/1/91 in DOE Small Conference Room
 ATL/YMPO Mgmt. Briefing : 8:15 a.m. Daily 10/29 - 11/1/91 in DOE Small Conference Room as necessary
 Post-Audit Conference: 3:00 p.m. on 11/1/91 in the VBB, Room 450

AUDITOR NOTES

The following notes are provided for information and guidance.

Schedule

10/23/91 10:00 a.m. Final Audit Team Planning/Preparation Meeting, Valley Bank Building (VBB), Room 660 (DOE Library)

10/28/91 8:00 a.m. Audit Team/Observer Meeting, VBB, Room 660

10/28/91 9:00 a.m. Pre-Audit Conference, VBB, Room 450

10/28/91 10:00 a.m. to 4:00 p.m. Perform Audit

10/28 - 10/31/91 4:15 p.m. Daily, Audit Team/Observer Caucus, VBB, Room 660

10/29 - 11/1/91 8:00 a.m. Daily, Audit Team/YMPO Liason, DOE Small Conference Room

10/29 - 11/1/91 8:15 a.m. Daily, ATL/YMPO Mgmt. Briefing, as necessary, DOE Small Conference Room

11/1/91 2:00 p.m. Draft CAR's and Evaluation Statements due to ATL

11/1/91 2:30 p.m. Audit Team Caucus, VBB, Room 660

11/1/91 3:00 p.m. VNB Building, Room 450-Post-Audit Conference

11/5/91 4:00 p.m. Completed Checklists and Audit Details due to ATL

11/8/91 Transmit Draft CAR's to DOE YMQAD

11/15/91 Transmit Audit Report to DOE YMQAD

Audit Team

Criteria

SDR/CAR Follow-up

Richard Powe, ATL		
Amy Arceo	15, 16, 17	YM-91-017, YM-91-065
Sandra Bates (AIT)	15, 16, 17	
Neil Cox	3, 19, 20, QA grading	
John Martin	1, 2 (except QA grad.)	596, YM-91-005
Dick Maudlin	4, 7, 8, 13	
Ken McFall	5, 6, 8	YM-91-045, -046
Charlie Warren	2, 3, 20 (Participation)	YM-91-085, -086

Observers

NRC James T. Conway
John Buckley
Robert D. Brient, Southwest Research Institute

State of Nevada Susan W. Zimmerman

Clark County Englebret von Tiesenhausen

Nye County Phillip A. Niedjielski-Eichner

Audit Guidelines

1. Checklists should refer to appropriate procedure(s). It is not necessary to refer to the YMP QAPD unless you cannot find a governing procedure that addresses the QAPD requirement. Emphasis should be on implementation.
2. Obtain status of OPEN CARs in your area of responsibility and be prepared to report that status at the end of the audit.
3. Starting point for audit will be to meet in the DOE Conference Room on the 6th floor of the Valley Bank Building, Room 660 at 8:00 a.m. on 10/28/91.
4. Report all potential CAR's to ATL on or before 4:00 p.m. each day
5. Prior to the Post-Audit Conference each auditor should provide the ATL with a written summary/evaluation statement on each element/activity audited and a draft copy of each proposed CAR
6. Completed, legible audit checklists and audit details should be provided to the ATL by each auditor no later than COB Tuesday 11/5/91

SDRs/CARs

Currently there are 1 SDR and 8 CARs open which involve YMPO. There are also 2 draft CARs pending issue.

SDR

596 QAPD Deficiencies
ECD: 11/29/91
QAR: T. W. Nolan

CARs

YM-91-005 No matrix for OCRWM procedures and QAPD/QARD
ECD: 12/31/91
QAR: M. R. Diaz

YM-91-017 A portion of the project office backlog is being held at the project office LRC without dual storage or one-of-a-kind storage
ECD: 5/1/1993 WOW!
QAR: W. B. Williams

YM-91-045 Revised procedures do not indicate where revisions have been made or do not indicate complete revisions
ECD: 10/3/91
QAR: R. L. Weeks

YM-91-046 Inadequate Procedure No. AP-5.19Q, Interface Control
ECD: 10/16/91
QAR: R. A. Kettell

YM-91-065 QA Records Illegible and Incomplete
ECD: 10/31/91
QAR: J. S. Martin

YM-91-082 Auditor Qualification Records have not been submitted to the LRC for auditors that are no longer on the program.
ECD: unknown
QAR: R. L. Weeks

YM-91-085 Failure to comply with AP-3.5Q "Field Change Control Process"
Response due 10/31/91
QAR: D. J. Harris

YM-91-086 AP-3.5Q does not meet QARD requirements
Response due 10/31/91
QAR: D. J. Harris

YM-91-087 Status Log for certification of Auditors and Lead Auditors was not maintained
NOT YET Issued
QAR: R. H. Klemmens

YM-91-088 Failure to provide date and signature where required on affected document Notices (refer to AP-3.3Q)
NOT YET Issued
QAR: T. J. Higgins

YMP Activities

The YMP activities shown below are provided as suggested activities that should have resulted in creation of objective evidence of YMPO involvement.

Surface Disturbing

- o Midway Valley Trenching
 - WBS 1.2.3.2.8.4.2, Rev. 2 Location and Recency of Faulting Near Prospective Surface Facilities
 - SCP 8.3.1.17.4.2 Location and Recency of Faulting Near Prospective Surface Facilities
- o Calcite-Silica Trench 14
 - WBS 1.2.3.5.3.18, Rev. 1 Calcite-Silica Drillholes and Trenches
 - SCP 8.3.1.5.2.1, Rev 0 Characterization of Quaternary Regional Hydrology
 - SCP 8.3.1.5.2.1.5 Studies of calcite and Opaline-silica vein deposits
 - WBS 1.2.3.5.3.22, Rev. 1 In situ Stress Drillholes and Tests, and Quaternary Fault Trenches
 - SCP 8.3.1.17.4.8
 - WBS 1.2.3.6.2.2.1, Rev. 0 Quaternary Regional Hydrology
 - SCP 8.3.1.5.2.1, Rev 0 Characterization of Quaternary Regional Hydrology
 - SCP 8.3.1.5.2.1.5 Studies of calcite and Opaline-silica vein deposits

LM-300 Drill Rig

Exploratory Studies Facility (ESF) Alternatives Study

Originated by: Powe, SAIC

WBS 1.2.9.3
QA

SEP 23 1991

Carl P. Gertz, Project Manager, YMP, NV

OFFICE OF QUALITY ASSURANCE (OQA) AUDIT YMP-91-I-01 OF THE YUCCA MOUNTAIN
SITE CHARACTERIZATION PROJECT OFFICE (YMPO)

Please be advised that a team of auditors from the Yucca Mountain Quality Assurance Division of the OQA will conduct an internal quality assurance (QA) audit of the Yucca Mountain Site Characterization Project (YMP) QA Program at the YMPO in Las Vegas, Nevada, from October 28 through November 1, 1991. The audit will be conducted in accordance with the enclosed audit plan.

Observers from the State of Nevada, U.S. Nuclear Regulatory Commission, or other interested parties may also accompany the audit team. The total number of auditors/observers is anticipated to be 15 or fewer people.

You are hereby requested to arrange for appropriate space to hold meetings, provide cognizant personnel to support the audit, and provide audit team access to appropriate current YMP documentation and records.

If you have any questions, please contact either James Blaylock at 794-7913 or Richard E. Powe at 794-7749.

Original Signed By
James Blaylock

for

Donald G. Horton, Director
Yucca Mountain Quality Assurance Division

YMQAD:JB-5775

Enclosure
Audit Plan YMP-91-I-01

CONCURREN
RTG. SYMB
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YMP
INITIALS
Blaylock
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9/23/91
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Carl P. Gertz

-2-

cc w/encl:

D. G. Horton, HQ (RW-3) FORS
R. W. Clark, HQ (RW-3) FORS
D. E. Shelor, HQ (RW-30) FORS
S. L. Skuchko, HQ (RW-331) FORS
J. W. Gilray, NRC, Las Vegas, NV
K. R. Hooks, NRC, Washington, DC
R. J. Brackett, TESS, HQ (RW-3) FORS
J. A. Jackson, TESS, Las Vegas, NV
R. R. Loux, NWPO, Carson City, NV
S. W. Zimmerman, NWPO, Carson City, NV
Cyril Schank, Churchill County Commission, Fallon, NV
Jay Bingham, Clark County Commission, Las Vegas, NV
D. A. Bechtel, Clark County Comprehensive, Las Vegas, NV
E. von Tiesenhausen, Clark County Comprehensive, Las Vegas, NV
Leo Vaughn, Esmeralda County Commission, Goldfield, NV
P. J. Goicoechea, Eureka County Commission, Eureka, NV
Gloria Derby, Lander County Commission, Battle Mountain, NV
M. L. Baughman, Lincoln County Commission, Pioche, NV
Keith Whipple, Lincoln County Commission, Pioche, NV
C. E. Jackson, Mineral County Commission, Hawthorne, NV
S. T. Bradhurst, Nye County Representative, Tonopah, NV
Barbara Raper, Nye County Commission, Pahrump, NV
P. A. Niedzielski-Eichner, Nye County Consultant, Fairfax, VA
Frank Sperry, White Pine County Commission, Ely, NV
Robert Campbell, County of Inyo, Bishop, CA
Robert Michener, County of Inyo, Bishop, CA
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE AUDIT PLAN

FOR AUDIT No. YMP 91-I-01

OF

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE

LAS VEGAS, NEVADA

OCTOBER 28 THROUGH NOVEMBER 1, 1991

Prepared by:

Richard E. Powe
Richard E. Powe
Audit Team Leader
Yucca Mountain Quality Assurance Division

Date:

9/18/91

Approved by:

Donald G. Horton
Donald G. Horton
Director
Office of Quality Assurance

Date:

9/23/91

ENCLOSURE

1.0 SCOPE

This internal audit, by a team of auditors from the Yucca Mountain Quality Assurance Division (YMQAD) of the Office of Quality Assurance (OQA), will evaluate the Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance Program to determine whether it meets the requirements and commitments imposed by the Office of Civilian Radioactive Waste Management (OCRWM). This will be done by verifying implementation and effectiveness of the system in place, as well as verifying compliance with requirements.

In addition to follow-up on open Standard Deficiency Reports and Corrective Action Requests, a representative sample of discrepancies identified during previous QA audits and surveillances of YMPO will be included in the scope of this audit to determine the effectiveness of YMPO corrective actions.

The programmatic elements and technical areas to be audited, as well as those programmatic elements not included in this audit, are identified in Section 4.0 of this plan.

2.0 AUDIT SCHEDULE

Pre-Audit Team/Observers Meeting	8:00 a.m., October 28, 1991, Las Vegas, Nevada
Pre-Audit Conference	9:00 a.m., October 28, 1991, Las Vegas, Nevada
Audit Activities	10:00 a.m. to 4:00 p.m., October 28, 1991 *
Audit Activities	8:00 a.m. to 4:00 p.m., October 29 - 31, 1991 *
Audit Activities	8:00 a.m. to 11:30 a.m. November 1, 1991
Post-Audit Conference	3:00 p.m., November 1, 1991 Las Vegas, Nevada

* There will be daily audit team/observer meetings starting at 4:00 p.m., there will be daily audit team/Project Office coordination meetings starting at 8:00 a.m. followed by Audit Team Leader/Project Office debriefings.

3.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

The requirements to be audited will be contained in the pre-approved programmatic and technical checklists. These checklists will be developed from the latest available revision of the following documents:

- o OCRWM Quality Assurance Program Description (DOE/RW-0215) and implementing procedures
- o YMPO Administrative Procedures (APs)

The conduct of the audit will be guided by the documents listed below:

- o Quality Assurance Administrative Procedure QAAP 18.1, Revision 3, "Audit Program"
- o QAAP 16.1, Revision 3, "Corrective Action Requests"
- o YMP Audit Observer Inquiry
- o Policy for Participation of State, Tribal and NRC Representatives as Observers on Department of Energy (DOE) Audits, dtd. July 14, 1987

4.0 ACTIVITIES TO BE AUDITED

Programmatic Elements

YMPO activities associated with the following QA Program elements will be audited:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Plans, Procedures, Instructions, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Materials, Parts, Components, and Samples
- 12.0 Control of Measuring and Test Equipment (M&TE)
- 13.0 Handling, Storage and Shipping
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 20.0 Scientific Investigation Control

The following programmatic elements will not be audited since the YMPO has no activities to which these elements apply.

- 9.0 Control of Processes
- 10.0 Inspection
- 11.0 Test Control
- 14.0 Inspection, Test, and Operating Status
- 18.0 Audits
- 19.0 Computer Software

No YMQAD activities will be audited. YMQAD activities will be covered by a separate OQA audit.

Technical Areas

None.

If the audit team identifies a need to verify additional programmatic or technical areas during the audit, they will be added to the audit checklist(s) and verified accordingly.

5.0 AUDIT TEAM MEMBERS

Richard E. Powe, Science Applications International Corporation
(SAIC)/YMQAD, Las Vegas, Nevada, Audit Team Leader
Amelia I. Arceo, SAIC/YMQAD, Las Vegas, Nevada, Auditor
Sandra D. Bates, SAIC/YMQAD, Las Vegas, Nevada, Auditor-In-Training
Neil D. Cox, SAIC/YMQAD, Las Vegas, Nevada, Auditor
John S. Martin, SAIC/YMQAD, Las Vegas, Nevada, Auditor
Richard. L. Maudlin, MAC Technical Services Company (MACTEC)/YMQAD,
Las Vegas, Nevada, Auditor
Kenneth T. McFall, SAIC/YMQAD, Las Vegas, Nevada, Auditor
Charles C. Warren, MACTEC/YMQAD, Las Vegas, Nevada, Auditor

6.0 AUDIT CHECKLIST

YMP-91-I-01-1, Programmatic checklist, will be used in conjunction with this audit.

Carl P. Gertz

-3-

bcc w/encl:

R. L. Maudlin, MACTEC, Las Vegas, NV, M/S 402

C. C. Warren, MACTEC, Las Vegas, NV, M/S 402

A. I. Arceo, SAIC, Las Vegas, NV, 517/T-06

S. D. Bates, SAIC, Las Vegas, NV, 517/T-06

N. D. Cox, SAIC, Las Vegas, NV, 517/T-06

J. S. Martin, SAIC, Las Vegas, NV, 517/T-06

K. T. McFall, SAIC, Las Vegas, NV, 517/T-06

R. E. Powe, SAIC, Las Vegas, NV, 517/T-06

M. B. Blanchard, YMP, NV

James Blaylock, YMP, NV

D. C. Dobson, YMP, NV

W. R. Dixon, YMP, NV

V. F. Iorii, YMP, NV

E. H. Petrie, YMP, NV

W. A. Wilson, YMP, NV



Department of Energy
Washington, DC 20585

NBS 1.2.9.3
QA

NOV 23 1990

John W. Bartlett, Director, Civilian Radioactive Waste Management,
RW-1 (FORS)

OFFICE OF QUALITY ASSURANCE (OQA) AUDIT 90-I-01 OF THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) PROGRAM

Enclosed is the report of QA Audit 90-I-01, which was conducted by the OQA at the OCRWM Headquarters facilities in Washington, D.C. from October 15 through 19, 1990, and at the Yucca Mountain Site Characterization Project Office in Las Vegas, Nevada, from October 22 through 26, 1990.

During the course of the audit, the audit team generated 19 Corrective Action Reports (CARs). Responses to the CARs (which were transmitted via separate letter) are due as dated on each CAR. The subject audit is considered completed as of the date of this letter; however, any open CARs will continue to be tracked until each has been closed to the satisfaction of the Audit Team Leader and the Director, OQA.

If you have any questions, please contact James Blaylock at (702) 794-7913 (FTS 544-7913) or Stephen R. Dana at (702) 794-7176 (FTS 544-7176) of the Yucca Mountain Quality Assurance Division staff.

A handwritten signature in cursive script, appearing to read "Donald G. Horton".

Donald G. Horton, Director
Office of Quality Assurance

Enclosures:
Audit Report 90-I-01
CARs HQ-91-001 through 012
and YM-91-005 through 011

cc w/encl:

C. P. Gertz, HQ (RW-20) FORS
D. G. Horton, HQ (RW-3) FORS
T. H. Isaacs, HQ (RW-4) FORS
R. A. Milner, HQ (RW-40) FORS
F. G. Peters, HQ (RW-50) FORS
Samuel Rousso, HQ (RW-10) FORS
J. D. Saltzman, HQ (RW-5) FORS
D. E. Shelor, HQ (RW-30) FORS
Bob Clark, HQ (RW-3) FORS
R. J. Brackett, TRW, HQ (RW-3) FORS
J. W. Gilray, NRC, Las Vegas, NV
K. R. Hooks, NRC, Washington, DC
R. R. Loux, NWPO, Carson City, NV
S. W. Zimmerman, NWPO, Carson City, NV
E. V. Tiesenhausen, Clark County, NV
Phillip Niedzielski-Eichner, Nye County, NV
Tom Colandrea, EEI, San Diego, CA
J. J. George, CER Corporation, Arlington, VA
M. J. Meyer, CER Corporation, Arlington, VA
W. F. Haslebacher, Weston, Washington, DC
A. W. Spooner, Weston, Washington, DC
R. J. Herbst, LANL, Los Alamos, NM
H. P. Nunes, LANL, Los Alamos, NM
L. J. Jardine, LLNL, Livermore, CA
D. W. Short, LLNL, Livermore, CA
R. E. Lowder, MACTEC, Las Vegas, NV
M. A. Fox, REECo, Las Vegas, NV
R. F. Pritchett, REECo, Las Vegas, NV
R. L. Bullock, RSN, Las Vegas, NV
M. J. Regenda, RSN, Las Vegas, NV
J. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
J. H. Nelson, SAIC, Las Vegas, NV, 517/T-04
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06
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L. R. Hayes, USGS, Las Vegas, NV

John W. Bartlett

-3-

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E. P. Bryant, SAIC, Las Vegas, NV, 517/T-26
J. E. Clark, SAIC, Las Vegas, NV, 517/T-12
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S. R. Dana, SAIC, Las Vegas, NV, 517/T-06
J. B. Harper, SAIC, Las Vegas, NV, 517/T-38
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J. S. Martin, SAIC, Las Vegas, NV, 517/T-06
R. L. Weeks, SAIC, Las Vegas, NV, 517/T-06
M. B. Blanchard, YMP, NV
James Blaylock, YMP, NV
R. B. Constable, YMP, NV
M. R. Diaz, YMP, NV
W. R. Dixon, YMP, NV
V. F. Iorii, YMP, NV
E. H. Petrie, YMP, NV
W. A. Wilson, YMP, NV

OFFICE OF QUALITY ASSURANCE AUDIT REPORT FOR

THE AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE PROGRAM

AUDIT NUMBER 90-I-01

CONDUCTED OCTOBER 15 THROUGH 19, 1990 (WASHINGTON, D.C.)

AND

OCTOBER 22 THROUGH 26, 1990 (LAS VEGAS, NEVADA)

Prepared by:

Stephen R. Dana
Stephen R. Dana
Audit Team Leader

Date: 11/20/90

Charles C. Warren
Charles C. Warren
Audit Team Leader

Date: 11/20/90

Martha J. Mitchell
Martha J. Mitchell
Lead Technical Specialist

Date: 11/20/90

Approved by:

Donald G. Horton
Donald G. Horton, Director
Office of Quality Assurance

Date: 11/20/90

ENCLOSURE

EXECUTIVE SUMMARY

The Quality Assurance (QA) audit of the Office of Civilian Radioactive Waste Management (OCRWM) QA Program and quality-related activities was conducted over a two-week period, the first week at OCRWM Headquarters (HQ) and the second week at the Yucca Mountain Site Characterization Project Office (Project Office).

In the opinion of the audit team, the OCRWM QA program is adequate for the initiation of quality-affecting activities. However, specific elements of the QA program were identified as either indeterminate (due to lack of implementation) or ineffective. The following is a summary of those elements of the OCRWM QA program judged by the audit team to be ineffective.

1. Criterion 2 (QA Program)—The area of management assessments at both HQ and the Project Office was determined to be ineffective because no management assessments have been performed as required.

Training was considered to be ineffective at the Project Office. The controls established for training of Project personnel does not effectively ensure that personnel are adequately trained prior to performing quality-affecting activities.

Because the matrix that cross-references OCRWM procedures and the Quality Assurance Program Description Document (QAPD) to the Quality Assurance Requirements Document requirements is not complete, this element of Criterion 2 was ineffective.

2. Criterion 3 (Design Control)—The process established to control the technical baseline at both HQ and the Project Office was ineffective. However, the status of the technical baseline documents was indeterminate.
3. Criterion 16 (Corrective Action)—The current deficiency reporting and tracking system at HQ was ineffective.
4. Criterion 17 (QA Records)—Because the records procedure does not contain a description of the Quality Records Center which is of fundamental importance to the protection of records, this element at HQ was ineffective.
5. Criterion 18 (Audits)—Because the required overview (verification) activities have not been adequately implemented at HQ, this element of the QA program was ineffective.

Based on the above, the audit team recommends that the following actions take place prior to the start of site characterization activities.

1. OCRWM should take whatever actions are necessary to correct elements of its QA program identified as ineffective. Subsequent to these actions, the Office of Quality Assurance should conduct the following surveillances to verify effectiveness of the QA program elements identified above as ineffective:
 - o Control of the technical baseline (including the change control process). (HQ)
 - o Corrective action system. (HQ)
 - o Quality Records Center. (HQ)
 - o Program Overview (audits and surveillances). (HQ)
 - o Preparation and review of the Technical Requirements for the Yucca Mountain Project (YMP/CM-0007). (Project Office)
 - o Sandia National Laboratories (SNL) activities relative to YMP/CM-0007. (Project Office)
 - o Training. (Project Office)
2. Closure of the following deficiencies identified during the audit:

Corrective Action Report (CAR) No.

HQ-91-002
HQ-91-007
HQ-91-008
HQ-91-009
HQ-91-011
YM-91-005
YM-91-006
YM-91-007
YM-91-008
YM-91-009

It was apparent to the audit team that OCRWM staff, at both HQ and the Project Office, had put forth a considerable effort to bring their program into compliance with the QA program requirements. Also, the staff should be commended for the considerable effort put forth to correct potential deficiencies identified during the audit.

As a result of this audit, 19 CARs (12 to HQ and 7 to the Project Office) were issued to OCRWM. It should be noted that during the course of the audit, OCRWM was able to correct 29 remedial deficiencies (11 at HQ and 18 at the Project Office) identified by the auditors. These 29 concerns and the actions taken to correct them are described in this report.

1.0 INTRODUCTION

This report contains the results of a Quality Assurance (QA) audit of activities conducted by the Office of Civilian Radioactive Waste Management (OCRWM). The audit was conducted at the OCRWM Headquarters (HQ) facility in Washington, D.C., from October 15 through 19, 1990, and at the Yucca Mountain Site Characterization Project Office (Project Office) facilities in Las Vegas, Nevada, from October 22 through 26, 1990.

2.0 AUDIT PURPOSE/SCOPE

The purpose of this audit was to evaluate OCRWM quality-affecting activities associated with the Mined Geologic Disposal System (MGDS). The audit focused on near-term new site characterization activities.

The scope of the audit was to verify the establishment of program level technical baseline documents and to verify adequacy of the OCRWM QA program. This was done by verifying implementation and effectiveness of the program in place, as well as verifying compliance with requirements.

The following program elements were audited to assess compliance with the OCRWM Quality Assurance Program Description Document (QAPD), Revision 3:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Plans, Procedures, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Materials, Parts, Components, and Samples (Project Office)
- 12.0 Control of Measuring and Test Equipment (Project Office)
- 13.0 Handling, Storage, and Shipping (Project Office)
- 15.0 Control of Nonconforming Conditions
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits
- 20.0 Scientific Investigation Control

The audit scope included a review and evaluation of the following technical activities:

- | 1. <u>SCP Section</u> | <u>Title</u> |
|-----------------------|--|
| 8.3.1.5.2.1 | Characterization of the Quaternary Regional Hydrology |
| 8.3.1.17.4.2 | Location and Recency of Faulting Near Prospective Surface Facilities |

2. Sample Management Facility (SMF) operations.
3. Establishment of the technical baseline.

In addition, the above technical activities were evaluated to determine adequacy in the following areas:

1. Qualification of technical personnel.
2. Understanding of procedural requirements as they pertain to technical activities.
3. Adequacy of technical plans and procedures.
4. Development of study plans and any related work products.

3.0 AUDIT TEAM PERSONNEL AND OBSERVERS

<u>Responsibility</u>	<u>Individual</u>
Audit Team Leader	Stephen R. Dana
Audit Manager	James Blaylock
Lead Auditor	Charles C. Warren
Auditors	Amelia I. Arceo
	Robert Clark
	A. Edward Cocoros
	Neil D. Cox
	Mario R. Diaz
	James J. George
	John S. Martin
	Arthur W. Spooner
	Richard L. Weeks
	Ardell M. Whiteside
Lead Technical Specialist	Martha J. Mitchell

Technical Specialists

E. Paul Bryant

Marc J. Meyer

William Haslebacher

Observers

Kenneth Hooks (Lead)
U.S. Nuclear Regulatory Commission (NRC)

William Belke
NRC

Robert Brient
Southwest Research Institute (SWRI)/NRC

Jim Conway
NRC

John Gilray
NRC

Bruce Mabrito
SWRI/NRC

R. James Brackett
TRW

Thomas Colandrea
EEI

Phillip Niedzielski-Eichner
Nye County, Nevada

Englebrecht Von Tiesenhausen
Clark County, Nevada

Susan W. Zimmerman
Nevada Waste Project Office (NWPO)

4.0 SUMMARY OF AUDIT RESULTS

4.1 Statement of Program Effectiveness

In the opinion of the audit team, the OCRWM QA program is adequate for the initiation of quality-affecting activities. However, OCRWM should take whatever actions are necessary to correct the following element of the QA program identified as ineffective:

- o Control of the technical baseline (including the change control process). (HQ)
- o Corrective action system. (HQ)
- o Quality Records Center. (HQ)
- o Program Overview (audits and surveillances). (HQ)
- o Preparation and review of the Technical Requirements for the Yucca Mountain Project (YMP/CM-0007). (Project Office)
- o Training. (Project Office)

The specific elements of the QA program identified as either indeterminate (due to lack of implementation) or ineffective are noted below:

1. Criterion 1 (Organization)—The organizational structure required to implement this element is in place at both HQ and the Project Office. However, because the Quality Assurance Controls Document (QACD), Revision 1 (at HQ), was issued just prior to the audit exit, the overall effectiveness at HQ was indeterminate.
2. Criterion 2 (QA Program)—The area of management assessments at both HQ and the Project Office was ineffective because management assessments have not been performed as required. Deficiency Report (DR) No. 90-021 at HQ and Standard Deficiency Report (SDR) No. 481 at the Project Office document that management assessments have not been performed.

Training was ineffective at the Project Office. The controls established for training of Project personnel does not effectively ensure that personnel are adequately trained prior to performance of quality-affecting activities.

A matrix that cross-references OCRM procedures and the QAPD, and Quality Assurance Requirements Document (QARD) requirements was not complete; therefore, this element was ineffective.

Effectiveness of the graded QA process at both HQ and the Project Office could not be determined because the QACD, Revision 1, and three grading packages at the Project Office were not issued until just prior to the audit exit. Therefore, the overall effectiveness of this element was indeterminate.

3. Criterion 3 (Design Control)—The process, established to control the technical baseline at both HQ and the Project Office, was ineffective. However, the status of the technical baseline documents was indeterminate.

4. Criteria 4 and 7 (Procurement Document Control and Control of Purchased Items and Services)—The process for issuance of procurement documents and control of purchased services at HQ was determined to be effective. A complete evaluation of the overall effectiveness at the Project Office could not be performed because of a lack of implementation to Quality Management Procedure QMP-04-02, Revision 0, "Yucca Mountain Project Office Procurement Actions."
5. Criterion 5 (Plans, Procedures, Instructions, and Drawings)—With the exception of a few isolated concerns, this element was considered effective at both HQ and the Project Office.
6. Criterion 6 (Document Control)—This element was considered to be effective at HQ. During the audit the Project Office issued a letter (Gertz to Nelson, dtd. 10/25/90) delegating responsibility for issuing, tracking, and maintaining all controlled documents to Technical and Management Support Services (T&MSS) as a participant. Upon issuance of the letter, control of documents was no longer within the audit scope at the Project Office.
7. Criteria 8, 12, and 13 (Identification and Control of Materials, Parts, Components and Samples; Control of Measuring and Test Equipment; and Handling, Storage, and Shipping)—The audit team was unable to determine effectiveness for Criteria 8 and 13 due to the limited implementation at the time of the audit.

Upon review of QA Grading Report No. RSE-007, Revision 0, "SMF Operations" (issued during the audit), the audit team verified that Criterion 12 had been graded as not applicable. Therefore, this element of the QA program was determined as not applicable to the scope of the audit.
8. Criterion 15 (Control of Nonconforming Items)—This criterion was determined as not applicable at HQ. The effectiveness of this element at the Project Office was indeterminate due to the issuance of Corrective Action Request (CAR) No. YM-91-004.
9. Criterion 16 (Corrective Action)—The current deficiency reporting and tracking system at HQ was ineffective. The corrective action program at the Project Office was effective. However, effectiveness of the trending program and the corrective action program per Quality Assurance Administrative Procedure QAAP 16.1, Revision 2 (issued just prior to the audit), was indeterminate due to lack of implementation.

10. Criterion 17 (QA Records)—This element at HQ was ineffective because procedure Implementing Line Procedure ILP-12.17.01, Revision 0, does not contain a description of the Quality Records Center (QRC). The HQ Central Records Facility (CRF) was determined to be outside the scope of this audit and was not evaluated.

The CRF at the Project Office was effective. Effectiveness of the Local Records Center (LRC) to Branch Technical Procedure BTP-YMP-001, Revision 0, could not be determined because of limited implementation.

11. Criterion 18 (Audits)—Because the required overview (verification) activities have not been adequately implemented at HQ, this element of the QA program was ineffective.

External audit coverage at the Project Office was effective. However, due to the lack of internal audits performed at the Project Office (addressed in CAR 90-01), this element, overall is marginally effective.

12. Criterion 19 (Computer Software)—This element of the QA program was not evaluated at the Project Office due to open SDR No. 449. All Project Office quality-affecting computer software activities are on hold until resolution and closure of the SDR. This criterion was determined as not applicable at HQ.

13. Criterion 20 (Scientific Investigation Control)—This element at both HQ and the Project Office was effective.

4.2 Summary of Programmatic Activities

1. Criterion 1—The auditors interviewed the following OCRM personnel to determine compliance with requirements of the QAPD, Revision 3, Section 1.

At HQ: the OCRM Director; Office of Quality Assurance (OQA) Director; the Office of Systems and Compliance (OSAC) Associate Director; the Office of Programs and Resources Management (OPRM) Associate Director; and the Director of the Analysis and Verification Division.

At the Project Office: the Project Manager; the Deputy Project Manager; the QA Division Director; the (Acting) Director of the Engineering and Development Division (E&DD); the Director of the Project and Operations Control Division (POCD); and the Director of the Regulatory and Site Evaluation Division (R&SED).

2. Criterion 2—At HQ the auditors interviewed D. Shelor, W. Lemeshewsky, J. Hale, S. Brocoum, and M. Mozumder. Personnel qualification records were reviewed for D. Shelor, J. Hale, B. Lemeshewsky, W. Stringfield, B. Dankar, R. Stein, J. Parker, M. Senderling, K. Mutrega, S. Brocoum, J. Kimball, M. Mozumder, S. Van Camp, J. Stockey, K. Mihm, I. Atterman, B. Scott, P. Kumar, J. Richardson, T. Trong, H. Cadoff, H. Cleary, E. Benz, D. Michlewicz, D. Fenster, A. Spooner, F. Shaffer, C. Weber, C. Walenga, and N. Frank.

At the Project Office the auditor reviewed and verified: (1) training plans; (2) letters (YMP:CGA-2216, YMP:CGA-3517, POCD:CGA-4435, and MNA-1990-3990) which substantiate that periodic evaluations of the training program have been performed; and (3) personnel qualification and training records for G. Dymmel, D. Harrison-Geisler, W. Dixon, J. White, R. Barton, R. Murthy, C. Fridrich, D. Dobson, J. Gardiner, G. Braun, J. Owens, R. Gates, L. Roy, R. Cameron, and J. Caldwell. Lead Auditor/Auditor qualifications files were verified for N. Cox, A. Arceo, F. Kratzinger, S. Dana, R. Klemens, R. Powe, R. Maudlin, C. Warren, R. Weeks, J. Martin, K. McFall, J. Blaylock, M. Diaz, R. Constable, E. Cocoros, and K. Tyger.

3. Criterion 3—At HQ the auditor reviewed QAAP-3.1, Revision 0; QAAP-3.5, Revision 0; and QAAP-3.7, Revision 0. The auditor reviewed and verified: (1) Technical Document Management Plan, Revision 3; (2) Waste Management System Requirements (WMSR), Volume I, Revision 1; (3) WMSR Volume III, Revision 0; and (4) WMSR Volume IV, Revision 1. The auditor interviewed D. Shelor, W. Lemeshewsky, and M. Senderling.

At the Project Office the auditor reviewed QMP-03-09, Revision 0; QMP-06-04, Revision 0; and Administrative Procedure AP-6.1Q, Revision 1. The auditor reviewed and verified YMP/CM-0007, Revision 0 and 1. The auditor interviewed T. Petrie, R. Barton, J. White, J. Waddel, and G. Dymmel.

4. Criterion 4 and 7—At HQ the auditors reviewed and verified: (1) procurement packages for CER Corporation, KOH, and TRW; and (2) program guidance letters for affected organizations. The auditors interviewed J. Bresee.

At the Project Office the auditors reviewed and verified the procurement package for T&MSS. The auditors interviewed W. Dixon.

5. Criterion 5—At HQ the auditor verified that Attachment V (standard format) contained in QAAP 5.1 and QAAP 5.2 meets the requirements of the QAPD, Revision 3, Section 5.

At the Project Office the auditor reviewed procedures QMP-17-01 and BTP-YMP-001 to verify that quantitative and qualitative acceptance criteria had been prescribed. Procedures QMP-02-09, AP-3.5Q, AP-3.3Q, and BTP-YMP-001 were reviewed for conformance to the QAPD, Revision 3, Section 5, Paragraph 5.0.

6. Criterion 6—At HQ the auditor reviewed procedure history files for QAAP 2.5, QAAP 18.2, and ILP-12-17-01, and the associated Document Review Sheets (DRSs) for each procedure. Minor changes processed for procedures QAAP 5.1, QAAP 6.1, and QAAP 16.1 were reviewed and verified for conformance to the definition in QAAP 5.1 and QAAP 5.2. Manuals (Nos. 1, 2, 5, 22, 44, 46, 96, 116, 122, 201, 204, 208, 229, 288) were reviewed for conformance to QAAP 6.1 requirements. The auditor verified that Document Control procedures include requirements stated in the QAPD, Revision 3, Section 6, and that controlled documents handled by DOE/RW-223, Revision 3, "Program Change Control Board," are listed in the controlled document register.

At the Project Office the auditor reviewed history files for procedures QMP-02-09, AP-3.5Q, AP-3.3Q, and BTP-YMP-001. During the audit it was determined that control of documents has been delegated to T&MSS in its participant role.

8. Criterion 8—This criterion was applicable only to audit activities at the Project Office. All audit verification activities were performed at the SMF. Using requirements of the QAPD, Revision 3, Section 8, and BTP-SMF-001, Revision 0, the auditor verified job descriptions for each position at the SMF; and whether the facility access log was utilized. Sample Collection Reports were examined, along with their associated records, and bar code labels on sample containers were verified per BTP-SMF-007, Revision 0.
9. Criterion 13—This criterion was applicable only to audit activities at the Project Office. The auditors verified that BTPs have been written to meet the requirements of the QAPD, Revision 3, Section 13. The only quality-affecting samples that are located at the SMF are samples collected by the U.S. Geological Survey (USGS) for paleoclimatology studies.
10. Criterion 15—At the Project Office the auditor reviewed QMP-15-01, Revision 2. The auditor verified: (1) the Nonconformance Report (NCR) Log (110 NCRs have been assigned from 2/19/86 to 2/13/90), and (2) that conditional releases were not required for NCRs WMPO-110, 109, and 107, and a conditional release was accepted for NCR WMPO-101

This criterion was determined as not applicable to activities at HQ.

11. Criterion 16—At HQ the auditor reviewed QAAP-16.1, Revisions 0 and 1. The auditor verified: (1) the CAR/DR/OBS Tracking Data Dump log; (2) DRs 89-002, 89-003, 80-004, 89-005, 89-006, 89-007, 89-008, 89-009, 89-010, 89-011, 89-012, 89-013, 89-014, 89-015, 89-017, 89-018, 89-019, 89-020, 89-021, 89-022, 89-023, 89-024, 89-025, 89-026, 89-027, 89-028, 89-029, 80-030, 89-031, 89-032, 89-033, 89-034, 89-035, 89-036, 90-001, 90-002, 90-003, 90-004, 90-005, 90-006, 90-007, 90-008, 90-009, 90-010, 90-011, 90-012, 90-013, 90-014, 90-015, 90-016, 90-017, 90-018, and 90-019 (untimely responses for 28 items, untimely response evaluation for 44 items, and untimely verification/ closeout for 23 items) (reference CAR No. HQ-91-008); and (3) CARs 89-001, 89-002, and 90-001.

At the Project Office the auditor reviewed QMP-16-01, Revision 0, QMP-16-03, Revision 1, and QAAP-16.1, Revisions 0 and 1. The auditor verified: (1) Deficiency Evaluation Reports (DERs) 050, 051, 052, 053, 054, and 055; (2) CAR Logs for FY 1986 through 1991; (3) CARs 89-001, 90-001, 90-002, 90-003, 90-004, YM-91-001, YM-91-002, and YM-91-003; and (4) SDRs 309, 350, 352, 449, 459, 473, 474, 475, 476, 477, 481, 484, 489, 497, 498, 508, 509, 548, 550, 551, 568, 569, 570, 579, 580, 581, 582, 522, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 596, 598, and 599.

12. Criterion 17—At the Project Office the auditor reviewed BTP-YMP-001, Revision 0; BTP-RMD-002, Revision 1; and QMP-17-01, Revision 1. The auditor verified: (1) DOE/YMP/90-4, Revision 0 (individual record document accession numbers NNA.900829.0211 to NNA.900917.0147); QMP-04-02, Revision 0; QMP-06-04, Revision 1; QMP-07-04, Revision 1; QMP-10-03, Revision 1; QMP-17-01, Revision 2; and QMP-18-02, Revision 2, for listing of QA records generated through implementation of the documents; (2) one-of-a-kind documents (accession numbers NNA.880503.0016, NNA.881115.0016, NNA.881128.0011, and NNA.890901.0139) for proper maintenance at the security archives; (3) the records list for records generated as a result of Project activities (letter Nos. YMP:ECR-162, YMP:ECR-163, YMP:ECR-165, YMP:ECR-164, YMP:ECR-275, YMP:ECR-260, and YMP:ECR-274); the list of signatures and initials of personnel authorized to authenticate records (C. Gertz, E. Wilmot, D. Morgan, D. Dobson, C. Muntean, C. Aiello, and J. Mukherjee; (4) that QA records are suitably controlled prior to turnover by POCD, ED&D, R&SED, and the QA Division; (5) that YMP/CM-0007 document records package was transmitted to the LRC; and (6) the Incoming and Outgoing Work Log and the Batch Tracking Log at the CRF. The auditor interviewed D. Dobson, S. Mattson, D. Horton, and D. Keller.

At HQ the auditor reviewed QAAP-17.1, Revision 0 and ILP-12.17.01, Revision 0. The auditor verified: (1) that procedures ILP-12.17.01, ILP-22.3.1, ILP-22.3.2, ILP-22.3.3, QAAP-2.1, QAAP-2.5, QAAP-2.6, QAAP-2.7, QAAP-3.1, QAAP-3.3, QAAP-3.5, QAAP-4.1, QAAP-16.1, QAAP-17.1, and QAAP-18.1 define the minimum QA records generated; (2) that the records dealing with review comments for the procedures in Item 1 (above) were legible, identifiable, accurate, and complete; (3) that a list was received by the QRC from RW-1, RW-2, RW-3, RW-10, RW-20, RW-30, RW-40, AND RW-50, which identifies personnel who are authorized to authenticate record packages; and (4) that QA records generated during implementation of the procedures identified in item 1 (above) are controlled from time of completion to time of storage. The CRF was determined as outside the audit scope; therefore, CRF activities were not verified.

13. Criterion 18—At HQ the auditor reviewed QAAP-18.1, Revision 1, and QAAP-18.2, Revision 1. The auditor verified: (1) the FY 90 audit schedule, dated 09/28/89; and (2) record packages for Surveillance Report (SR) Nos. SR-90-001, SR-90-002, SR-89-018, SR-89-017, and SR-89-016. (Reference CAR No. HQ-91-011).

At the Project Office the auditor reviewed QAAP-18.1, Revision 1 and QMP-18-02, Revision 1. The auditor verified: (1) FY 90, Revisions 3, 4, and 5, and FY 91, Revision 0, audit schedules; (2) audit record packages for Audit Nos. 90-02, 90-06, and 90-07; (3) FY 90, Revision 0, and FY 91, Revision 1, surveillance schedules; and (4) surveillance record packages for Surveillance Nos. YMP-SR-90-039, YMP-SR-90-021, YMP-SR-90-034, YMP-SR-90-040, YMP-SR-90-037, and YMP-SR-90-031.

14. Criterion 20—See Section 4.3, Summary of Technical Activities, for a summary of this criterion.

4.3 Summary of Technical Activities

1. Study Plan Review

The study plan review process was technically evaluated during the audit at both HQ and the Project Office. This was done in conjunction with the programmatic audit of Criterion 20. The primary emphasis for the technical portion of the audit was the Midway Valley study plan prepared by SNL and the Calcite/Silica activity, which is part of a USGS Study Plan. As a reference, additional study plans were included in the technical evaluation. The following Study Plans were involved in the evaluation during the audit:

NOTE: The following abbreviations have been used to indicate the type of evaluation and the location:

T - technical evaluation
P - programmatic evaluation
HQ - Headquarters
PO - Project Office

8.3.1.17.4.2—Location and Recency of Faulting near Prospective Surface Facilities. [SNL, referred to as Midway Valley] (P&T, HQ; P&T, PO)

8.3.1.5.2.1—Characterization of the Quaternary Regional Hydrology [USGS Activity 5 of this study plan is "Studies of Calcite and Opaline-Silica Vein Deposits," referred to as Calcite/Silica] (P&T, HQ; P&T, PO)

8.3.1.15.1.2—Laboratory Thermal Expansion Testing. [SNL] (P, HQ; P&T, PO)

8.3.1.17.3.3.2—Ground Motion from Regional Earthquakes and Underground Nuclear Explosion [SNL] (P, HQ; P&T, PO)

8.3.1.5.1.4—Paleoenvironmental History of the Yucca Mountain Region [USGS] (P, HQ; P&T, PO)

8.3.1.2.2.1—Unsaturated Zone Infiltration [USGS] (P, HQ; P&T, PO)

8.3.1.2.2.7—Hydrochemical Characterization of the Unsaturated Zone [USGS] (P, HQ; P&T, PO)

8.3.4.2.4.1—Characterization of Chemical and Mineralogic Changes in the Post-emplacement Environment [Lawrence Livermore National Laboratory] (P, HQ; P&T, PO)

8.3.1.17.4.1—Historical and Current Seismicity [USGS] (P, PO)

Those study plans evaluated during the technical portion of the audit differed in some cases from those evaluated programmatically during the audit.

The procedures for Study Plan Review are AP-1.10Q for the Project Office and ILP-22.3.1 at HQ.

No significant difficulties or technical concerns were identified during the audit in this area. The technical team acknowledges the many hours spent in administrative coordination that was necessary to complete the review cycle for each study plan. The technical staff was knowledgeable of the activities planned in the studies, the procedures in use, and the review process. During the past year there has been considerable and consistent improvement in documentation of the review process and in the consistency of the technical review itself.

The documents that result from the review process are technically consistent from document to document and meet the Level of Detail Agreement (LODA) with the NRC. In discussion with the staff during the audit, there was considerable variation in what the commitment to the LODA is (i.e., whether the LODA is a requirement or simply guidance). If the LODA is a requirement, is the information needed for appropriate technical review in the document or is the level of detail attained through the review process? If the review process is radically changed, then these questions need to be addressed in the design of the new review process, or, potentially, the quality of the review will be compromised.

The verification process, which establishes the agreed upon comment resolutions, has improved along with other aspects of the review process. Strength in this area ensures that cases in which (1) the comment resolution does not appear to fully address the original comment or (2) where the final text change does not reflect the comment as resolved, are satisfactorily resolved and do not jeopardize the review.

The review process for study plans is effective as currently implemented. This is consistent with the evaluation performed during the programmatic portion of the audit.

2. Technical Baseline Document Development and Approval

Technical baseline document development and the review process were evaluated by the technical team at both HQ and the Project Office. The technical baseline documents evaluated or utilized as part of the audit at HQ were as follows:

- o WMSR Volume I, Revision 0
- o WMSR Volume I, Revision 1
- o WMSR Volume III, Revision 0
- o WMSR Volume IV, Revision 0
- o WMSR Volume IV, Revision 1
- o Waste Management System Description (WMSD), Revision 0
- o Technical Document Management Plan, Revision 3, for WMSR documents

The documents listed below are the procedural control documents for the technical baseline:

- o QAAP 3.1—Technical Document Review
- o QAAP 3.5—Preparation of Technical Documents
- o QAAP 3.6—Technical Document Input Control
- o QAAP 3.7—Interface Control
- o ILP-30.3.2—Study Plan Review

The review packages from the document reviews were also part of the information audited.

Documents utilized in the Project Office section of the audit were as follows:

- o Technical Requirements for the Yucca Mountain Project (Midway Valley Trenching and Calcite/Silica Activities) (YMP/CM-0007), Revision 1. Note: this document (YMP/CM-0007) is the current technical baseline at the Project Office and is designed to be limited to the technical requirements only to the extent that is needed for the Midway Valley and Calcite/Silica activities.
- o Plan for Development of the Midway Valley and Calcite/Silica Activity Requirements.
- o Interface Memorandum of Understanding contract number DE-AC08-87NV10576.
- o QMP-06-04, Revision 0, "Project Office Document Development, Review, Approval and Revision Control Process."

The appropriate document review packages were also part of the audited information.

The evaluation was impacted by the unavailability of the QACD, Revision 1, during the HQ portion of the audit, and the unavailability of the Grading Package for YMP/CM-0007. The Grading Package at the Project Office became available just prior to the audit exit. This situation did not invalidate or negate the effectiveness of the audit process.

The technical audit team is concerned that the QACD and the Grading Package impose different controls on the same document system at the two organizations. The review cycles and level of review control are different at the two locations.

The review process for YMP/CM-0007 at the Project Office was ineffective. Not all of the technical review criteria were used in the review process. No single reviewer could be expected to have the background and skills necessary to fully review the document. (Reference Car No. YM-91-009).

The technical audit team is concerned about the level of control of interfaces to the technical baseline as an entity. This includes the inputs and outputs at all levels of the baseline hierarchy. There was no master list of reference documents established for WMSR I, which prevents complete flow-down verification. There is also a concern for how elements from the U.S. Department of Energy (DOE) Orders enter the requirements system. As an example, DOE imposed systems engineering requirements from DOE Order 4700.1A in WMSR, Volume I.

The technical audit team is concerned with establishment and control of the organizational interfaces associated with the development and use of the technical baseline. This is most apparent at the Project Office, where sections of the baseline document have been prepared by a participant organization without separate acceptance review or acceptance criteria.

During staff interviews, the audit team encountered problems with the level of understanding of individual staff, relative to methods and procedures being used in development of the technical baseline. This problem was more prevalent at HQ. There was often a lack of understanding of how failure to comply with procedures would impact the technical product at both HQ and the Project Office. Both staff groups had conceptual problems with establishment of interfaces, how to appropriately verify flow down of requirements, and the importance of the control of inputs. Project Office staff had difficulty explaining how the full technical baseline at the Project Office would be developed from the existing document, and whether or not changes to the controls for the baseline would be required. If changes were made to the controls, there was little understanding of how these changes, once made, would have to be implemented.

The process that developed the technical baseline documents is ineffective and the status of the documents themselves is indeterminate until the identified adverse conditions are corrected. The design of the technical baseline as a system appears to be sufficient to provide the required information to other program and Project functions.

The technical audit team believes that technical baseline development requires rethinking and greater coordination between the two locations than has taken place. The engineering groups have taken immediate action in correcting the deficiencies identified, as is evidenced by the items corrected during the audit (reference Sections 6.2 and 6.3 of this report). This should be commended. In addition, a very positive action in the system engineering areas is the Systems Engineering Training Course developed for the Project. Technical training of a non-procedural nature, which is available to a broad spectrum of the technical staff, appears to be an important factor in implementing the technically-driven aspects of the project.

3. Sample Management Facility (SMF)

Activities at the SMF were evaluated during the Project Office section of the audit in the following areas:

- o Sample, item, and data control.
- o Measuring and test equipment control.
- o Handling, shipping, and storage.

The Project Office has responsibility for management and operation of the SMF, located at the Nevada Test Site. The T&MSS contractor is responsible for the curation and control of samples housed at the SMF. The operation of the SMF is described and controlled via SMF Branch Technical Procedures BTP-SMF-001 through 008. These procedures describe and control the various aspects of SMF activity in a logical fashion, without specific separation by quality assurance function as identified by the audit criteria. Support for the facility including calibration is provided by Reynolds Electrical and Engineering Company, Inc. (REECO).

Operation of the SMF was evaluated using the "vertical slice" method. The aim of the evaluation was to determine the status of implementation of the technical procedures and to determine that the implementing procedures (technically) do ensure that the controls imposed by the QAPD are met. At the time during which the audit of this facility began, the QA Grading Package covering the SMF activities had not yet been approved. However, this situation was corrected during the course of the audit. The technical audit team identified which controls were in place at the facility and the appropriateness of these controls to the activities performed.

Through discussions with SMF staff, it was determined that there has been little implementation of the procedures for samples identified as quality-affecting, with the exception of USGS surface sample splits that are maintained by the SMF. The sample barcode identification system is in general use for Project samples.

The Apache Leap prototype drilling activity is viewed as a positive step in debugging and testing of the procedures prior to doing quality-affecting work. The BTPs will be revised to reflect the lessons learned from the activity.

The primary area of weakness identified during the audit of the SMF was associated with the identification and control of organizational interfaces encountered during SMF operation. This includes the interface with REECo for transfer of drilled core to the SMF that takes place on the floor of the drill rig.

In summary, sample management at the SMF should be expected to function as designed, when implemented. The weakness associated with interface identification and control should be rectified prior to for site characterization drilling.

From a technical standpoint, the SMF procedures, when fully implemented, should provide sufficient controls to provide unique sample identification and custodial accountability, to the associated records. The technical audit team concurs with the evaluation for the programmatic audit function, that the status should be considered indeterminate until implementation is attained.

Control of Measuring and Test Equipment (calibration) is limited to equipment such as balances. A balance, used as a sample, was uniquely identified and included in a calibration recall and periodic calibration system. The balance was currently in a calibrated condition, records for the calibration process were locally available, and the instrument was tagged "not to be used for quality-affecting work." This tagging is consistent with the currently approved QA Grading Package of the SMF that excludes Criterion 12 from the controls applied to the SMF activities. Maintaining such instruments in a calibrated condition constitutes good technical practice and should be commended. The audit team concurs with the decision to eliminate Criterion 12 from SMF controls.

It was determined that the technical controls for handling, storage, and shipping were consistent with those used in Criterion 8. Considerable effort has gone into establishing storage methods for the samples expected to be encountered at the SMF. The system, as indicated previously, has not been fully implemented or exercised and is indeterminate. However, the prognosis for successful implementation appears good.

4. Conclusion

The most widespread concerns determined by the technical audit team are in the following areas:

1. Technical procedural training is weak. Technical staff with heavy administrative duties should have general technical training opportunities to remain current and expand their areas of technical expertise.
2. The understanding, identification and control of interfaces in many areas is weak.
3. The QA Grading Package preparation and approval system is cumbersome. The time expended and the number of interactions required to produce a grading package has slowed the review and approval cycle.

4.4 Summary of Audit Findings

A total of 19 CARs (12 to HQ and 7 to the Project Office) were generated during the course of this audit. Information copies of the CARs are attached as Enclosure 2. A synopsis of CARs is presented in Section 6 of this report. Additionally, this synopsis includes 29 remedial deficiencies (11 at HQ and 18 at the Project Office) that were corrected during the course of the audit.

5.0 AUDIT MEETINGS

5.1 Pre-audit Conference

A pre-audit conference with key staff was conducted at 10:30 a.m. at HQ on October 15, 1990, and at the Project Office in Las Vegas, Nevada, on October 22, 1990. The purpose, scope, and proposed agenda for the audit were presented and the audit team and observers were introduced. A list of those attending is attached as Enclosure 1.

5.2 Persons Contacted During the Audit

(See Enclosure 1 for a list of those persons contacted during the audit).

5.3 Preliminary Post-audit Conference

A preliminary post-audit conference was conducted at HQ on October 19, 1990 and at the Project Office on October 29, 1990. The purpose of the preliminary post-audit conference was to present a synopsis of potential CARs to key staff at each location.

5.4 Post-audit Conference

The post-audit conference was conducted at 9:00 a.m. on October 31, 1990, at HQ in Washington, D.C. A synopsis of the preliminary CARs identified during the course of the audit was presented to the OCRWM Director and his staff. A list of those attending the post-audit conference is attached as Enclosure 1.

5.5 Audit Status Meeting

Audit status meetings were held with management representatives at 8:45 a.m. on each day of the audit at HQ and the Project Office. A status of how the audit was progressing and identification of discrepancies were discussed.

6.0 SYNOPSIS OF CORRECTIVE ACTION REQUESTS AND REMEDIAL DEFICIENCIES CORRECTED DURING THE AUDIT

6.1 Corrective Action Requests

- YM-91-005 Documented evidence of a matrix that cross-references OCRWM procedures and the QAPD to the QARD requirements does not exist.
- YM-91-006 The controls established for training Project personnel do not effectively ensure that personnel are adequately trained prior to performance of quality-affecting activities.
- YM-91-007 The flow-down of requirements from the WMSR Volume IV to the MGDS Systems Requirements (SR), the MGDS Site Requirements Document (SRD), the Test & Evaluation Planning Basis (T&EPB), and the Surface-Based Testing Facilities Requirements Document (SBTFRD) is not apparent.

- YM-91-008 Inputs to YMP/CM-0007, "Technical Requirements for the Yucca Mountain Project (Midway Valley Trenching and Calcite/Silica Activities)," Revision 1, are not always traceable.
- YM-91-009 The review process for YMP/CM-0007, Revision 1, was deficient.
- YM-91-010 At the time YMP/CM-0007, Revision 1, was completed and processed, QMP-03-09 was not issued for implementation. It was unclear as to what controls were applied to processing YMP/CM-0007.
- YM-91-011 Interim Change Notices (ICNs) were classified as being a minor change, when, in fact, they do not meet the definition of a minor change.
- HQ-91-001 Draft version OG of QAAP 2.2, "Verification of Personnel Qualification," was issued for interim use prior to formal controlled distribution and completion of the formal review process.
- HQ-91-002 Potential interfaces was not approved per the Program Change Control Procedure with approval of WMSR Volume I, per QAAP 3.7, Revision 0.
- HQ-91-003 Technical Adequacy Assessment Group (TAAG) comment sheets for WMSR Volume I, Revision 1, and Volume IV, Revision 1, are not signed by the TAAG Chair.
- HQ-91-004 There does not appear to be a system for addressing comments resulting from the review of one volume of the WMSR, which affects other volumes.
- HQ-91-005 QAAP 5.1, Revision 2, and QAAP 5.2, Revision 1, do not clearly delineate what constitutes a minor change.
- HQ-91-006 During review of revisions for QAAPs 6.1 and 16.1, which were classified as minor changes, it was found that the revision record did not list all the changes that were accomplished during the revision of these QAAPs.
- HQ-91-007 Control requirements for the WMSR and WMSD Technical Document Management Plans are inconsistent with the stated requirements.

- HQ-91-008 The Deficiency Tracking report and the Monthly Action Due report have not been effective in conveying the status of open items to ensure timeliness of responses, response evaluations, or verification and close-out.
- HQ-91-009 Procedure ILP-12.17.01 does not contain a description of the QRC. In addition, the storage facility does not meet the minimum requirements for a temporary storage facility.
- HQ-91-010 Procedural requirements for Lead Auditors, Auditors, and Technical Specialists are not being implemented accordingly.
- HQ-91-011 The required overview (verification) activities have not been adequately implemented.
- HQ-91-012 The approved list of input sources for each WMSR document has not been provided by the Systems Engineering Branch Chief to the Configuration Management Branch Chief. Also, a controlled master list of input sources has not been generated.

6.2 Remedial Deficiencies Corrected During The Audit At HQ

1. The QACD did not provide a description of each office's applicable function or work definitions, nor did it identify the applicable QA program controls to be implemented for the present organizational structure. HQ corrected this deficiency by issuing Revision 1 to the QACD.
2. Evidence of Weston TAAG members reviewing the revised Volume III of the WMSR was not available. HQ corrected this deficiency by placing documentation in the records file. The document indicates that the second signature on TAAG review sheets represents concurrence by the reviewers that comments were resolved by the Technical Document Management Plan.
3. The Proficiency Review Report for a Weston individual, submitted with the WMSR Volume I, Revision 1, and Volume IV, Revision 1, TAAG documentation, is that of a licensing engineer. The review performed by the Weston individual was as a QA review, in that individual's capacity as a Senior Quality Engineer. HQ corrected this deficiency by generating a Proficiency Review Report for the individual as a QA Engineer, and included the document in the records package.

4. For the CER Corporation procurement, the Document Review Record (DRR) form submitted by RW-3 (for the QA review) contained mandatory comments that were not indicated as being resolved by RW-50. Additionally, although the mandatory comments were incorporated in the procurement documents, the reviewer (RW-3) did not indicate agreement with the resolution of these comments in the column on the DRR form provided for this purpose. HQ corrected this deficiency by having RW-50 respond to the mandatory comments and signing the DRR in the appropriate space. Also, RW-3 indicated (by initial and date) agreement with the resolution of the comments on the DRR form.
5. There was no documented evidence that the procurement process was conducted and documented as specified in QAAP 4.2, paragraphs 5.2.1, 5.2.2, and 5.3; and QAAP 7.1, paragraphs 5.1.1 a) through g), and 6.1. HQ corrected this deficiency by revising the remedial action for Deficiency Report (DR) 90-008.
6. A review of DRRs associated with ILP-12.17.01, Revision 0, provided evidence that the commentator had not signed off on the DRR indicating acceptance of the proposed resolution. HQ corrected this deficiency by having the commentator sign concurrence to the responses on the DRR.
7. Trend analysis had not been conducted to date. QAAP 2.9, Revision 0 (10/15/90), had revised the trending program and no reports had been issued under this new program. The Project Office recognized the lack of trend analysis and issued CAR No. YM-91-001 (10/19/90) to document this deficiency.
8. HQ (except RW-50) had not transmitted the QA Records List and the authorized records authentication lists to the QRC as QA records, per QAAP 17.1, Revision 0. HQ corrected this deficiency by transmitting the required lists to the QRC.
9. HQ QA had not transmitted copies of issued audit or surveillance schedules to the QRC as required by QAAP 18.2, Revision 1, and QAAP 18.3, Revision 0. HQ corrected this deficiency by transmitting the audit and surveillance schedules to the QRC.
10. The list of personnel qualified as Lead Auditors, required by QAAP 18.1, Revision 0, did not exist. HQ corrected this deficiency by issuing the list, which will be maintained by RW-3 with the Lead Auditor records.

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CORRECTIVE ACTION REQUEST
(continuation sheet)

5 Requirements (continued)

QAAP-16.1, Revision 0, Para. 4.4 includes responsibilities for the Director, OQA, or designee to track the status of all CARs and DRs.

6 Adverse Condition (continued)

- B. Untimely response evaluation actions for 44 items. (Based on time from Response Received to Accepted/Rejected)

NOTE: For the purpose of this deficiency, evaluations that occurred within 14 days of receipt of the response were considered acceptable.

Response evaluations ranged from 15-200 + days after receipt of response for 44 items, which included three CARs for significant deficiencies that noted 17, 19, and 23 days.

(DRs 89-01, -08 thru -13, -17; CARs 89-01, -02, and 90-01.)

- C. Untimely verification/close-out actions for 23 items (Based on time from Corrective Action completion to close-out).

NOTE: For the purpose of this deficiency, close-outs that occurred within 30 days of completion of actions were considered acceptable.

Close-outs ranged from 31-337 days for 23 of 41 items.

(DRs 89-02, 03, 04, 06, 08 thru 11, 13, 15, 17, 24, 26 thru 29, 31 thru 34; 90-09, 10; CAR 89-01)

- D. Only one item (DR-89-07) was voided. However, the DR was initiated in 3/89 and was not closed until 9/90. Therefore, the QA Evaluation of the cited problem was not timely.

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 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAPD, Revision 3	2 Related Report No. Audit No. 90-I-01
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3 Responsible Organization RW-10	4 Discussed With B. Cerny
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10 Response Due 11/29/90	11 Responsibility for Corrective Action S. Rousso	12 Stop Work Order Y or N N
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5 Requirement:

QARD, Rev. 3, Para. 17.6 states in part "Temporary storage, preservations, ... is performed in accordance with requirements applicable to the storage of records delineated in the QARD."

QARD, Rev. 4, Para. 17.0, states "The provisions of NQA-1, Basic Requirement 17 and supplemental 17S-1 shall apply."

ASME NQA-1, Supplement 17S-1, Para. 4.1 states in part, "Prior to storage of records, a written storage procedure shall be prepared and shall include a description of the storage facility."

6 Adverse Condition:

ILP 12.17.01 procedure does not contain a description of the storage facility.

Without this description, it is not possible to verify if the Quality Records Center (QRC) meets additional requirements found in Section 4 of Supplement 17S-1.

The storage facility at this time does not meet the minimum requirements for a temporary storage facility.

7 Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar conditions to those listed on the CAR. Identify these deficiencies and provide the measures

8 Initiator Mario R. Diaz	Date: 10/19/90	9 Severity Level - 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <u>Jane Blaylock</u>	Date: 11/9/90
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: OAR _____ Date _____	17 Closure Approved By: OQA _____
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**CORRECTIVE ACTION REQUEST
(continuation sheet)**

7 Recommended Action(s) (continued)
required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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14CAR NO.: HQ-91-010
 DATE: 11/09/90
 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAAP 18.1, Revision 0	2 Related Report No. Audit No. 90-I-01
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3 Responsible Organization RW-3	4 Discussed With R. Clark/R. Lahoti/D. Miller
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10 Response Due 11/29/90	11 Responsibility for Corrective Action D. Horton	12 Stop Work Order Y or N N
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5 Requirement:

QAAP 18.1, Rev. 0, Para. 6.3.3 states in part: "Based on annual evaluations, the Director, OQA, may extend the certification...The Director, OQA, dated signature on Attachment I, indicates results of the evaluations are satisfactory and the certification is extended for a period of one year from the date of the evaluation."

Para. 6.5.3 states:

"A file for each Lead Auditor, auditor, and technical specialist is established and maintained by the Director, OQA, and contains copies of the individual's resume, documentation relating to or supporting the individual's qualifications, educational degree(s), training course certificates, training attendance records, audit participation records and applicable examination results."

6 Adverse Condition:

Procedural requirements for Lead Auditors, auditors, and technical specialists are not being implemented accordingly.

- o Recertification for Lead Auditors are not being documented.
- o Files of Lead Auditor, auditor, and technical specialist do not contain all required documentation.
- o Objective evidence of the examination contents for Lead Auditors does not exist.

7 Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Identify the cause of the condition and the planned corrective action to prevent recurrence.

8 Initiator Mario R. Diaz	Date: 10/19/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <u>James Blaylock</u>	Date: <u>11/9/90</u>
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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**CORRECTIVE ACTION REQUEST
(continuation sheet)**

5 Requirements (continued)

Para. 6.6.1 states:

"The Director, OQA, develops and administers the examination for a Lead Auditor."

Para. 6.6.4 states:

"The Director, OQA, retains a record of the objective evidence of the examination contents."

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CORRECTIVE ACTION REQUEST
(continuation sheet)

5 Requirements (continued)
management information..."

- D) Section 18, Audits, Para. 18.1.1: "Procedures...address accomplishment of the planning and scheduling...to ensure that Program-deliverable products and processes are evaluated commensurate with importance... Internal audits are scheduled to ensure that applicable elements of the QA program are audited at least once a year."

6 Adverse Condition (continued)

DR actions did not include an evaluation of important activities or applicable elements of the QA program that were addressed by other means (surveillances, reviews, etc.). The DR was deemed as not significant so the actions taken by CAR-90-01 did not apply to this condition.

- o OCRWM (HQ) QA Division has not conducted surveillances since March 1990. (Requirement B).

QAAP-18.3, Rev. 0, "Surveillance Program," was effective 3/27/89.

Twenty surveillances were conducted until March 1990. None have been conducted since that time.

OCRWM (HQ) QA Division did not fully implement the Trend Analysis Program. (Requirement A).

QAAP-2.9 Rev. 0, "QA Program Status Reporting," was effective 10/2/89 with Rev. 1 effective 10/15/90. (See CAR No. YM-91-001)

- o Present Deficiency Document reporting and tracking system is not accurate or effective (Requirement D).

(See CAR No. HQ-91-008 from this Audit)

Also refer to DR-90-011 issued 3/1/90 and closed 10/3/90.

Discussion: A comprehensive review was conducted in February 1990 and issued reports were published in March 1990. Review 90-001 identified 15 DRs and 27 observations (some of which identified deficiencies or potential problems). The text of the report states that the audit procedure was used as a guidance. The DRs were issued but responses to observations were not required.

Recent reorganization and resultant efforts taken have shown an improvement in certain areas.

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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14 CAR NO.: YM-91-005
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 SHEET: 1 OF 1
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAPD, Revision 3	2 Related Report No. Audit No. 90-I-01
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3 Responsible Organization Quality Assurance Division	4 Discussed With Donald G. Borton
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10 Response Due 11/29/90	11 Responsibility for Corrective Action D. Borton	12 Stop Work Order Y or N N
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5 Requirement:

QAPD, Rev. 3, Para. 2.1.1 states in part:

"A matrix, which cross-references OCRWM procedures and the QAPD to the QARD requirements, is established and maintained by the Office of Quality Assurance."

6 Adverse Condition:

Documented evidence of a matrix that cross-references OCRWM procedures and the QAPD to the QARD requirements does not exist.

NOTE: The auditor was aware that this matrix was in the process of being developed based on the fact that the portion related to the YMPO was almost finished at the time of the Audit Exit Meeting. However, the document has not been approved as required by the implementing procedure.

7 Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiency noted in Block 6.

8 Initiator Mario R. Diaz	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/>	13 Approved By: OQA <u>James Blaylock</u>	Date: <u>11/9/90</u>
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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14 CAR NO.: YM-91-006
 DATE: 11/09/90
 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAPD, Revision 3	2 Related Report No. Audit No. 91-I-01
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3 Responsible Organization Training	4 Discussed With M. Anderson and W. Thomas
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10 Response Due 11/29/90	11 Responsibility for Corrective Action C. Aiello	12 Stop Work Order Y or N N
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5 Requirement:
 QAPD, Rev. 3, Para. 2.1.9, states in part, "Personnel assigned to perform activities that affect the quality of an item or activity will receive appropriate indoctrination and training prior to performing work."

6 Adverse Condition:
 The controls established for training Project personnel do not effectively assure that personnel are adequately trained prior to performance of quality-affecting activities.

- o Qualification evaluation dates may not reflect or coincide with dates necessary for training.
- o Additional training (after an individual becomes qualified) cannot be determined as having been accomplished on time. This may be due to the fact that a time limitation is not reflected or documented on the appropriate forms.
- o Tracking mechanism to ensure necessary and adequate training is achieved does not exist.
- o Training matrix seems to be an important part of the training program. However, it does not exist.

7 Recommended Action(s):
 Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar

8 Initiator Mario R. Diaz	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <u>James Blyford for</u>	Date: <u>11/9/90</u>
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: OAR _____ Date _____	17 Closure Approved By: OQA _____
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SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST
(continuation sheet)

6 Adverse Condition (continued)

7 Recommended Action(s) (continued)

conditions to those listed on the CAR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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14 CAR NO.: YM-91-007
 DATE: 11/09/90
 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document
 EDD-001, Rev. 0, and YMP/CM-007, Rev. 1

2 Related Report No.
 Audit 90-1-01

3 Responsible Organization
 Engineering & Development Division

4 Discussed With
 G. Dymmel and J. Waddell

10 Response Due
 11/29/90

11 Responsibility for Corrective Action
 E. Petrie

12 Stop Work Order Y or N
 N

5 Requirement:

QA Grading Report No. EDD-001, Page 4, Item F, states "The document shall cover all requirements necessary to establish the flowdown of requirements from source documents."

Page I-1 of Technical Requirements for the Yucca Mountain Project (YMP/CM-0007) states in part, "This document defines a basis traceable from the Waste Management Systems Requirements Document..."

6 Adverse Condition:

The flowdown of requirements from the WMSR Volume IV to, respectively, the MGDS System Requirements (SR), Site Requirements Document (SRD), Test & Evaluation Planning Basis (T&EPB), and Surface-Based Testing Facilities Requirements Document (SBTFRD), as shown in Figure I-1 of YMP/CM-0007 is not apparent. Examples are as follows:

- Requirements in Section IV (SRD) should flow down from Section III (SR). Page IV-2 states, "All requirements in this section are based on the Site Characterization Plan..."
- Requirements in Section V (T&EPB) should flow down from Section IV (SRD). The only references in Section V are to Neal, 1985, and the SCP. However, Page V-1 says the two figures in Section V are based on inputs from Section III (SR) and page V-5 says requirements to control testing are based on "[NEV]."

7 Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar conditions to those listed on the CAR. Identify these deficiencies and provide the measures

8 Initiator
 Marc Meyer

Date:
 10/26/90

9 Severity Level -
 1 2 3

13 Approved By:
 OQA James Blaylock for 11/9/90

Date:

15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted:
 OAR _____ Date _____

17 Closure Approved By:
 OQA _____

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CAR NO: TK-91-007
DATE: 11/09/90
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**CORRECTIVE ACTION REQUEST
(continuation sheet)**

7 Recommended Action(s) (continued)
required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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14CAR NO.: YM-91-008
 DATE: 11/09/90
 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document EDD-001, Revision 0		2 Related Report No. Audit 90-I-01	
3 Responsible Organization Engineering & Development Division		4 Discussed With G. Dymmel and J. Waddell	
10 Response Due 11/29/90	11 Responsibility for Corrective Action E. Petrie	12 Stop Work Order Y or N N	
5 Requirement: QA Grading Report No. EDD-001, Page 4, Items B and C states, "All inputs shall be documented. Use of inputs shall be documented and traceable."			
6 Adverse Condition: Inputs in Revision 1 of YMP/CM-0007, "Technical Requirements for the Yucca Mountain Project (Midway Valley Trenching and Calcite/Silica Activities)" are not always traceable. Examples are as follows: 1. The source of functional requirements on pages III-8, 10, and 11 is not apparent. 2. References on page IV-5 to Ross, 1987, and DOE, 1986, are not traceable. 3. Page IV-B-1 references 42USC9601 as the emergency planning and community Right-to-Know Act and a source of input. The reference is not traceable to the Act nor is it traceable to a requirement in Section III. 4. Page IV-B-1 references "N49602 Spang to Gertz 10/10/89" as a source of input. The letter does not exist. A letter dated 10/10/89 from Spang to the DOE Nevada Operations Office exists;			
7 Recommended Action(s): Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar conditions to those listed on the CAR. Identify these deficiencies and provide the measures			
8 Initiator Marc Meyer	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <u>James Blaylock</u> for <u>11/9/90</u>
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted: QAR _____ Date _____		17 Closure Approved By: OQA _____	

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DATE: 11/09/90
SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST
(continuation sheet)

6 Adverse Condition (continued)

however, the letter number is N48602.

5. None of numerous references to "[NEV]" are traceable because no such source of input exists.

6. Requirements in Section IV, Paragraph 2.8, are not traceable.

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document
 QAPD, Revision 3; QMP-06-04, Revision 0

2 Related Report No.
 Audit No. 90-I-01

3 Responsible Organization
 Engineering & Development Division

4 Discussed With
 Jon White and George Dymmel

10 Response Due
 11/29/90

11 Responsibility for Corrective Action
 E. Petrie

12 Stop Work Order Y or N
 N

5 Requirement:

QAPD, Para. 3.1.6, states in part, "Technical reviews are performed by any competent individual(s) or groups..."

QMP-06-04, Step 12, states, "Assign reviewer(s) by entering name(s) on Page 1 of DRS (name & discipline of the qualified, independent reviewer for technical reviews); provide reviewer(s) with review package and established review criteria. Attachment 7 provides examples for guidance in establishing criteria."

QMP-06-04, Step 13, states in part, "Review document as instructed in the review package."

6 Adverse Condition:

The following conditions are associated with review of the Technical Requirements for the Yucca Mountain Project (YMP/CM-0007):

1. The scope of expertise of the person who performed a technical review was not broad enough to cover the entire spectrum of characteristics requiring review. For example, the reviewer stated he did not perform a "flowdown" review because he had no systems engineering experience. The reviewer was unfamiliar with the fact that YMP/CM-0007 was to be based on WMSR requirements.
2. The reviewer was not familiar with technical review criteria in Attachment 7 to QMP-06-04. These were the only criteria provided the reviewer.

NOTE: The reviewer received no classroom instruction on QMP-06-04 and did not seek

7 Recommended Action(s):

Identify the remedial action(s) to be taken to correct the deficiencies noted in Block 6. Identify the condition and the planned action to prevent recurrence.

8 Initiator
 Marc Meyer

Date: 10/26/90

9 Severity Level -
 1 2 3

13 Approved By:
 OQA Jane Blaylock

Date: 11/9/90

15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted:
 QAR _____ Date _____

17 Closure Approved By:
 OQA _____

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

CAR NO.: YM-91-009
DATE: 11/09/90
SHEET: 2 OF 2

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

6 Adverse Condition (continued)

clarification on criteria during the course of his review.

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

14CAR NO.: YM-91-010
 DATE: 11/09/90
 SHEET: 1 OF 1
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document <u>QMP-06-04, Revision 1</u>	2 Related Report No. <u>Audit No. 90-I-01</u>
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3 Responsible Organization <u>Engineering & Development Division</u>	4 Discussed With <u>G. Dymmel</u>
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10 Response Due <u>11/29/90</u>	11 Responsibility for Corrective Action <u>E. Petrie</u>	12 Stop Work Order Y or N <u>N</u>
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5 Requirement:
QMP-06-04, Rev. 1, states in part, "...that documents will be processed in accordance with QMP-03-09.

6 Adverse Condition:
Contrary to the above, at the time Rev. 1 of Technical Requirements for the Yucca Mountain Project (YMP/CM-0007) was completed and processed, QMP-03-09 was not issued for implementation. It is unclear as to what controls were applied to processing YMP/CM-0007.

7 Recommended Action(s):
Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Identify the cause of the condition and the planned corrective action to prevent recurrence.

8 Initiator <u>Art Spooner</u>	Date: <u>10/26/90</u>	9 Severity Level - <u>1</u> <input type="checkbox"/> <u>2</u> <input checked="" type="checkbox"/> <u>3</u> <input type="checkbox"/>	13 Approved By: <u>OQA James Blaylock jr</u>	Date: <u>11/9/90</u>
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

14 CAR NO.: YM-91-011
 DATE: 11/09/90
 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QMP-06-04, Revision 1	2 Related Report No. Audit No. 90-I-01
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3 Responsible Organization Regulatory & Site Evaluation Division	4 Discussed With Ram Murthy
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10 Response Due 12/03/90	11 Responsibility for Corrective Action D. Dobson	12 Stop Work Order Y or N
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5 Requirement:
 QMP-06-04, Para 3.3 states:
 "A minor change is an alteration to an approved document such as an organizational title change; a change to the alpha-numeric identifier of the document; minor wording changes for clarity; editorial, typographical, grammar, punctuation, or spelling corrections; where the basic content of the document does not change."
 NOTE: Any other change is considered major.

6 Adverse Condition:
 Contrary to the above, the following ICNs were classified as being a minor change when in fact they do not meet the definition of a minor change. ICN #1 to BTP-QRB-001, ICN #2 to AP-5.28Q, and ICN #4 to AP-5.28Q.

7 Recommended Action(s):
 Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar conditions to those listed on the CAR. Identify these deficiencies and provide the measures

8 Initiator John S. Martin	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA James B. [Signature]	Date: 11/9/90
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

CAR NO: YM-91-011
DATE: 11/09/90
SHEET: 2 OF 2

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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

14 CAR NO.: HQ-91-012
DATE: 11/21/90
SHEET: 1 OF 1
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAAP 3.6, Revision 0		2 Related Report No. Audit No. 90-I-01
3 Responsible Organization RW-30		4 Discussed With W. Lemeshevsky/M. Senderling
10 Response Due 12/07/90	11 Responsibility for Corrective Action Dwight Shelor	12 Stop Work Order Y or N N

5 Requirement:

Section 6.2.1 states, "The approved list of input sources, and revisions thereto, for each document shall be provided by the Branch Chief responsible for the technical document to the Branch Chief, CMB who shall maintain a controlled master list of input sources for the technical documents."

6.2.2 states, "The Branch Chief, CMB shall determine which Branch Chief has cognizance for the functional area relating to each specific input (for example, licensing inputs to the Licensing Branch, environmental inputs to the Environmental Compliance Branch), and shall so indicate on the controlled master list of input sources."

6 Adverse Condition:

- The approved lists of input sources for each document has not been provided by the Systems Engineering Branch Chief to the Branch Chief, CMB.
NOTE: The list of input sources for the WMSR Volume I, Revision 1 has been transmitted to the Branch Chief, CMB.
- A controlled master list of input sources has not been generated.

7 Recommended Action(s):
Identify the remedial actions to be taken to correct the deficiencies noted in Block 6.

8 Initiator E. P. Bryant	Date: 11/19/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/>	13 Approved By: 	Date: 11/20/90
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

¹⁴ CAR NO. _____
DATE: _____
SHEET: _____ OF _____
QA
WBS NO.: _____

CORRECTIVE ACTION REQUEST

¹ Controlling Document		² Related Report No.	
³ Responsible Organization		⁴ Discussed With	
¹⁰ Response Due	¹¹ Responsibility for Corrective Action	¹² Stop Work Order Y or N	
⁵ Requirement:			
⁶ Adverse Condition:			
⁷ Recommended Action(s):			
⁸ Initiator	Date:	⁹ Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	¹³ Approved by OQA _____ Date:
¹⁵ Verification of Corrective Action:			
¹⁶ Corrective Action Completed and Accepted: QAR _____ Date _____		¹⁷ Closure Approved By: OQA _____	

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

CAR NO. _____

DATE: _____

SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

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

CAR NO. _____
DATE: _____
SHEET: _____ OF _____

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

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

CAR NO. _____

DATE: _____

SHEET: _____ OF _____

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

**YUCCA MOUNTAIN PROJECT
AUDIT OBSERVER INQUIRY**

N-QA-084
4/89

Audit No. _____
Log No. _____
Name _____ Organization _____
YMP Requirement Reference _____

Question/Concern _____

Response _____

Observer's Acknowledgement

Cleared for Submittal to YMP Participant _____
Lead Auditor / Lead Technical Specialist

Incorporated in YMP Audit Checklist...Ref _____

Audit Team Leader

**YUCCA MOUNTAIN PROJECT
AUDIT OBSERVER INQUIRY**

N-CA-084
4/89

Audit No. _____

Log No. _____

Name _____ Organization _____

YMP Requirement Reference _____

Question/Concern _____

Response _____

Observer's Acknowledgement

Cleared for Submittal to YMP Participant

Lead Auditor / Lead Technical Specialist

Incorporated in YMP Audit Checklist...Ref

Audit Team Leader

**YUCCA MOUNTAIN PROJECT
AUDIT OBSERVER INQUIRY**

N-QA-084
4/89

Audit No. _____

Log No. _____

Name _____ Organization _____

YMP Requirement Reference _____

Question/Concern _____

Response _____

Observer's Acknowledgement

Cleared for Submittal to YMP Participant

Lead Auditor / Lead Technical Specialist

Incorporated in YMP Audit Checklist...Ref

Audit Team Leader

**YUCCA MOUNTAIN PROJECT
AUDIT OBSERVER INQUIRY**

N-QA-084
4/89

Audit No. _____

Log No. _____

Name _____ Organization _____

YMP Requirement Reference _____

Question/Concern _____

Response _____

Observer's Acknowledgement

Cleared for Submittal to YMP Participant

Lead Auditor / Lead Technical Specialist

Incorporated in YMP Audit Checklist...Ref

Audit Team Leader

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE AUDIT NO. YMP-91-I-01
OF
YUCCA MOUNTAIN SITE CHARACTERIZATION
PROJECT OFFICE

AUDIT CHECKLIST NO. 91-I-01-01

PAGES 1 THROUGH 113

CHECKLIST APPROVED BY: Richard E. Powe

RICHARD E. POWE - AUDIT TEAM LEADER

DATE: 10/16/91

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,NA	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
1-1	QMP-01-01, Rev. 2, Para. 4.0 and Attachment 1	1. Verify that procedures contain appropriate titles and organizations based upon titles and responsibilities listed within QMP-01-01.			
1-2	QMP-01-01, Rev. 2, Paras. 4.0 and 4.1	1. Interview the Associate Director, Office of Geologic Disposal/Project Office Project Manager (ADGD/PM). Verify his/her cognizance relative to functional responsibilities. Areas to be covered include: <ul style="list-style-type: none"> a. Overall authority b. Responsibility c. Accountability for Project technical and quality performance d. Cost and schedule 			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

2 Page 2 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
1-3	QMP-01-01, Rev. 2, Para. 4.1 (10)	1. Referenced QMP requires the ADGD/PM to develop and maintain implementing line and quality procedures for which OGD/Project Office has lead responsibility. Verify and determine how lead responsibility is determined by the OGD/Project Office.			
1-4	QMP-01-01, Rev. 2, Para. 4.2	1. Interview the Deputy Project Manager. Verify his/her knowledge of responsibilities and duties to the ADGD/PM. In addition, determine his/her responsibilities for: <ul style="list-style-type: none"> o Project Training o Information Management System o Records Management 			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

2 Page 3 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
1-5	QMP-01-01, Rev. 2, Paras. 4.3, 4.5, 4.6, and 4.7	1. Verify that Division Directors are knowledgeable of their duties and responsibilities. In addition, verify that they have reviewed and approved indoctrination and training requirements for Branch Chiefs and other personnel under their supervision.			
1-6	QMP-01-01, Rev. 2, Paras. 4.4, 4.5.1, 4.5.2, 4.5.3, 4.6.1, 4.6.2, 4.6.7, 4.7.1, and 4.7.2	1. Verify that Branch Chiefs are knowledgeable of their responsibilities and duties. In addition, verify that they report quality-related issues and problems that affect or potentially affect activities of the Branch to the Division Directors and obtain satisfactory resolution.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
1-7	QMP-01-01, Rev. 2, Paras. 4.11, 4.11.1, 4.11.2 and 4.11.3	1. Verify/determine what controls exist to control work performed by matrixed organizations (i.e., when individuals wear two hats, that is when a person performs work for T&MSS and the Project Office, how do you know what program and reporting relationships exist). In addition, determine support and interaction with DOE/NV.			
1-8	QMP-01-02, Rev. 1, Para. 5.0	1. Verify whether or not a Stop Work Order has been issued subsequent to the last audit of the Project Office. If yes, continue with checklist items numbers 1-9 through 1-10. If no, continue with checklist item number 1-11.			

⁹ AUDITOR SIGNATURE _____

¹⁰ DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

2 Page 5 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
1-9	QMP-01-02, Rev. 1, Para. 5.0	1. Verify that, upon receipt of the Stop Work Order, the Project Manager/Responsible Organization performs the following: <ul style="list-style-type: none"> a. Responds within 24 hours that affected work has been stopped. b. Within 5 working days, completes appropriate sections of the Stop Work Order. 			
1-10	QMP-01-02, Rev. 1, Para. 5.0	1. Verify that when all actions are complete that the PM/Responsible Organization notifies the DQA. If all actions cannot be completed as scheduled, a written extension request must be submitted a minimum of ten days in advance of the scheduled completion.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-3	AP-5.13Q, Rev. 2, Paras. 5.0; (4) and 5.0; (5)	1. Verify that the Readiness Review Board Chairperson completes, signs, and dates a Readiness Review Board Selection Record. NOTE: Ensure team members are appropriately trained.			
2-4	AP-5.13Q, Rev. 2, Paras. 3.2; (1), (2), (3) and (4), and 5.0; (8), (9), (10), (11), (12) and (13)	1. Verify that checklists are prepared/completed by the Readiness Review Team. In addition, verify that the checklists contain elements as listed within AP-5.13Q and that proper approvals are obtained.			
				9 AUDITOR SIGNATURE _____	10 DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-8	QMP-02-01, Rev. 3, Para. 3.4 NOTE: QMP-02-01, Rev. 4 effective 10/15/91	1. Verify that position descriptions have been generated for individuals to be trained to YMPO procedures.			
2-9	QMP-02-01, Rev. 3, Paras. 3.6 and 5.0; (7)	1. Verify that position qualification evaluations have been documented.			

⁹ AUDITOR SIGNATURE _____

¹⁰ DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

2 Page 12 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-10	QMP-02-01, Rev. 3, Para. 5.0; (5) and (6)	1. Verify that the Training Manager develops and maintains a tracking system of training requirements to affected employees. In addition, verify that training status/ completion of training is maintained.			
2-11	QMP-02-01, Rev. 3, Para. 5.0; (8), (15), and Attachments 2 and 3	1. Verify that employee initial training is basedlined for employers by the supervisor on Attachments 2 and 3. NOTE: It is a procedural requirement to complete the assignment within 30 days.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-12	QMP-02-01, Rev. 3, Para. 5.0; (12)	1. Verify that the Training Manager has obtained a documented statement from personnel attesting to completion of verification of education and experience.			
2-13	QMP-02-01, Rev. 3, Para. 5.0; (21)	1. Verify that supervisors monitor the performance of employees involved in activities affecting quality and determine the need for additional training, retraining, and/or replacement.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

2 Page 14 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-14	QMP-02-01, Rev. 3, Para. 5.0; (27) and (32)	1. Verify that the Training Manager notifies the supervisor and employee if training assignment is not completed within specified time.			
2-15	QMP-02-01, Rev. 3, Para. 5.0; (30) and (31)	1. Verify that the Training Manager monitors changes in documents which are a part of an employee's baseline training requirements and issues a Completion of Reading Assignment form.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

2 Page 15 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-16	QMP-02-01, Rev. 3, Para. 5.0	1. Verify that, if completion of reading is dated after the effective date of a document, that an evaluation of post-effective date reading is documented.			
2-17	QMP-02-01, Rev. 3, Para. 5.0; (39)	1. Verify that supervisors notify training in writing when an employee under their cognizance terminates employment.			
				9 AUDITOR SIGNATURE _____	10 DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-19	QMP-02-09, Rev. 1, Para. 5.0, Step 12	1. Verify that, for Project Instructors, a Project Instructor Qualification form has been generated.			
2-20	QMP-02-09, Rev. 1, Para. 5.0, Steps 13, 14, 15, 16, 17, 18, 19 and 20	1. Verify that training materials consist of instructional objectives and an approved lesson plan. In addition, verify that Attachments 3 and 4 are properly completed.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
2-21	QMP-02-09, Rev. 1, Para. 5.0, Step 22	1. Verify that examinations are administered as required.			
2-22	QMP-02-09, Rev. 1, Para. 5.0, Step 26, NOTE	1. Verify that MACTEC Training Coordinator maintains training documentation. In addition, determine which procedure is utilized by MACTEC.			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

2 Page 19 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
3-1	<p>QARD, Rev. 4 para. 20.1 (c) AP-1.10Q, Rev. 4 step 9</p> <p>Step 10</p>	<p align="center">SCIENTIFIC INVESTIGATIONS</p> <p>NOTE: Also see Checklist Item 20-1</p> <p>{When a Study Plan is judged to be acceptable for Project Review, the Branch Chief, RIB, initiates quality assurance and technical reviews of the Study Plan The written request establishes the proposed reviewing organization and the schedule for completing the review. Review criteria are in step 10. OCRWM review may be in parallel.} In cases where OCRWM will conduct a technical review, the Branch Chief, RIB, may specify {this meets the requirements of this procedure.} }</p> <p>1. Verify that written requests for reviews contains the three items of information described above.</p> <p>Reviews of Study Plans are performed only by qualified staff. Documentation of the qualifications of reviewers will be completed internally by participant organizations prior to initiation of the Project review.</p> <p>2. Verify that there is evidence of staff qualifications in the study plan packages.</p>			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMP0

2 Page 20 of 113

3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
3-2	<p>QARD, Rev. 4 para. 20.1 (c) AP-1.10Q, Rev. 4 steps 11, 12, 13, and 14</p> <p>steps 14-22 and 5.3.2</p>	<p>Reviewers document mandatory and nonmandatory comments on CRFs and Section 2 of Exhibit 4. After completion of the review, the responsible TPO returns the completed CRFs to the Branch Chief, RIB.</p> <p>1. Verify that the CRFs (Attachment 1) and Attachment 4 (effective date 7/5/91) are properly filled out.</p> <p>The Branch Chief, RIB, consolidates the CRFs from all reviews. (The consolidated set is reviewed by the PI(s) (who prepares responses) and then a comment resolution meeting may be scheduled to discuss mandatory comments, if required.</p> <p>2. Verify that any comments withdrawn were with the concurrence of the reviewer.</p> <p>3. Verify that mandatory comments were resolved by the PIs.</p> <p>4. Verify that the PIs revised the revised Study Plans and completed CRFs were resubmitted.</p>			
				9 AUDITOR SIGNATURE	10 DATE

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

1 ORGANIZATION YMPO

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
3-5	QARD, Rev. 4 para. 2.5 AP-6.17Q, Rev. 0 para. 4.2(2)	<p align="center">QUALITY ASSURANCE GRADING</p> <p>The Assessment Team (AT) Manager is responsible for developing and revising the AT controlled List of documents from which information is obtained for the analysis and evaluation of items and activities. The documents on the AT Controlled List are identified in this procedure as the bases information.</p> <p>1. Verify that the AT Controlled List is consistent with the latest list of Controlled Documents.</p>			
3-6	para. 5.11.7 AP-6.17Q, Rev. 0 Section 4/5 step 1	<p>The reviewer(s) (QRB Members) shall be trained in the trained in the application of the governing review procedure and BTP-QRB-001. Chairman establishes training requirements for QRB members and Technical Advisors.</p> <p>1. Verify that all QRB members have been trained prior to beginning work with this procedure.</p>			
				⁹ AUDITOR SIGNATURE _____	¹⁰ DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

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3-7	<p>QARD, Rev. 4 para. 2.5 AP-5.28Q, Rev. 2 step 14</p> <p>BTP-QRB-001, Rev. 1 Section 4/5 step 10</p>	<p align="center">QUALITY ASSURANCE GRADING</p> <p>In accordance with criteria determined under the approved QRB review procedure, determine the adequacy and completeness of the QAG Report, commensurate with basis information maturity.</p> <p>Administrative Assistant prepares and distributes review packages to members and selected Technical Advisors.</p> <p>1. Verify that QRB Members reviewed each (all) QAG Reports in accordance with the QRB Review Procedure.</p>			
				9 AUDITOR SIGNATURE _____	10 DATE _____

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3-8	QARD, Rev. 4 para. 2.5 AP-5.28Q, Rev. 0 step 14 BTP-QRB-001, Rev. 1 Section 4/5 step 7 a	<p align="center">QUALITY ASSURANCE GRADING</p> <p>In accordance with criteria determined under the approved QRB review procedure, determine the adequacy and completeness of the QAG Report, commensurate with basis information maturity. (A selected member shall determine whether specific technical criteria are required. If required, member prepares them and the Chairman approves them.</p> <p>1. Verify that a selected member determines whether specific technical criteria are required.</p>			
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3-10	QARD, Rev. 4 para. 2.5 AP-5.28Q, Rev. 2 step 23 BTP-QRB-001, Rev. 1 Sect. 4/5 step 18	<p align="center">QUALITY ASSURANCE GRADING</p> <p>QRB Secretary prepares a QRB Record that describes in brief the issues discussed by the board, action items and their assignment, the results of any board action (including each members accept/return record), the signatures of each member, and the meeting time and place.</p> <p>1. Verify that the QRB Record contains the information above.</p>			
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3-16	QARD, Rev. 4 App. A, para. 3.1 and para. 20.10 c QMP-03-01, Rev. 1 para. 5.1	<p>PEER REVIEWS</p> <p>... A peer review is performed by two or more qualified individuals (, with verifiable technical credentials,) other than those who performed the work being reviewed, but who may be from the same organization. A peer review may be used as design verification of an activity or portion thereof.</p> <p>1. Verify that each peer review was performed by at least two persons with verifiable technical credentials.</p>			
3-17	QMP-03-01, Rev. 1 para. 5.2.2	<p>The appropriate Project Office Division Director or designee also issues the Peer Review Notice Figure 1)</p> <p>...</p> <p>1. Verify that a Peer Review Notice was issued by the Division Director or designee.</p>			

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3-18	QARD, Rev. 4 App. A, paras. 3.1 and 20.10 c QMP-03-01, Rev. 1 para. 5.2.3	<p>PEER REVIEWS</p> <p>The Chairperson (appointed by the Div. Director) shall prepare a Peer Review Plan that describes the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to arrive at a peer review report.</p> <p>1. Verify that such a Review Plan was prepared, approved by the Project Quality Manager, or designee and distributed.</p>			
3-19	QMP-03-01, Rev. 1 para. 5.2.4	<p>The list of potential peer reviewers (established by the Peer Review Chairperson), and the selection process (either by Chairperson or a Peer Review Selection Committee established by the Div. Dir.) shall be documented in the Peer Review Data Package.</p> <p>1. Verify that peer reviewers were selected as described above.</p>			
				⁹ AUDITOR SIGNATURE _____	¹⁰ DATE _____

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3-20	QARD, Rev. 4 App. A, paras. 3.1 and 2.10 c QMP-03-01, Rev. 1 para. 5.3.3	<p>PEER REVIEWS</p> <p>The Peer Review Chairperson ensures that the assigned review team members are cognizant of, and understand, this procedure and other applicable documents.</p> <p>1. Verify how this was accomplished since there are no specific instructions.</p>			
3-21	QMP-03-01, Rev. 1 para. 5.3.4	<p>The Peer Review Chairperson obtains the following information for each of the review team members: name of the person and a statement that the review team member (from whom?) meets the education, experience, and independence qualifications established for the review. This information shall be documented by a resume and a statement (from whom?) of independence of the review team member. This documentation shall be made available for surveillance and audit by the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy.</p> <p>1. Verify that the above requirements are satisfactorily satisfied.</p>			
<p>⁹ AUDITOR SIGNATURE _____</p>				<p>¹⁰ DATE _____</p>	

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3-22	QARD, Rev. 4 APP. A, paras. 3.1 and 20.10 c QMP-03-01, Rev. 1 para. 5.4.3	PEER REVIEWS A compilation of consensus opinions, minority positions, conclusions and recommendations, including open items, is to be documented. 1. Verify that such documentation is present in the review package.			
3-23	QMP-03-01, Rev. 1 para. 5.5.2	The Chairperson acknowledges receipt of author responses and resolutions to the appropriate TPO. 1. Verify that such an acknowledgment was sent.			
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3-24	QARD, Rev. 4 App. A, paras. 3.1 and 20.10 c QMP-03-01, Rev. 1 para. 5.5.6	<p>PEER REVIEWS</p> <p>The Peer Review Secretary or Chairperson records a summary report of the meetings conclusions and recommendations; collects comments and resolutions; and prepares the Review Record Memorandum.</p> <p>1. Verify the preparation of an accurate Review Record Memorandum.</p>			
3-25	QMP-03-01, Rev. 1 para. 5.5.8	<p>The peer review team, including the Chairperson, reviews, signs, and dates the Review Record Memorandum (even if some comments are left open).</p> <p>1. Verify signatures of the above.</p>			
<p>⁹ AUDITOR SIGNATURE _____</p>				<p>¹⁰ DATE _____</p>	

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3-26	QARD, Rev. 4 App. A, paras. 3.1 and 20.10 c QMP-03-01, Rev. 1 para. 5.5.5 (2)	<p>PEER REVIEW</p> <p>If agreement on the resolution of a comment cannot be reached, the team member may request assistance from successively higher levels of management.</p> <p>1. Verify that in any such case of unresolved comment, the team member may take it to higher management.</p>			
3-27	QMP-03-01, Rev. 1 para. 5.5.7	<p>The Peer Review Chairperson may complete the Review Record Memorandum with documented unresolved issues (provided that supplements to it will be added with a cross reference to the issue.)</p> <p>1. Verify that a data package and letter of transmittal make it clear there is/are unresolved issues.</p>			
<p>9 AUDITOR SIGNATURE _____</p>				<p>10 DATE _____</p>	

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3-28	QARD, Rev. 4 App. A, paras. 3.1 and 20.10 c QMP-03-01 para. 5.8	<p>PEER REVIEWS</p> <p>{The Peer Review data package consists of:</p> <ol style="list-style-type: none"> 1. Peer Review Notice and Peer Review Plan. 2. List of potential peer reviewers and the selection process. 3. Peer Review Team Selection Record, and the documentation of the reviewers qualifications. 4. Peer Review Package. 5. Peer Review Record Memorandum, including any supplements as described in Section 5.5.6. 6. Any other significant correspondence relating to the peer review as identified by the Chairperson. <p>The Peer Review Chairperson provides for maintenance of the data package in accordance with QMP-17-01, QA Records.</p> <ol style="list-style-type: none"> 1. Verify that the PEER REVIEW data packages comply with the above requirements. 			
				⁹ AUDITOR SIGNATURE _____	¹⁰ DATE _____

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3-29	QAPD, REV. 3, ICN 1 para. 20.2 AP-5.21Q, Rev. 3 Sect. 5 step 1	FIELD WORK ACTIVATION -- CRITERION 3 20.2 SCIENTIFIC INVESTIGATION MANAGEMENT The YMP Manager has the management responsibility for direction, guidance, and review of scientific investigations in accordance with approved procedures. The responsibility for performing scientific investigations has been delegated to affected organizations. The Div. Dir. shall complete Section I of the Job Package Initiation Form (Attachment 1; and forward it to the Project Control Branch (PCB). 1. Verify that each Attachment 1 contains a logic diagram, a statement of work, and 3 other stated items of information.			
3-30	AP-5.21Q, Rev. 3 Section 5 step 2	The PCB assigns a unique number to the Job Package, completes Section II of the Job Package Initiation Form, updates the Job Package Log, and distributes information copies to DD, DQA, and SM 1. Verify that the above actions are taken by the PCB.			

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3-31	AP-5.21Q, Rev. 3 Section 5 step 4	<p>The Job Package Coordinator (JPC) prepares a Job Package Outline using the initiation package and the Job Package guidelines provided by the PCB.</p> <p>1. Verify that the JPC did incorporate the guidelines into the Job Package Outline.</p>			
3-32	AP-5.21Q, Rev. 3 Section 5 step 9	<p>The PCB reviews the Job Package, AND ENTERS COST AND SCHEDULE THRESHOLDS OF CHANGE AUTHORITY, and then returns the Job Package to the JPC.</p> <p>1. Verify that the PCB did provide the cost and schedule change authority information.</p>			
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3-33	AP-5.21Q, Rev. 3 Section 5 steps 12, 13	<p>The JPC prepares the Job Package Approval form (Attachment 3) and coordinates obtaining concurrence signatures of the PCB, DDs, and the SM prior to sending for the Job Package to the Project Manager (PM) approval.</p> <p>1. Verify that all specified signatures were obtained, and if possible, prior to the PM's.</p>			
3-34	AP-5.21Q, Rev. 3 Section 5 steps 15,16	<p>Upon PM approval, the PCB makes appropriate entry into the LOG, prepares Attachment 4, "Notice to Proceed", and obtains PM approval.</p> <p>1. Verify that all Attachment 4 documents are included in packages.</p>			
<p>9 AUDITOR SIGNATURE _____</p>				<p>10 DATE _____</p>	

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3-35	AP-5.21Q, Rev. 3 Section 5 Step 16	<p>The PCB submits record package to the Project Office Local Records Center (LRC) and to the Document Control Center (DCC), in accordance with AP-1.5Q.</p> <p>1. Verify that the Job Packages are in the LRC and DCC with their Attachments.</p>			
3-36	AP-5.21Q, Rev. 3	<p>Upon receipt, the Site Manager (SM) has his staff review the package for possible additional administrative requirements, has a Job Package Cover letter prepared , and sends all to the affected participants and to the SITE OFFICE LRC and to the SITE OFFICE DCC, and the SITE OFFICE Plan Room, except that Site Office gets only the cover letter and notice to proceed.</p> <p>1. Verify the above actions including the existence of SITE LRC and DCC and PLAN ROOM.</p>			
3-37	<p>QAPD para. 20.2</p> <p>AP-3.5Q, Rev. 0 section 5 step 4</p>	<p>FIELD CHANGE CONTROL PROCESS See item 3-29</p> <p>{If the project Office identifies the need for a change and the change is within FCCB authority} the identification section of the FCR is completed {,including a unique number.}</p> <p>1. Verify who assigns the FCR number, how, and when.</p>			
				<p>⁹ AUDITOR SIGNATURE _____</p>	<p>¹⁰ DATE _____</p>

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3-39	AP-3.5Q, Rev. 0 Section 5 Step 14	<p>{after the FCCB Board makes its determination and passes this on to the Chairperson and after the Project Participant submits the revised documents) the FCCB Chairperson signs and the FCCB Secretary documents the implementation instructions on the FCR form. (Unless the change exceeds the CCB established threshold.)</p> <p>1. Verify that the above steps are always completed.</p>			
3-40	AP-3.5Q, Rev. 0 Section 5 step 16	<p>The QA Field Representative shall verify that applicable Office of Civilian Radioactive Waste Management QA Requirements have been satisfied and sign the FCR form.</p> <p>1. Verify the signature of the QA Field Representative on the FCR form.</p>			
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3-41	AP-3.5Q, Rev. 0 Section 5 Step 17	{The Site Manager/FCCB Chairperson now signs and dates the FCR. NOTE: The text does not say that he must indicate approval or not on the spaces provided. 1. Verify the approval signature and the ultimate use of the boxes on the form.			
3-42	AP-3.5Q, Rev. 0 Section 5 step 18	{All FCRs, approved or disapproved, are submitted to the Field Local Records Center.} 1. Determine if there is a log of FCRs submitted, and whether all submitted forms were received by the Field LRC.			
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4-1	QMP-04-02, Rev. 0, ICN 1	<p align="center">PROCUREMENT DOCUMENT CONTROL</p> <p>(YMPO Procurement Actions)</p> <p>1. Identify all new or modified procurements for services that have taken place since the last HQ audit (Oct. 1990).</p> <p>NOTE: If the answer to this question is none, then disregard questions related to this QMP.</p>			
4-2	Step 1	<p>1. For new procurements of services, has a Procurement Plan been developed which determines: What, why and where it is to be accomplished, how and who is to accomplish it, and when and where it is to be accomplished?</p>			

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4-4	QMP-04-02, Rev. 0, ICN 1, Step 5	Upon approval of the Procurement Plan by the Cognizant Division Director for services, was a PRP prepared which includes: <ul style="list-style-type: none"> o Procurement Authorization Form; o Scope of Work Statement; o Design Bases and other technical information; and o Specific QA requirements (Define PRP)			
4-5	Step 7	1. Upon completion of the PRP, is it forwarded to the cognizant DD for review and concurrence? Did the cognizant DD indicate concurrence by signing and dating the PRP cover letter?			
<p align="right">⁹ AUDITOR SIGNATURE _____</p>				<p align="right">¹⁰ DATE _____</p>	

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4-6	QMP-04-02, Rev. 0, ICN 1, Step 11	1. Did the Project Manager approve the PRP by signing and dating the cover letter to the PRP?			
4-7	Steps 13, 14, 15 & 16	1. Were bid evaluations performed by the DD and were these evaluations forwarded to the Contracting Officer's technical representative in the form of an EPA? (Define EPA)			
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4-8	QMP-04-02, Rev. 0, ICN 1, Step 17	1. Do modifications to EPA follow the same course as the PRP?			
4-9	Steps 19, 20 & 21	1. Prior to issuing a notice to the COTR to proceed, is supplier of services on the Approved QSL and has QA concurred with the EPA at this point?			
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4-10	QAPD Sects. 7.0 & 7.1 (b)	1. At this point in the process, have all open items relative to the acceptability of the suppliers QA program been resolved and or agreed to be resolved in ting, been obtained prior to the release to proceeding with quality affecting activities?			
4-11	Step 25	1. Are copies of the PRP, related procurement plans, EPA, and all associated memos, letters, and notices to the POCD transmitted to the LRC?			
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4-12	AP-4.1Q, Rev. 0, ICNs 1 & 2, Sect. 4.8	(Procurement) 1. How is it determined when a participant is to submittment actions to the YMPO Contracting Officer prior to release of the procurement package?			
4-13	Sect. 5.3.1	1. The procuring organization will submit the award package to the YMPO Contracting Officer, if required. When is it required and how is this conveyed to the procuring organization (i.e., Project Participants)?			
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5&6-2 cont	QMP-06-04, REVISION 3	PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, REVISION AND PROCESSES			
	Para. 5.2	PCB. Assemble and forward a request package Action Request Form, Document Action Initiation Form, attached document, and/or supporting material) to the responsible DD.			
		1. Verify that a request package is prepared that includes the following:			
		a. Action Request Form			
		b. Document Action Initiation Form			
		c. Attached document			
		d. Supporting material			
	Para. 5.8	SME. No more than 3 ICNs can be posted against a document at any time.			
	Note, 1st sentence	2. Verify that there are no more than 3 ICN posted against any document.			

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5&6-2 cont	Para. 5.14	Reviewer(s). "...number and record any comments, including page, paragraph, step or other identifier (place an asterisk adjacent to each major comment) on DRS(s) or enter No Comments in the Review Comments Column; sign and date DRS(s); return review package to PCB on or before the comment due date." 3. Verify that reviewers comply with the above requirements.			
	Para. 5.14, Note	Reviewer(s). If a secondary reviewer is assigned to replace a primary reviewer, the primary reviewer or manager of the reviewing organization shall complete Section II of the Document Review Cover Sheet. 4. Verify that in the case of secondary reviewers, Section II of the Document Review			
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5&6-2 cont	Para. 5.21	<p>SME. Document responses to all major comments (response to minor comments are recommended, but not required) in the Response column of the applicable DRS(s).</p> <p>5. Verify that all major comments have documented responses in the Response column</p>			
	Para. 5.24	<p>SME. Instruct reviewers to check accept or reject with initials and date to each major comment response on the DRS(s) to indicate acceptance or rejection of response.</p> <p>6. Verify that reviewers have accepted or rejected each major comment response by the DRS.</p>			
	<p>⁹ AUDITOR SIGNATURE _____</p>				<p>¹⁰ DATE _____</p>

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5&6-2 cont	Para. 5.24.b Note, Second para., 1st sentence	<p>SME. When all major comment responses have been incorporated into the document, instruct the reviewers to sign and date Part d of Section III on the Document Review Cover Sheet.</p> <p>7. Verify that all comment responses have been incorporated into the document and that the Section III on the Document Review Cover Sheet.</p>			
	Para. 5.24.b, Note, 2nd para., 2nd sentence	<p>SME. Reviewers with disputed comment responses shall indicate exceptions to those items by entering the comment numbers beneath their signatures in Part d.</p> <p>8. Verify that reviewers with disputed comments indicate exception by entering the comment numbers beneath their signature in Part d.</p>			
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5&6-2 cont	Para. 5.25	SME. Incorporate comments, including any disputed comment response resolutions, into the draft.			
		9. Verify that comments are incorporated into the draft.			
	Para. 5.26	PCB. Process the document, and obtain SME acceptance of final document prior to submitting for approval.			
		10. Verify that the SME has accepted the document.			
	Para. 5.27	PCB. "...obtain Training Officer or designee's signature for the number of days required for training."			
		11. Verify that the Training Department has signed and indicated the amount of training.			

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5&6-2 cont	Para. 5.28, Note	PCB. "Establishment of the effective date shall include training needs as defined on the Approval Sheet,...." 12. Verify that the effective date is after the approvals and provides enough time for training.			

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5&6-3	AP-6.1Q, REVISION 3	PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL CONTROL AND REVISION			
	Para. 5.1	Requesting Organization. Determine document need, then complete appropriate sections of the Project Document Action Request form (Attachment 1).			
		1. Verify that the appropriate sections of the Project Document Action Request forms are complete.			
		Para. 5.4.a Project Office PCB. If requested action is concurred with, inform the Requesting Organization, then perform Project Office document review, approval and acceptance in accordance with QMP-06-04. 2. If requested action is concurred with, verify that QMP-06-04 has been followed.			

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5&6-3 cont	Para. 5.4.b	Project Office PCB. "If requested action is rejected, document the justification for rejection,...." 3. If requested action is rejected, verify that documentation of justification for the rejection is provided.			
	Para. 5.6	1st sentence, Requesting Organization. Resolve and incorporate comments, as required or as instructed. 4. Verify that all comments have been resolved and incorporated.			
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5&6-4	AP-1.17Q, REVISION 1	FORMS CONTROL			
	Para. 5, Note, 2nd sentence	Each manual will contain a content list indicating the form unique identification number, the form title, revision number, and effective date.			
		1. Verify that each manual contains a content list with the required information.			
	Para. 5, Note, 3rd sentence	The content list and master controlled copies of forms will be arranged in alphanumeric sequence.			
		2. Verify that the content list and master controlled copies are arranged in alphanumeric sequence.			
	Para. 5.1	User Organization. Use only forms control manual copies of the latest revision of forms called for in approved APs and Project Office internal procedures (as applicable).			
		3. Verify that forms in the manual match the forms in the procedures.			

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5&6-4 cont.	Para. 5.3.b	Project Office PCB. Assigning form numbers, date in manner of MM/DD/YY, and revision numbers beginning with Revision 1. 4. Verify that forms have the above required information.			
				_____ 9 AUDITOR SIGNATURE	_____ 10 DATE

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5&6-4 cont.	Para. 8.0	<p align="center">RECORDS</p> <p>The following documents shall be QA records and shall be maintained in accordance with applicable procedures:</p> <ul style="list-style-type: none"> a. Draft SCP SP Submitted by TPO to RSED Director for review b. Completed SP Review Checklists c. Statement by Lead Reviewer that OCRWM HQ Review is satisfactorily completed (applies only to those SPs reviewed under ILP 22.3.1) d. Approved SCP SP e. Approved ICNs f. Approved Revisions of the SP g. Documentation of the Submittal of CRs that accompany SP <p>6. Verify that the above records are complete and available for Study Plans.</p>			
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5&6-5	AP-3.6Q, REVISION 0 Para. 5.1.3.1	<p>CONFIGURATION MANAGEMENT</p> <p>The TBD data will be listed in the TBD Log contained in the preface of the affected document, directly after the table of contents and directly before any change pages.</p> <p>1. Verify that TBD data is listed in the TBD Log contained in the preface of affected documents.</p>			
	Para. 5.1.3.1	<p>The scheduled TBD data shall be tracked until development, resolution, and acceptance of these data is completed.</p> <p>2. Verify that scheduled TBD data is tracked until development, resolution, and acceptance of the data is complete.</p>			
	<p align="right">9 AUDITOR SIGNATURE _____ 10 DATE _____</p>				

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5&6-5 cont	Para. 5.1.3.1	<p>The scheduled resolution, the name of the organization responsible for the resolution, and the section or paragraph of the affected document(s) shall be tracked in a TBD Log contained in the document.</p> <p>3. Verify that the following are tracked in a TBD Log contained in documents:</p> <ul style="list-style-type: none"> a. Scheduled resolution b. The name of the organization responsible for the resolution c. The section or paragraph of the affected document(s) 			
				<p>9 AUDITOR SIGNATURE _____ 10 DATE _____</p>	

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5&6-5 cont	Para. 5.3.2.1	<p>The T&MSS CMO shall provide a monthly report of the status of CRs to the Project Office Division Directors and participant TPOs. This report of tracking information, extending from CR submittals through implementations, shall contain the following minimum information:</p> <ul style="list-style-type: none"> a. CR identification number. b. Brief descriptive title of the CR. c. Individual and organization originating the CR. d. Project configuration identification documents affected by the proposed change. e. CI(s) affected by the proposed change. f. Current status of the proposed change (e.g., approved, disapproved, evaluation). g. Subsequent action required on the proposed change. h. Individual or organization responsible for required subsequent action. <p>4. Verify that the T&MSS CMO provides a monthly report of the status of CRs including the above minimum information.</p>			
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5&6-5 cont	Para. 5.4.2	<p>CIS configuration audits shall be conducted at intervals not to exceed 12 months, to verify the CIS information against the corresponding documentation.</p> <p>5. Verify that CIS configuration audits are conducted at intervals not exceeding 12 months.</p>			
	Para. 5.4.4	<p>The configuration audit team will prepare a configuration audit plan on which the configuration audit activities will be based. The configuration audit plan at a minimum will address the following:</p>			
		<p>a. Purpose and scope of the configuration audit. b. Resources required for the configuration audit. c. Schedule of configuration audit activities.</p>			
		<p>6. Verify that configuration audit plans address the above information.</p>			
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7-1	QMP-07-04, Rev. 1, ICNs 1, 2, 3	<p>CONTROL OF PURCHASED ITEMS AND SERVICES</p> <p>(Supplier Evaluation/Qualified Suppliers List)</p> <p>1. Identify all new or modified procurements for services that have taken place since the last HQ audit (Oct. 1990).</p> <p>NOTE: If the answer to this question is none, then disregard questions related to this QMP.</p> <p>2. Verify that the Contracting Officer Technical Representative has fulfilled his or her duties in accordance with QMP-17-04.</p>			
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8-1	AP-6.2Q, Rev. 0 Para. 5.5.1.4	<p>IDENTIFICATION OF MATERIALS, PARTS, COMPONENTS, AND SAMPLES</p> <p>(Management and Operation of Sample Handling Activities at Borehole Sites)</p> <p>1. Do core samples have a pair of colored orientation stripes placed lengthwise? Are footage marks present? Do marking devices have to be approved?</p>			
8-2	Para. 5.5.2	<p>1. Have photographs been taken of core immediately after it has been staged? Does the photographic log contain as a minimum the borehole number, film roll number, exposure number, and interval of the core?</p>			

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8-3	AP-6.2Q, Rev. 0, Para. 5.5.3.2	2. Have any cores been removed from the NTS? If yes, was a Whole Core Specimen Field Removal Checklist and Contract been completed prior to removing the core from the NTS?			
8-4	Para. 5.5.4	1. Does the core logging by the Field Operations Manager (FO) occur in two distinct phases: structural information and lithologic information?			
				<p align="right">9 AUDITOR SIGNATURE _____</p>	<p align="right">10 DATE _____</p>

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8-5	AP-6.20, Rev. 0, Para. 5.5.6	1. Is an instant photograph of the core made and placed in the core box prior to sealing?			
8-6	Para. 5.6	1. Are cuttings handled in accordance with BTP-SMF-008?			
8-7	Para. 5.8	1. Does temporary storage of borehole samples include a lockable facility protected from moisture, wind, and freezing temperature?			

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8-8	AP-6.3Q, Rev. 0, ICN 1, Para. 5.4.3	<p>(Interaction of Participants and Outside Interests with Yucca Mountain Project Sample Management)</p> <p>1. Para. 5.4.3 requires the Specimen Removal Contract to delineate: (1) The approved tests to be performed on Specimen; (2) The Study Plan Number, and (3) Title that delineates those tests.</p> <p>NOTE: Exhibit 3 of AP-6.3Q does not appear to require this information to be entered.</p>			
8-9	Para. 5.5	<p>1. Have any qualified samples been released to users? If so, was a Unqualified Sample Agreement completed? Was a Sample Examination Request submitted to SMF prior to examination?</p>			
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8-10	AP-6.3Q, Rev. 0, ICN 1, Para. 5.7.1	1. If the user used a collection report other than the one referenced in the APQ, did this report as a minimum contain all of the information referenced on the Sample Collection Report, Exhibit 5?			
8-11	Para. 5.7.3	1. Do samples stored at the SMF contain a Bar Code Label and is this label affixed to the sample, where possible?			
8-12	Para. 3.10	1. How does information provided on QA Records get into CSITS?			
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8-13	AP-6.4Q, Rev. 0, ICN 1,	(Submittal, Review, and Approval of Requests for YMPO Geologic Samples) 1. Have any requests been submitted for YMPO Geologic Specimens? If so, was AP-6.4Q implemented?			
8-14	BTP-SMF-001, Rev. 1, Paras. 5.4.1 & 5.4.2	(Sample Management for YMPO) 1. Is access to the SMF controlled?			
	Para. 5.8	2. Have any samples been identified as nonconforming? If so, take note and pass along to personnel auditing Criteria 15.			
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8-15	BTP-SMF-002, Rev. 2, Step 1	(Transport, Receipt, Admittance, and Processing of Borehole Samples for SMF) 1. Prior to transporting a sample to the SMF, is a Field Container Summary and Transmittal Document prepared?			
8-16	Steps 2, 3, 4 & 5	1. If possible, witness the transport of a sample. Is the vehicle properly prepared to transport the sample?			
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8-17	BTP-SMF-002, Rev. 2, Step 10	1. Did person receiving the sample at SMF sign the "Person Accepting Custody" on the Transmittal Document?			
8-18	Step 16	1. Upon opening the sample container, does SMF staff prepare a Confirmation Checklist?			
8-19	Steps 25 thru 34	1. Have any cuttings been received by SMF? If so, were the requirements for cuttings met?			
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8-20	BTP-SMF-002, Rev. 2, Step 35	1. When a core is ready to be processed, is a Core Processing Checklist prepared?			
8-21	Step 36	1. Are five permanent labels or markings applied to each box?			
8-22	Step 41	1. Is each core photographed to visually record its original condition?			
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8-23	BTP-SMF-005, Rev. 2, Step 1	(Examination of Samples by Participants) 1. Is a Sample Examination Request completed by the requester per the requirements of AP-6.3Q? (How is this accomplished since AP-6.3Q has been deleted?)			
	Step 5	2. Is a Sample Examination Record prepared by SMF staff?			
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8-24	BTP-SMF-006, Rev. 2	<p>(Removal of Whole or Other Specimens from Samples by the SMF for Shipment and Remnant Return)</p> <p>1. Have any specimens been transported to other facilities or participants? If so, were the requirements of the BTP met?</p>			
8-25	BTP-SMF-007, Rev. 0, ICN 1	<p>(Acceptance for Curation by the SMF of Selected Samples and Documentation)</p> <p>1. Have any samples or documentation been received by the SMF which were accomplished not using the YMPO Administrative Procedures or YMPO BTPs? If so, were the requirements of this BTP met?</p>			
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8-26	BTP-SMF-008, Rev. 2	<p>(Field Logging, Handling, and Documenting Borehole Samples)</p> <p>1. Have field operations trailers been set up? If so, verify compliance with this BTP.</p>			
8-27	BTP-SMF-010, Rev. 0	<p>(Gamma-Ray Logging of YMPO Core)</p> <p>1. Has an Gamma-Ray Logging of Unqualified Core Samples occurred? If so, were the requirements of this BTP implemented?</p>			
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8-28	BTP-SMF-013, Rev. 0	(Staging, Packaging, and Documenting Neutron-Access Borehole Samples) 1. Verify implementation of this procedure.			

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16-2	QAAP 16.1, Rev. 3, Para. 6.2	1. Verify that the manager assigned responsibility for response to a CAR, developed a corrective action response, on a Continuation Sheet, and submitted to OQA Division Director the response for evaluation and acceptance. 2. Verify that the responsible manager submitted a written request for an extension if it becomes apparent that the requested response due date cannot be met. 3. Verify that the responsible manager notified OQA if the corrective actions in previously submitted CAR response needed to be changed and submitted an amended response if requested by OQA.			
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17-1	QARD, Rev. 4, ICN No. 4.1, Section 17, Para. 17.2	1. Verify that QA records that contain personnel training and qualification information, including certification records, are collected and maintained as a special system of records in accordance with the requirements of the Privacy Act of 1974; Proposed Establishment of a New System of Records, 55 FR 32288, August 8, 1991 (DOE System 80). VERIFY THE FOLLOWING:			
17-2	QAPD, Rev. 3 ICN 3.1, Sec. 17 Para. 17.9	1. A special system of records is established for QA training, qualification, and certification records. Requirements for this records system are described in the Federal Register notice, Privacy Act of 1974: Proposed Establishment of a New System of Records, 55 FR 32288, August 8, 1990 (DOE System 80). 2. DOE System 80 is managed by the Director, OQA, OCRWM Headquarters. Responsibility for managing the system is delegated to the QA Training Officer at Headquarters and to the Training Center Officer at the YMPO.			

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17-3	QMP-17-01, Rev. 3, ICN 1, Para. 5.0, Step 4	1. Verify that Records Lists have been submitted to the LRC that identify the title of the records or records packages to be generated and the plan, procedure, instruction, or other documents from which those records will be generated.			
	Step 5	2. Verify that Records Lists are approved by the Division Director or Contractor Equivalent.			
				<p align="right">9 AUDITOR SIGNATURE _____ 10 DATE _____</p>	

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17-3 cont	QMP-17-01, Rev. 3, ICN 1, Para. 5.0 Step 9	5. Verify that the Division Director(s) or Contractor Equivalent(s) have submitted to the LRC a current list of signatures and initials of personnel authorized to authenticate records.			
	Step 11	6. Verify that final technical or scientific reports have the accession number on the inside of the back cover or within the acknowledgment section of the report.			
		7. Verify that final technical or scientific reports contain the accession numbers for all references cited in the final report except for readily available references.			
		8. Verify that record sources submit the reference(s) to the LRC if it was determined that the reference(s) has not been previously submitted.			
		9. Verify that titles of documents identify and describe the contents of the document.			
		10. Verify that records are complete and include all attachments and enclosures except where exempted by the table of contents.			

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17-3 cont	QMP-17-01, Rev. 3, ICN 1, Para. 5.0 Step 11, (Cont')	<p>11. Verify that records, including photo reductions, are legible and that there is a clear and distinct image with sharp contrasts between the character or pictorial information recorded and the recording medium.</p> <p>12. Verify that illegible portions of documents that do affect the technical content are corrected or regenerated to ensure they are legible.</p> <p>NOTE: Documentation may be accepted in cases where the record cannot be corrected or regenerated.</p> <p>13. Verify that data on records and drawings is recorded in black ink against a light background.</p> <p>14. Verify that all applicable blanks and signatures on are completed or that NA has been entered or indicated by NA and arrow.</p>			
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17-3 cont	QMP-17.01, Rev. 3, ICN 1, Para. 5.0, Step 11 (Cont')	15. Verify that corrections to errors were made by a mperson in the organization who is authorized to make corrections, by drawing a single line of black ink through the incorrect information, placing the correct information in close proximity, and initialing (or signing) and dating the correction.			
		16. Verify that records were authenticated by personnel on the signature authentication list maintained in the LRC. The authenticator for record packages should be someone other than the originator of the package.			
		17. Verify that technical data records are prepared and submitted in accordance with AP-5.1Q.			

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-3 cont	QMP-17-01, Rev. 3 ICN 1, Para. 5.0, Step 14	18. Verify that the WBS number and quality-affecting designation of QA are in the upper right portion of the first page of records that are not part of a record package.			
	Step 15	19. Verify that record packages assembled by the Record Source include a table of contents that includes: a. The WBS number and QA designation. b. The record package identifier. c. The page count for each item on the table of contents. d. Signature and date of the Record Source and an authentication signature.			
	Step 16	NOTE: Before Step 16: 20. Verify that Sample Management Facility records are submitted to the T&MSS LRC.			

9 AUDITOR SIGNATURE

10 DATE

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³ AUDIT ITEM NO.	⁴ QUALITY REQUIREMENT REFERENCE(S)	⁵ QUALITY REQUIREMENT/GUIDELINE	⁶ RESULTS S,X,N/A	⁷ SUMMARY OF INVESTIGATION	⁸ PERSON CONTACTED
17-3 cont	QMP-17.01, Rev. 3, ICN 1, Para. 5.0 Step 17	21. Verify that individual records, record package segments, and record packages are submitted using the Record Source Transmittal Form.			
	Step 18	22. Verify that individual records are submitted no later than 10 working days after the date of completion or receipt, and that record packages are submitted no later than 10 working days after the record package has been authenticated.			
	Step 22	23. Verify that LRC Rejection Forms are returned with corrected records within 10 working days of the Record Source receipt.			

⁹ AUDITOR SIGNATURE _____

¹⁰ DATE _____

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4	BTP-YMP-001, Rev. 0, ICN 1, Step 1	1. Verify that the LRC Branch Chief prepared and maintained lists that contain the signatures and initials of personnel authorized to authenticate records.			
	Step 2	2. Verify that the RPC/RC supervisor initiates internal tracking of outgoing/incoming correspondence.			
	<p align="right">9 AUDITOR SIGNATURE _____ 10 DATE _____</p>				

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1, Step 3	3. Verify that records received are the best copy available, and have QA designation and a WBS number.			
	Step 4	4. Verify that records are acceptable for processing and microfilming, and meet the requirements of Attachments 5 and 6.			
	Step 6, A/B	5. Verify that the record packages being compiled by the LRC have a records package tracking number, title of the records package, the record source name, a records package identifier, and a quality affecting designation.			

9 AUDITOR SIGNATURE _____ 10 DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

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³ AUDIT ITEM NO.	⁴ QUALITY REQUIREMENT REFERENCE(S)	⁵ QUALITY REQUIREMENT/GUIDELINE	⁶ RESULTS S,X,N/A	⁷ SUMMARY OF INVESTIGATION	⁸ PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1 Step 6C	6. Verify that the record package logbook contains the tracking number, the title of the record package, and the record sources name for record packages that are being assembled by the LRC.			
	Step 9	7. Verify that record package segments of record packages assembled by the LRC are being copied and stored in two controlled access facilities sufficiently remote from each other that they cannot be damaged by the same natural disaster.			
	Step 10	8. Verify that the table of contents is updated as additional record package segments are received.			
	⁹ AUDITOR SIGNATURE _____			¹⁰ DATE _____	

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4	BTP-YMP-001, Rev. 0, ICN 1 Step. 11	9. Verify that a verification signature is obtained on the table of contents of completed record packages assembled by the LRC.			
	Step. 15	10. Verify that a copy of the LRC Record Rejection Form and a copy of the record are in the Records Rejected File for unacceptable records returned to the Record Source.			
	Step 17	11. Verify that LRC Branch Chief assistance is obtained to reconcile discrepancies in records that are not resolved within 30 working days.			
	9 AUDITOR SIGNATURE	10 DATE			

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1 Step 18	12. Verify that the Record Source provides an explanation on the rejection form as to why the record could not be corrected if it was not corrected.			
	Step 22	13. Verify that a LRC Transmittal Form is used to transmit records to the CRF.			
	Step 23	14. Verify that the LRC Transmittal Forms include titles/ subjects of other descriptive data, the number of pages, the record date, whether or not the items are records or record packages, any identifying numbers, and any special instructions or remarks.			
				<p align="right">9 AUDITOR SIGNATURE _____ 10 DATE _____</p>	

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1 Step 24	15. Verify that Special Processed Records are accompanied by an LRC Special Instruction Sheet (Attachment 3).			
	Step 25	16. Verify that duplicates of records submitted to the CRF for processing are stored in the transmittal hold file and protected from deterioration, loss, larceny, or damage.			
	Step 28	17. Verify that the LRC transmits records to the CRF within 30 working days of receipt.			
	9 AUDITOR SIGNATURE _____				10 DATE _____

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1 Step 31	20. Verify that inspections for completeness of microfilm are documented by including the accession and reel numbers in the LRC Records Management System.			
	Steps 32 & 33	21. Verify that the LRC Branch Chief maintains an Access Authorization List and a Key Authority list that are approved by the Administrative Officer.			
				<p align="right">9 AUDITOR SIGNATURE _____</p>	<p align="right">10 DATE _____</p>

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1 ORGANIZATION YMP0

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1 Step 34	22. Verify that records are stored in areas where access is controlled by the LRC staff.			
	Step 35	23. Verify that records are filed by accession number, microfilm reels are filed by reel number, and aperture cards are filed by aperture card number.			
					<p align="right">9 AUDITOR SIGNATURE _____ 10 DATE _____</p>

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
17-4 cont	BTP-YMP-001, Rev. 0, ICN 1 Step 36	24. Verify that those who are not on the Access Authorization List are escorted.			
	Step 38	25. Verify that records/record packages and microfilm reels for aperture cards removed from the file are replaced with an Out Card that contains the accession number, the name of the person removing the record/record package, and date removed from the file. Verify that the Out Card is initialed when the record/record package is returned to the file.			
	Step 41	26. Verify that records can be retrieved by RC Personnel.			
				<p align="right">9 AUDITOR SIGNATURE _____ 10 DATE _____</p>	

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
20-1	AP-1.10Q, REVISION 4 Para. 5.11, Part b., sentences 1 & 2 Para. 5.12 Para. 5.23	PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS (See Checklist Item 3-2) Technical Reviewers. If mandatory or nonmandatory comment, then complete lines 1-12 of CRF. On line 12, reviewers are to suggest a proposed resolution for comment... 1. Verify that all mandatory or nonmandatory comments have a proposed resolution included on line 12. Technical Reviewers. Prepare and sign SP Review Checklist by completing Blocks 1 and 2. 2. Verify that the technical reviewers have signed the SP Review Checklist. Reviewers. Review and verify resolutions of their mandatory comments in the verification draft SP. 3. Verify that reviewers have verified resolutions of their mandatory comments in the verification draft.			
				9 AUDITOR SIGNATURE _____	10 DATE _____

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
20-2	AP-5.32Q, REVISION 1	TEST PLANNING AND IMPLEMENTATION REQUIREMENTS			
	Para. 5.2	RSED Director. Issue Test Planning Package Request (Attachment 1) and assign PE. Maintain log of test planning packages. 1. Verify that Test Planning Package Requests are issued and that a log of test planning packages is maintained.			
	Para. 5.10	DDs/TPOs. Provide documentation of prerequisites to PE. 2. Verify that documentation of prerequisites is provided.			
	9 AUDITOR SIGNATURE _____			10 DATE _____	

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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
20-3	QMP-03-09, REVISION 3	<p align="center">PROJECT CHANGE CONTROL BOARD PROCESS</p> <p>CCB Members. Evaluate the Change Document Package as it relates to cognizant area of responsibilities, and prepare the CE in accordance with Attachment 1 instructions.</p> <p>1. Verify that the CCB Members have evaluated the Change Document Package and have prepared the CE properly.</p> <p>CCB Secretary. Prepare Attachment 2, Change Evaluation Summary (CES) Form, in accordance with instructions provided.</p> <p>2. Verify that the Change Evaluation Summary (CES) is properly prepared.</p> <p>CCB Secretary. Prepare Attachment 3, CD Form, in accordance with the instructions provided.</p> <p>3. Verify that the Change Directive (CD) is properly prepared.</p>			
	Para. 5.5				
	Para. 5.8				
Para. 5.9					

9 AUDITOR SIGNATURE _____ 10 DATE _____

OCRWM AUDIT CHECKLIST NO. YMP-91-01-01

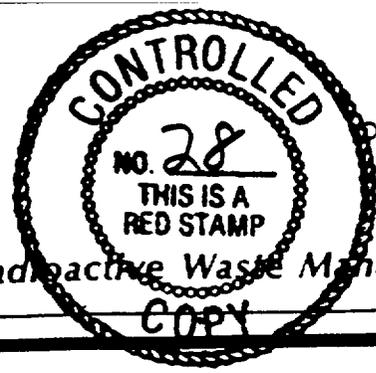
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3 AUDIT ITEM NO.	4 QUALITY REQUIREMENT REFERENCE(S)	5 QUALITY REQUIREMENT/GUIDELINE	6 RESULTS S,X,N/A	7 SUMMARY OF INVESTIGATION	8 PERSON CONTACTED
20-3 cont	Para. 5.14	<p>CCB Secretary. Ensure completion of applicable portions of Attachment 4, Document Change Notice (DCN), and submit modified CCB controlled documents, including DCN, to the Document Control Center in accordance with AP-1.5Q.</p> <p>4. Verify that the CCB Secretary has completed the Document Change Notice (DCN).</p>			
	Para. 5.15	<p>CCB Secretary. Update the CIS to reflect the current status of the CD.</p> <p>5. Verify that the CIS has been updated to reflect the current status of documents.</p>			
	Para. 5.16.a	<p>CCB Secretary. Ensure that written delegation of authority is on file for the change control documentation and is attached to the records package prior to records package turnover.</p> <p>6. Verify that written delegation of authority is on file for change control document.</p>			

9 AUDITOR SIGNATURE

10 DATE



DOE/RW-0215

Rev. 3

Office of Civilian Radioactive Waste Management



Quality Assurance Program

Description Document

October 1990

*U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Washington, DC*

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

INTERIM CHANGE NOTICE (Continuation Sheet)

AFFECTED DOCUMENT (Including Revision): Quality Assurance Program Description (QAPD) Revision 3	EFFECTIVE DATE: September 3, 1991	ICN NO. 3.1
INTERIM CHANGE AND RATIONALE: 8.0 <u>Section 12.0</u> (continued) 12.1 APPLICABILITY AND SCOPE OF THE M&TE CONTROL PROGRAM Controls noted in this section apply to M&TE (tools, gages, instruments, etc.). However, controls of M&TE are also applied to activities used to calibrate, measure, gage, test, or inspect for the purpose of either: (1) controlling or acquiring data to verify conformance to a specified requirement; or (2) establishing characteristics or values not previously known. The methodology for control of M&TE is described in approved procedures. 12.2 M&TE REQUIREMENTS 12.2.1 Selection Selection of M&TE is controlled to ensure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Each device has a unique identification number. The type, range, accuracy and tolerance of a measuring device is specified in approved procedures. This number is recorded on the data sheet, log, or equivalent, along with the measurement taken, to ensure traceability of the measurement to the device used to take the measurement. 12.2.2 Calibration Measuring and test equipment is calibrated against certified equipment having known valid relationships to the National Institute of Standards and Technology or other nationally recognized standards and is calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the acceptability of the calibration standard used is justified. Calibrating standards have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible PROGRAM personnel. 12.2.3 Control The method and interval of calibration for each M&TE item is defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. M&TE is labeled, tagged, or otherwise documented in a manner that indicates the due date of the next calibration and provide traceability to calibration data. If M&TE is found to be out of calibration, an evaluation is made and documented on the validity of previous results obtained, on acceptability of items previously inspected or tested or on data gathered since the last calibration. Out of calibration devices require the condition be documented in accordance with Section 15 of this QAPD, tagged or segregated, and not used until they have been dispositioned and corrective action has been satisfactorily verified. If any M&TE is found to be consistently out of calibration, it is repaired or replaced. Calibration is performed when the accuracy of equipment is suspect.		PAGES AFFECTED 12-1

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

INTERIM CHANGE NOTICE (Continuation Sheet)

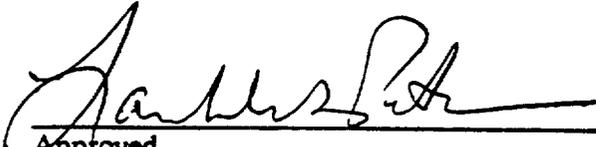
<p>AFFECTED DOCUMENT (Including Revision): Quality Assurance Program Description (QAPD) Revision 3</p>	<p>EFFECTIVE DATE: September 3, 1991</p>	<p>ICN NO. 3.1</p>
<p>INTERIM CHANGE AND RATIONALE:</p> <p>Access is limited to authorized supervisory, QA, records management processing personnel, and those provided access under a routine use. DOE System 80 permits disclosure of records to state and local agencies, the NRC, and other Federal agencies for audit purposes. Requests for access to DOE System 80 records are directed to the Director, OQA, OCRWM."</p> <p>II QAPD, Appendix A</p> <p><u>Appendix A, Section 2.0 first sentence and Paragraphs 2.0.c, -d and -f</u></p> <p>Change "items and activities" (1st sentence); "activities" (paragraphs c&d); "items or activities" (paragraph f)</p> <p>to "... items and their related activities..."</p> <p><u>Appendix A, Paragraph 3.2.1</u></p> <p>"Delete" first paragraph on the top of page A-8.</p> <p><u>Appendix A, Paragraphs 12.0 through 12.3.6</u> Delete in its entirety.</p> <p><u>Appendix A, Paragraphs 13.0 through 13.3.5</u> Delete in its entirety.</p> <p><u>Appendix A, Paragraph 20.4.2</u></p> <p>Delete.</p> <p>III QAPD, Appendix B</p> <p><u>Appendix B, Subsection 1.0</u></p> <p>Change the word "shielding" in Paragraph 1.0.a to "scheduling".</p> <p>Revise Paragraph immediately following Paragraph 1.0.d by inserting the word "and" between "Systems" and "Compliance".</p>		<p>PAGES AFFECTED</p> <p>17-3</p> <p>A-6</p> <p>A-8⁷</p> <p>A-10 & A-11</p> <p>A-12 & A-13</p> <p>A-14</p> <p>B-1</p>

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR THE
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM



Donald G. Horton, Acting Director
OCRWM Office of Quality Assurance

10/3/90
Date



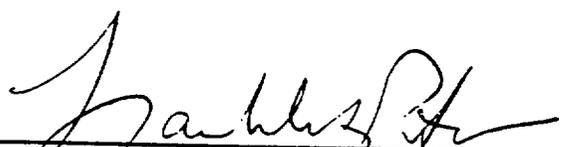
Approved
John W. Bartlett, Director
Office of Civilian Radioactive Waste
Management

10/3/90
Date

POLICY

The U.S. Department of Energy is authorized by the Nuclear Waste Policy Act (NWPA), as amended in 1987, to site, obtain a license for, construct, and operate a geologic repository and a monitored retrievable storage facility, and to provide for the safe transportation of radioactive waste to those locations. It is the policy of the Office of Civilian Radioactive Waste Management (OCRWM) that these obligations will be met through the implementation of quality assurance controls that complement management actions to achieve the level of quality needed for the safe transportation, storage, and disposal of high-level radioactive waste.

This quality assurance program meets the requirements of Title 10 of the Code of Federal Regulations (CFR) Parts 50, 60, 71, and 72. The quality assurance controls necessary to achieve the high level of quality demanded by the transportation and storage of radioactive waste are mandatory, imposed on, and implemented by, each organization participating in the program through DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD). The QARD provides the requirements for development of a consistent framework for implementing quality assurance programs at every level within the Civilian Radioactive Waste Management Program.



John W. Bartlett, Director
Office of Civilian Radioactive Waste
Management

10/3/90
Date

INTRODUCTION

This document serves as the quality assurance program description document for Program activities performed by OCRWM. This document and DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD) reflect OCRWM policies and serve as the principal documents of the Program quality assurance program.

Sections 1 through 19 of this document, including the appendices, describe the provisions established by OCRWM to meet the requirements of the QARD. The appendices to this document describe amplifications to the quality assurance program requirements in Sections 1 through 19 which are specific to the geologic repository, monitored retrievable storage, and transportation activities.

This QAPD is developed under the assumption that OCRWM will establish three Project Offices, one each for the Mined Geologic Disposal System (MGDS), Transportation, and the Monitored Retrievable Storage (MRS). Currently, the Yucca Mountain Project (YMP) Office, is the only established Project Office. This QAPD supersedes the Yucca Mountain Project Office Quality Assurance Program Plan (YMPO/88-1).

The definitions given in ANSI/ASME NQA-1-1989, and supplemented by the definitions in the QARD are applicable to this document.

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SECTION 1 ORGANIZATION

1.0 GENERAL

This section describes organizational responsibilities for the Office of Civilian Radioactive Waste Management (OCRWM) and identifies organizational interfaces among Headquarters (HQ), HQ-managed program participants, Project Offices, and Project Office-managed program participants, and other affected organizations. The assignment of responsibilities reflects the philosophy that the line organization achieves quality and the quality organization overviews to verify the achievement of quality.

It is the responsibility of the Director, OCRWM, to ensure that appropriate quality assurance requirements and procedural controls are in place to provide confidence that structures, systems, and components will not cause undue risk to either the health or safety of the public or of the workers associated with high-level radioactive waste transportation and monitored retrievable storage or geologic repository facilities. Quality assurance controls for the Program are instituted in a flow-down management approach from the Director, OCRWM, through the Associate Directors; Director, Office of Quality Assurance (OQA); and the Operation Office and Project Office managers to each program participant and affected organizations.

1.1 OCRWM ORGANIZATION

OCRWM includes Headquarters (HQ) which is comprised of the Office of the Director and the Offices of: Quality Assurance (OQA), External Relations (OER), Strategic Planning and International Programs (OSPIP), Systems and Compliance (OSAC), Contract and Business Management (OCBM), Storage and Transportation (OST), Geologic Disposal (OGD), and Program and Resources Management (OPARM). OQA, OER and OSPIP are headed by Directors who report to the Director, OCRWM. The remaining offices, OSAC, OSD, OGD and OPARM are headed by Associate Directors who also report to the Director, OCRWM. In addition to the HQ Offices, OCRWM is also comprised of Project Offices. The organizational relationship of each office is illustrated in Figures 1-1A through 1-1I. The functional and quality assurance program responsibilities for positions within OCRWM are described in the following paragraphs.

1.1.1 Office of Civilian Radioactive Waste Management (OCRWM)

The Director, OCRWM is directly responsible to the Secretary of Energy and has overall responsibility for carrying out the functions of the Secretary under the Nuclear Waste Policy Act of 1982, as amended.

The quality assurance responsibilities of the Director, OCRWM, are to:

- a. Establish and execute a quality assurance program that ensures compliance with applicable regulatory requirements, satisfies the performance objectives of the Program, and meets licensing requirements.
- b. Establish quality assurance policy direction and controls that are commensurate with DOE management and quality assurance policies for Radioactive waste, (RW), RW contractors, and DOE waste generators.
- c. Approve DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD).
- d. Approve DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program (QAPD).
- e. Provide for adequate funding and resources to effectively support the quality assurance objectives of the Program.
- f. Provide for, or participate in, interactions with Federal regulatory agencies; the nuclear industry; and affected States, local governments, and Indian Tribes on quality assurance matters specifically related to their areas of interest.
- g. Maintain awareness of quality assurance issues and problems and effect resolution.
- h. Provide for the annual assessment of the scope of, status of, adequacy of, and compliance to the quality assurance program by OCRWM management, who are independent of the Office of Quality Assurance.
- i. Retain responsibility for the quality of work delegated to program participants, such as contractors, agents, and consultants.
- j. Establish and administer a system to prevent the continuance of work where public health and safety may be at risk.

1.1.2 Office of Quality Assurance (OQA)

1.1.2.1 Director, Office of Quality Assurance

The Director, OQA, reports directly to the Director, OCRWM, and has been delegated the management responsibility and authority to direct and control quality assurance functions to ensure that Program quality assurance objectives are consistently met. The Director, OQA, has direct access to, and maintains liaison with, the Director, OCRWM; other Directors and Associate Directors and management of other affected organizations. This reporting relationship provides the organizational freedom and authority to identify quality problems; initiate, recommend, or provide solutions; and prevent or control further processing, delivery, or use of nonconforming items or activities, until disposition is obtained.

The Director, OQA, is responsible for coordination, integration, and overview of Program quality assurance activities and for ensuring that appropriate quality management, policy, training, and verification controls are in place. The Director, OQA, has appropriate management and quality assurance knowledge and experience and has no responsibilities that prevent his full attention to quality activities. This position is independent from cost and schedule when opposed to safety and waste isolation-related concerns.

The responsibilities of the Director, OQA, are to:

- a. Establish integrated Program quality assurance policies and requirements in baselined or other controlled documents.
- b. Coordinate development of the OCRWM quality assurance program documents including the QARD, the QAPD, and quality assurance procedures.
- c. Provide quality assurance guidance and direction to affected organizations.
- d. Serve as the focal point for OCRWM's quality assurance activities; provide coordination with other OCRWM offices and the Nuclear Regulatory Commission (NRC); and assure that Program activities affecting quality are conducted in accordance with OCRWM policies and objectives and in compliance with NRC regulations.

- e. Overview Program quality assurance activities by conducting internal and external verifications and selectively participating in Operation Office and Project Office verification activities, such as assessments, readiness reviews, or audits, and issue schedules for audits and surveillances.
- f. Review the quality assurance program descriptions (including revisions to and interpretations thereof) of HQ-managed program participants and other affected organizations, for compliance with established Program quality assurance policies and requirements, develop recommendations relative to acceptance and submit recommendations to appropriate Associate Directors for action.
- g. Review procurement documents for inclusion of quality assurance requirements.
- h. Assure development and implementation of a quality assurance indoctrination program for all Program personnel.
- i. Establish and maintain the indoctrination and training requirements for Headquarters OQA personnel as well as maintain the qualification and training records for Headquarters OQA personnel.
- j. Establish and maintain a Program quality assurance information system to facilitate effective communication of the status of the quality assurance program; status of resolution of issues, trends, and significant conditions adverse to quality; and a summary of management overview results.
- k. Manage the OQA staff and QA direct-support contractors.
- l. Ensure that OQA personnel who perform activities affecting quality are qualified by experience, education or training to perform assigned tasks.
- m. Establish and administer the resolution of allegations program.

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1.1.2.2 Quality Assurance Divisions

The Director, OQA is assisted in the execution of duties by the HQ QA Division and the Yucca Mountain Project QA Division. These two Divisions report to the Director, OQA, and have the responsibility to direct and control quality assurance functions as delegated by the Director, OQA.

1.1.3 Office of Strategic Planning and International Programs (OSPIP)

The Director, Strategic Planning and International Programs (DSPIP) reports directly to the Director, OCRWM and has primary responsibility for developing mission plans, strategic and contingency planning, risk management and communications program development, international program development, and oversight (including policy development, requirements, guidance and compliance oversight for integration of international work with domestic activities), and serves as the negotiator interface.

The DSPIP is responsible for the following quality assurance program activities.

- a. Establishing or approving the scope of OSPIP activities affecting quality, commensurate with the QARD.
- b. Ensuring that OSPIP personnel who perform activities affecting quality are qualified by experience or training to perform assigned tasks.
- c. Evaluating results of activities that verify quality achievement within the scope of work assigned to OSPIP.
- d. Assigning responsibility for the quality of delegated work, prior to initiating the work activities.
- e. Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OSPIP has lead responsibility, and the implementation of effective management controls.
- f. Acting on the Director, OQA's recommendations relative to acceptance of OSPIP managed program participants' and other affected organizations' quality assurance programs.
- g. Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed program participants' and other affected organizations' activities affecting quality, for which OSPIP has lead responsibility, and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.
- h. Ensuring that adequate funds and resources are provided for OSPIP activities affecting quality.

- i. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality-related problems and issues within OSPIP's area of responsibility.
- j. Developing and maintaining those implementing line and quality assurance procedures and other quality assurance documents and records for which the OSPIP has lead responsibility.

1.1.4 Office of External Relations (OER)

The Director, External Relations (DER) reports directly to the Director, OCRWM and has primary responsibility within OCRWM for technical and institutional integration, program relations and communication, educational institution program development and is generally responsible for all external OCRWM interactions.

The DER is responsible for the following quality assurance program activities:

- a. Establishing or approving the scope of OER activities affecting quality commensurate with the QARD. This includes the assignment of controls to OER activities.
- b. Ensuring that OER personnel, who perform activities affecting quality are qualified by experience, education, or training to perform assigned tasks.
- c. Assigning responsibility for the quality of delegated work, before the initiation of work activities.
- d. Acting on the Director, OQA's recommendations relative to acceptance of OER managed, affected organizations' quality assurance programs.
- e. Ensuring that adequate funds and resources are provided for OER activities affecting quality.
- f. Reviewing and approving indoctrination and training requirements for OER Division Director.
- g. Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OER has lead responsibility.
- h. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality related issues and problems in OER's area of responsibility.

- i. Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed program participants' and other affected organizations' activities affecting quality, for which OER has lead responsibility, and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.

1.1.5 Office of Systems and Compliance (OSC)

The Associate Director, Systems And Compliance (ADSC), reports directly to the Director, OCRWM, and has primary responsibility for planning, managing, and overseeing integration of the Civilian Radioactive Waste Management system; managing programs for the development of technologies for use at the geologic repository or MRS (e.g. storage modules); development, implementation, and maintenance of a Program Management System; developing a transportation system; preparation and coordination of Environmental Impact Statements; and serving as the official contact for the Program with the NRC and other regulatory agencies.

OSC also develops licensing plans, license applications, and safety analysis reports for the geologic repository and MRS facility.

The ADSC, has the following quality assurance program responsibilities:

- a. Establishing or approving the scope of OSC activities affecting quality, commensurate with the QARD. This includes the assignment of controls to OSC activities.
- b. Ensuring that OSC personnel, who perform activities affecting quality, are qualified by education, experience, or training to perform assigned tasks.
- c. Evaluating results of activities that verify quality achievement within the scope of work assigned to OSC.
- d. Assigning responsibility for the quality of delegated work, prior to initiation of work activities.
- e. Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OSC has lead responsibility and the implementation of effective management controls.
- f. Acting on the Director, OQA's recommendations relative to acceptance of OSC-managed, program participants' and other affected organizations' quality assurance programs.

verification of HQ-managed, program participants' and other affected organizations' activities affecting quality, for which OSC has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.

- h. Ensuring that adequate funds and resources are provided for OSC activities affecting quality.
- i. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality-related problems and issues in OSC's area of responsibility.
- j. Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OSC has lead responsibility.
- k. Reviewing and approving indoctrination and training requirements for OSC Division Directors and providing for the indoctrination and training of Project personnel.

1.1.6 Office of Storage and Transportation (OST)

The Associate Director, Office of Storage and Transportation (ADST) reports directly to the Director, OCRWM and has primary responsibility for project management for the MRS, transportation and cask development, waste acceptance system development, utility contract management, Management and Operations (M&O) and other contractor technical management, system logistics development, fee verification, and is the waste generator technical interface.

The ADST has the following quality assurance program responsibilities:

- a. Establishing or approving the scope of OST activities affecting quality, commensurate with the QARD. This includes the assignment of controls to OST activities.
- b. Ensuring that OST personnel, who perform activities affecting quality, are qualified by education, experience, or training to perform assigned tasks.
- c. Evaluating results of activities that verify quality achievement within the scope of work assigned to OST.

- d. Assigning responsibility for the quality of delegated work, prior to initiation of work activities.
- e. Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OST has lead responsibility and the implementation of effective management controls.
- f. Acting on the Director, OQA's recommendations relative to acceptance of OST-managed, program participants' and other affected organizations' quality assurance programs.
- g. Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed, program participants' and other affected organizations' activities affecting quality, for which OST has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.
- h. Ensuring that adequate funds and resources are provided for OST activities affecting quality.
- i. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality-related problems and issues in OST's area of responsibility.
- j. Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OST has lead responsibility.
- k. Reviewing and approving indoctrination and training requirements for OST Division Directors and providing for the indoctrination and training of Project personnel.

1.1.7 Office of Geologic Disposal (OGD)

The Associate Director, Office of Geologic Disposal (ADGD), reports directly to the Director, OCRWM and has primary responsibility for characterization of the geologic repository site; repository facility development, design, and engineering and for providing management oversight of the technical direction to Program geoscience activities and for socioeconomic and institutional planning. The ADGD also serves as the project manager for the Yucca Mountain Project (YMP).

The ADGD has the following quality assurance program responsibilities:

- a. Establishing or approving the scope of OGD activities affecting quality, commensurate with the QARD. This includes the assignment of controls to OGD activities.
- b. Ensuring that OGD personnel, who perform activities affecting quality, are qualified by education, experience, or training to perform assigned tasks.
- c. Evaluating results of activities that verify quality achievement within the scope of work assigned to OGD.
- d. Assigning responsibility for the quality of delegated work, prior to initiation of work activities.
- e. Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OGD has lead responsibility and the implementation of effective management controls.
- f. Acting on the Director, OQA's recommendations relative to acceptance of OGD-managed, program participants' and other affected organizations' quality assurance programs.
- g. Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed, program participants' and other affected organizations' activities affecting quality, for which OGD has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.
- h. Ensuring that adequate funds and resources are provided for OGD activities affecting quality.
- i. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality-related problems and issues in OGD's area of responsibility.
- j. Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OGD has lead responsibility.
- k. Reviewing and approving indoctrination and training requirements for OGD Division Directors and providing for the indoctrination and training of Project personnel.

1.1.8 Office of Program and Resources Management (OPRM)

The Associate Director, Program and Resources Management (ADPRM), reports directly to the Director, OCRWM, and has primary responsibility for the development, implementation, and maintenance of a program management information system, project decision schedule, and program schedule. The ADPRM is also responsible for management and administration of the Nuclear Waste Fund.

The Associate Director, OPRM, has the following quality assurance program responsibilities:

- a. Establishing or approving the scope of OPRM activities affecting quality commensurate with the QARD. This includes the assignment of appropriate controls to OPRM activities.
- b. Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed program participants' and other affected organizations' activities affecting quality for which OPRM has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OPRM prior to initiation of work activities.
- c. Ensuring that information and data systems meet the QA records requirements specified in the QARD.
- d. Reviewing and approving the indoctrination and training requirements for OPRM Division Directors and providing for the indoctrination and training of all OPRM personnel.
- e. Ensuring that OPRM personnel, who perform activities affecting quality are qualified by experience, education, or training to perform assigned tasks.
- f. Acting on the Director, OQA's, recommendations relative to acceptance of OPRM-managed program participants' and other affected organizations' quality assurance programs.
- g. Developing and maintaining those implementing line and quality assurance procedures and other quality assurance documents and records for which OPRM has lead responsibility.
- h. Ensuring that adequate funds and resources are provided for OPRM activities affecting quality.

- i. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality-related issues and problems in OPRM's area of responsibility.

1.1.9 Office of Contract Business Management (OCBM)

The Associate Director, Office of Contract Business Management (ADCBM) reports directly to the Director, OCRWM and has primary responsibility for business management of M&O and support services contracts, control of all other contractor business management, contract consolidation plan implementation, administration of conflict of interest forms for contractors, establishing OCRWM's annual procurement plan, coordinating the preparation, review, approval, and control of procurement documents with DOE's procurement and assistance management directorate and acts as a liaison with the Procurement Office.

The ADCBM has the following quality assurance program responsibilities:

- a. Establishing or approving the scope of OCBM activities affecting quality, commensurate with the QARD. This includes the assignment of controls to OCBM activities.
- b. Ensuring that OCBM personnel, who perform activities affecting quality, are qualified by education, experience, or training to perform assigned tasks.
- c. Evaluating results of activities that verify quality achievement within the scope of work assigned to OCBM.
- d. Assigning responsibility for the quality of delegated work, prior to initiation of work activities.
- e. Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OCBM has lead responsibility and the implementation of effective management controls.
- f. Acting on the Director, OQA's recommendations relative to acceptance of OCBM-managed, program participants' and other affected organizations' quality assurance programs.
- g. Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed, program participants' and other affected

organizations' activities affecting quality, for which OCBM has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.

- h. Ensuring that adequate funds and resources are provided for OCBM activities affecting quality.
- i. Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and resolving quality-related problems and issues in OCBM's area of responsibility.
- j. Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OCBM has lead responsibility.
- k. Reviewing and approving indoctrination and training requirements for OCBM Division Directors.

1.1.10 Project Office Managers

Project Office Managers are delegated the authority, responsibility, and accountability for Project Office cost, schedule, technical, and quality performance, for activities performed by the Project Office. The following responsibilities directly affecting the quality assurance program are specifically included:

- a. Approving plans as necessary to establish the basis for orderly achievement of technical and quality objectives.
- b. Ensuring adequate staffing and funding for essential technical and quality assurance activities.
- c. Ensuring effective implementation of the OCRWM quality assurance program by line management.
- d. Monitoring quality assurance program implementation on an ongoing basis and taking remedial action as necessary.
- e. Authorizing readiness reviews of Project Office-managed activities.
- f. Ensuring that Project Office personnel, who perform activities affecting quality, are qualified by education or experience to perform assigned tasks.
- g. Evaluating results of activities that verify quality achievement within the scope of work assigned to the Project Office.

- h. Assigning responsibility for the quality of delegated work, prior to initiation of work activities.
- i. Ensuring the technical adequacy of items and activities for which the Project Office has lead responsibility and the implementation of effective management controls.
- j. Concurring with the Project Office, QA organization's recommendations for the approval or disapproval of affected organizations' quality assurance programs for which the Project Office has lead responsibility.
- k. Ensuring that applicable quality assurance program documents are approved, prior to initiation of work activities.
- l. Identifying and reporting quality-related issues and problems to responsible management and the QA organization, and effect resolution of quality related problems and issues in Project Office's area of responsibility.
- m. Developing and maintaining those line and administrative procedures and other OCRWM quality assurance program documents, and records for which the Project Office has lead responsibility.
- n. Reviewing and approving indoctrination and training requirements for his/her immediate subordinates and providing for the indoctrination and training of Project personnel through the Project training officer.
- o. Ensuring that activities are performed in an environmentally acceptable manner.

1.1.11 OCRWM Division Directors and Site Managers

The OCRWM Division Directors and site managers report to the appropriate Associate Directors or the Project manager, as applicable, and have the following quality assurance program responsibilities.

- a. Establishing the scope of quality assurance activities and requirements for those activities under their purview, obtaining the approval of the Associate Director, or Project manager, as applicable.
- b. Ensuring that personnel who are under the direction of the Division Directors or site managers and perform activities affecting quality are qualified by experience, education, or training to perform assigned tasks.

- c. Ensuring, by using methods that verify quality achievement, the technical adequacy of items and activities and the effectiveness of management controls.
- d. Coordinating with other involved OCRWM Divisions, the performance of quality verification activities.
- e. Ensuring adequate resources are available for quality achievement and verification activities.
- f. Identifying and reporting quality related issues and problems that affect, or potentially affect, the Division or site activities, to the Associate Director or Project Manager, as appropriate, and obtaining resolution.
- g. Developing and maintaining those implementing line and quality assurance procedures and other quality assurance program documents and records for which the Division or site has lead responsibility.
- h. Reviewing and approving indoctrination and training requirements for Branch Chiefs or other personnel under their supervision.

1.1.12 Branch Chiefs

The Branch Chiefs report to the Division Directors and have the following quality assurance program responsibilities.

- a. Ensuring that technical personnel under their direction and who perform activities affecting quality, are qualified by experience or training to perform assigned tasks.
- b. Identifying indoctrination and training requirements for Branch personnel.
- c. Ensuring the technical adequacy of items and activities within their area of responsibility.
- d. Coordinating the verification of quality achievement of technical activities of OCRWM and affected organizations that are within their area of responsibility.
- e. Reporting quality-related issues and problems that affect, or potentially affect, activities of the Branch to the Division Director and obtaining satisfactory resolution.

1.1.13 Organizational interfaces

The organizational interfaces between OCRWM, and affected organizations are described in the appendices. Interfaces and the flow of Program direction and quality assurance overview direction from OCRWM to Project Offices and other affected organizations are illustrated in Figure 1-2. Activities performed by affected organizations are identified in Section 1 of Appendix A.

1.1.13.1 OCRWM Headquarters Managed Affected Organizations

Quality assurance requirements for each OCRWM-managed affected organization are identified in the appropriate procurement documents. OCRWM provides overview of each affected organization's quality assurance activities, by various verification methods, such as reviews, audits, and surveillances.

OCRWM direct-support contractors perform activities affecting quality under controls of the OCRWM quality assurance program. OCRWM direct-support contractors and their activities include:

- a. WESTON, which provides program management, institutional, technical, scientific, and quality assurance support to OCRWM.
- b. CER Corporation which provides quality assurance support services to OCRWM.
- c. SAIC, which provides records management services related to the licensing support system.

1.1.13.2 Operations Offices and DOE Offices

The Operations Offices and DOE Offices Managers have overall line management responsibility and accountability for implementation of assigned tasks. Each Office Manager or Assistant Secretary or equivalent establishes a management organization, and delegates responsibility and authority for management and direction of Program tasks.

The Office Manager or Assistant Secretary or equivalent, has direct, primary responsibility and accountability for the execution and implementation of Program tasks in accordance with established management plans. In addition, the Office Manager is the point of contact for the flow of information to and from the Director, OCRWM, and other affected organizations and is responsible for implementing the quality assurance program.

Interfaces between Offices and affected organizations are addressed in quality assurance program descriptions and the implementing line and quality assurance procedures.

The Office Manager or Assistant Secretary or equivalent, identifies a position for directing and managing the respective quality assurance programs. These positions are occupied by individuals with appropriate management and quality assurance knowledge and experience and have:

- a. A responsibility and authority level equal to or higher than the highest-level, line manager responsible for performing activities affecting quality.
- b. Sufficient independence from cost and schedule.
- c. Responsibility for recommending approval of quality assurance program descriptions.
- d. No other duties or responsibilities unrelated to quality assurance that would prevent full attention to quality assurance matters.
- e. Authority to identify quality problems.
- f. Responsibility for initiating, recommending, or providing solutions to problems.

Areas of responsibility assigned to the respective Operations Offices are listed herein:

- a. Nevada Operations Office. This Operations Office is responsible for providing support to the Yucca Mountain Project Office.
- b. Chicago Operations Office. This Operations Office is responsible for institutional planning, analysis, and management integration of the transportation systems and for providing regulatory and administrative support, such as review of regulations on an as-needed basis, quality assurance support, and international program support. This Operations Office performs preclosure performance assessments and waste package studies.

- c. Idaho Operations Office. This Operations Office is responsible for review of transportation cask development, engineering development, and the waste form from the West Valley Demonstration Project (WVDP).
- d. Richland Operations Office. This Operations Office is responsible for materials characterization and preclosure performance assessment. This Operations Office also provides technical support for waste isolation and characterization and for systems integration activities.
- e. Oak Ridge Operations Office. This Operations Office provides geosciences, shielding, systems integration, operations, and public relations support to the Program.
- f. Albuquerque Operations Office. This Operations Office provides technical support of postclosure performance assessment work.
- g. San Francisco Operations Office. This Operations Office provides geoscientific support and defense waste studies.

1.1.14 Delegation of Work

Responsibility for the overall Program is retained by the Director, OCRWM. The tasks of establishing and implementing selected parts of the overall OCRWM quality assurance program for work associated with the Program have been delegated as indicated in Figures 1-2 and 1-3.

1.1.15 Resolution of Disputes

Differences of opinion involving quality assurance concerns at a given organizational level are brought to the attention of management at that level and, if not resolved, are elevated progressively to the Director, OQA, and, if necessary, to the Director, OCRWM.

1.1.16 Resolution of Allegations

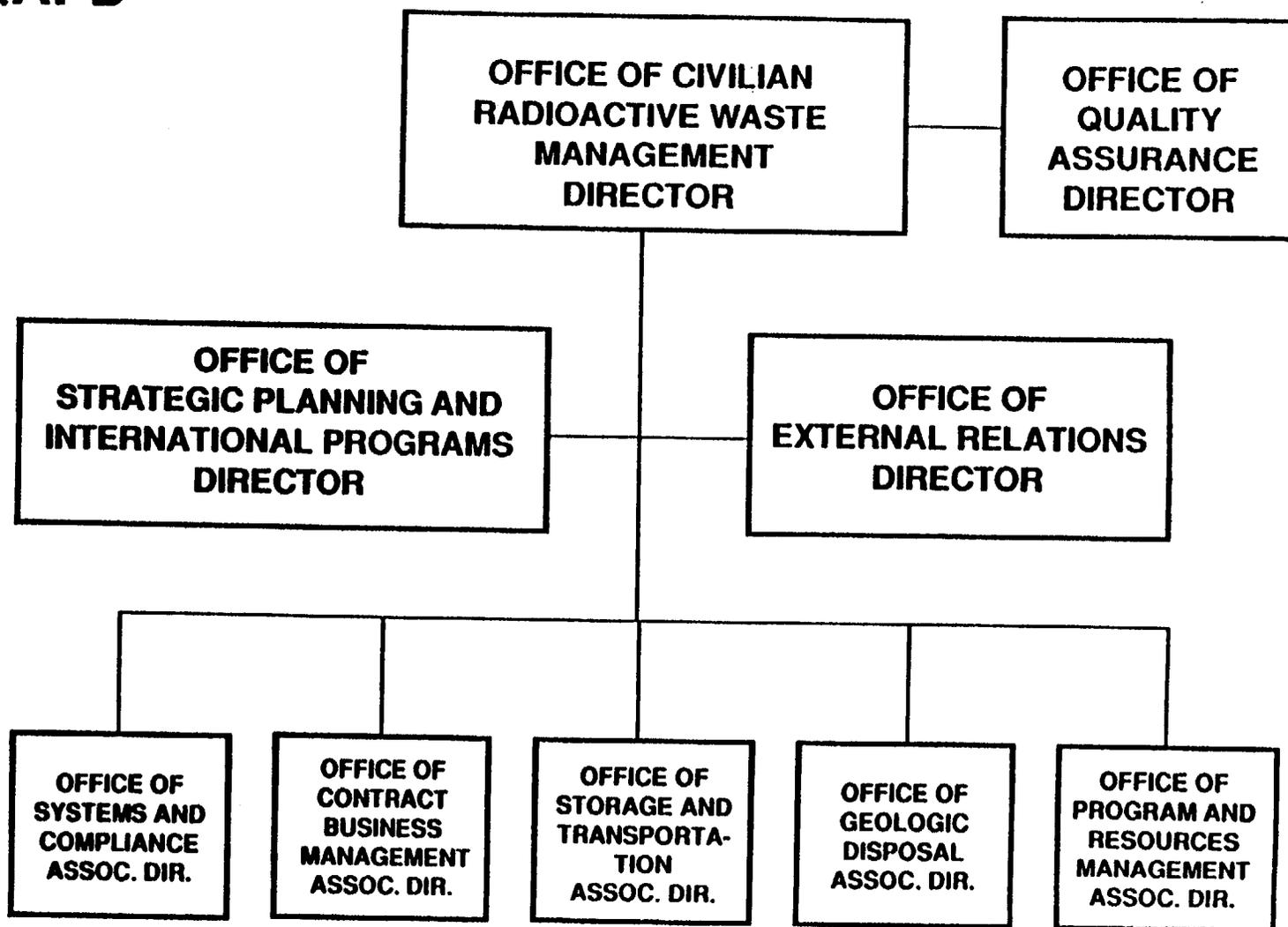
A system is being established that provides individuals a means of registering an allegation of inadequate quality to OCRWM without fear of reprisal. Each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity. The investigation results are to be made available to the individual who registered the concern.

This system is available to employees of affected organizations and persons outside the Program. Employees of an affected organization are encouraged to use this system only when adequate resolution of a concern that involves potential inadequate quality cannot be obtained through normal reporting channels.

| 1.1.17 Stop-Work Authority

Stop-work authority at OCRWM is vested in line management whenever imminent danger to personnel is involved or continued work will produce results that are not in accordance with Program requirements or would be considered unacceptable. The stop-work process is delineated in approved procedures.

QAPD



1-20

FIGURE 1-1A. OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT ORGANIZATION

QAPD

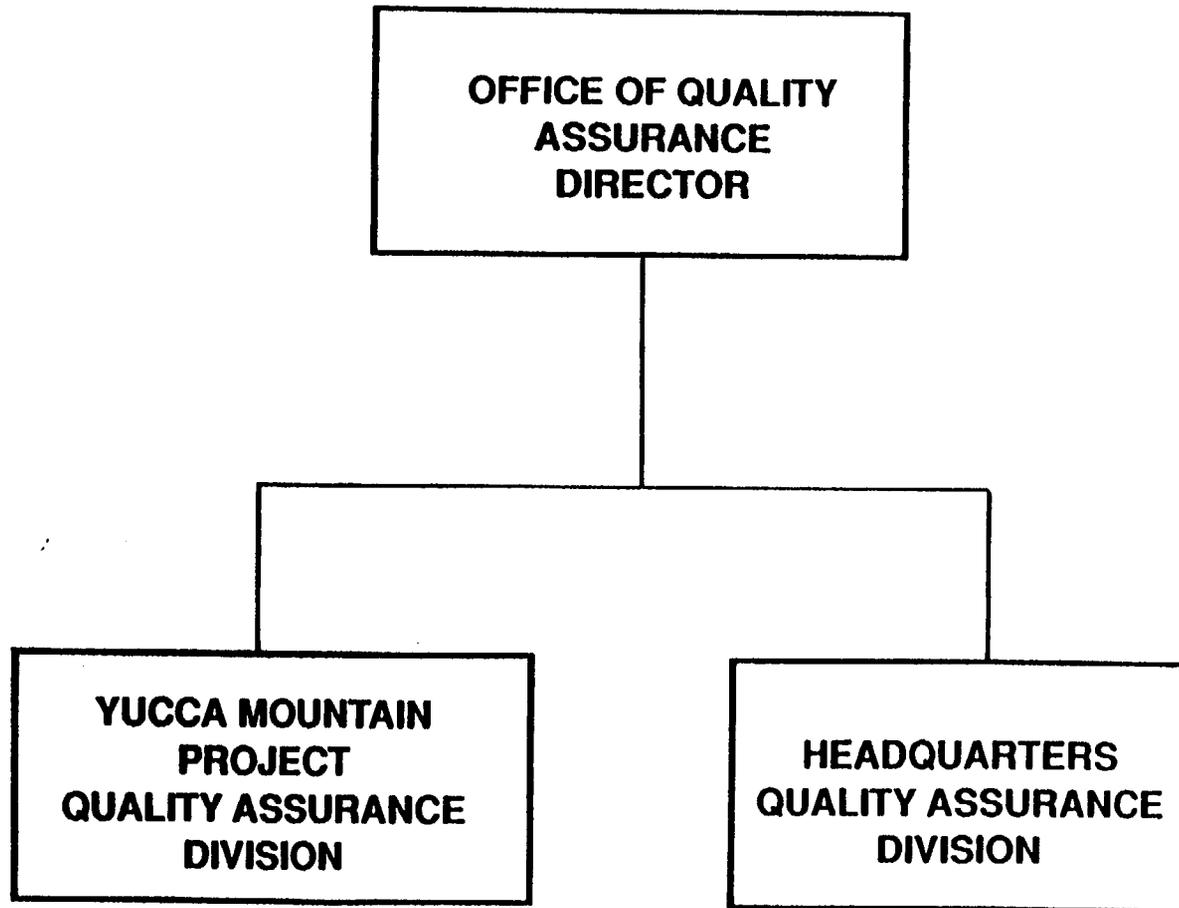


FIGURE 1-1B. OFFICE OF QUALITY ASSURANCE ORGANIZATION

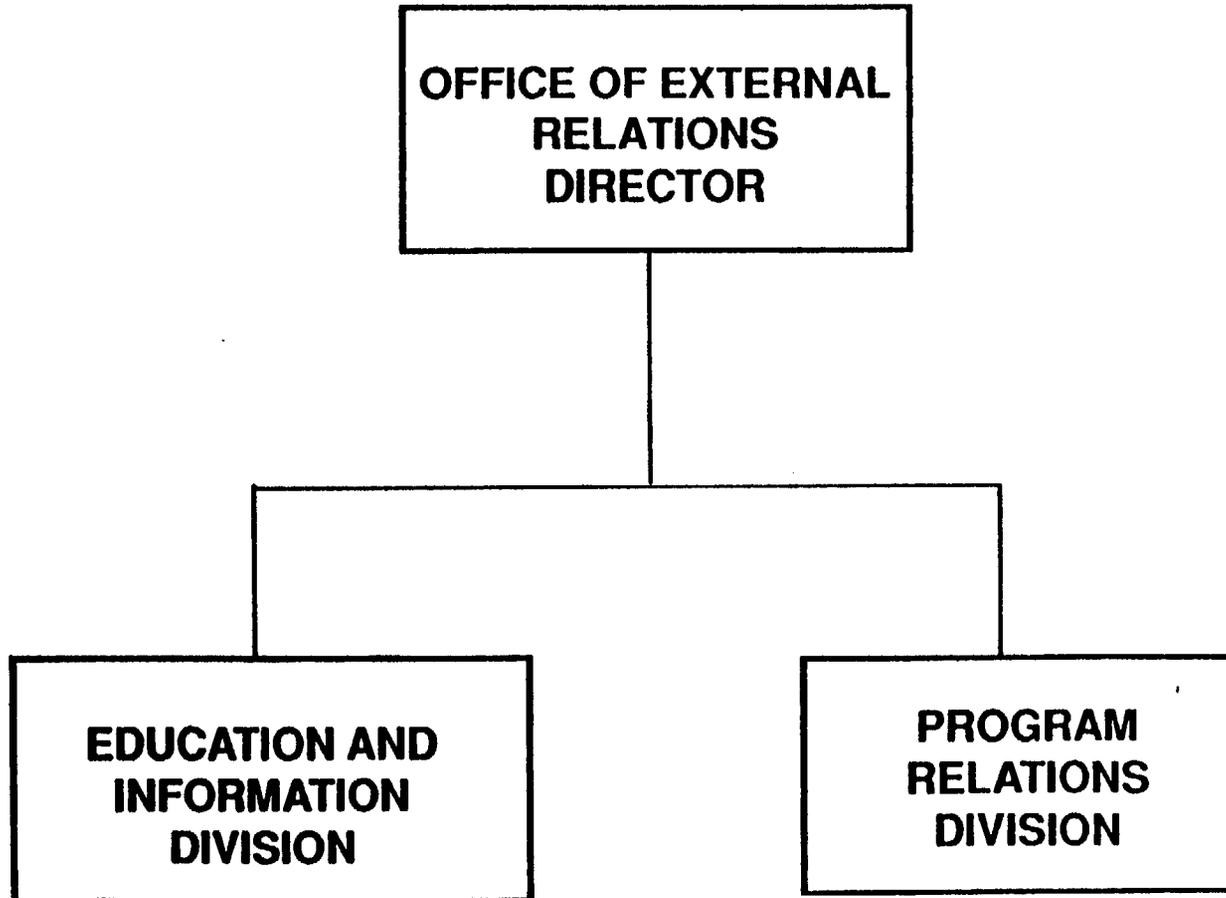
QAPD

**OFFICE OF STRATEGIC AND
INTERNATIONAL
PROGRAMS
DIRECTOR**

1-22

FIGURE 1-1C. OFFICE OF STRATEGIC AND INTERNATIONAL PROGRAMS

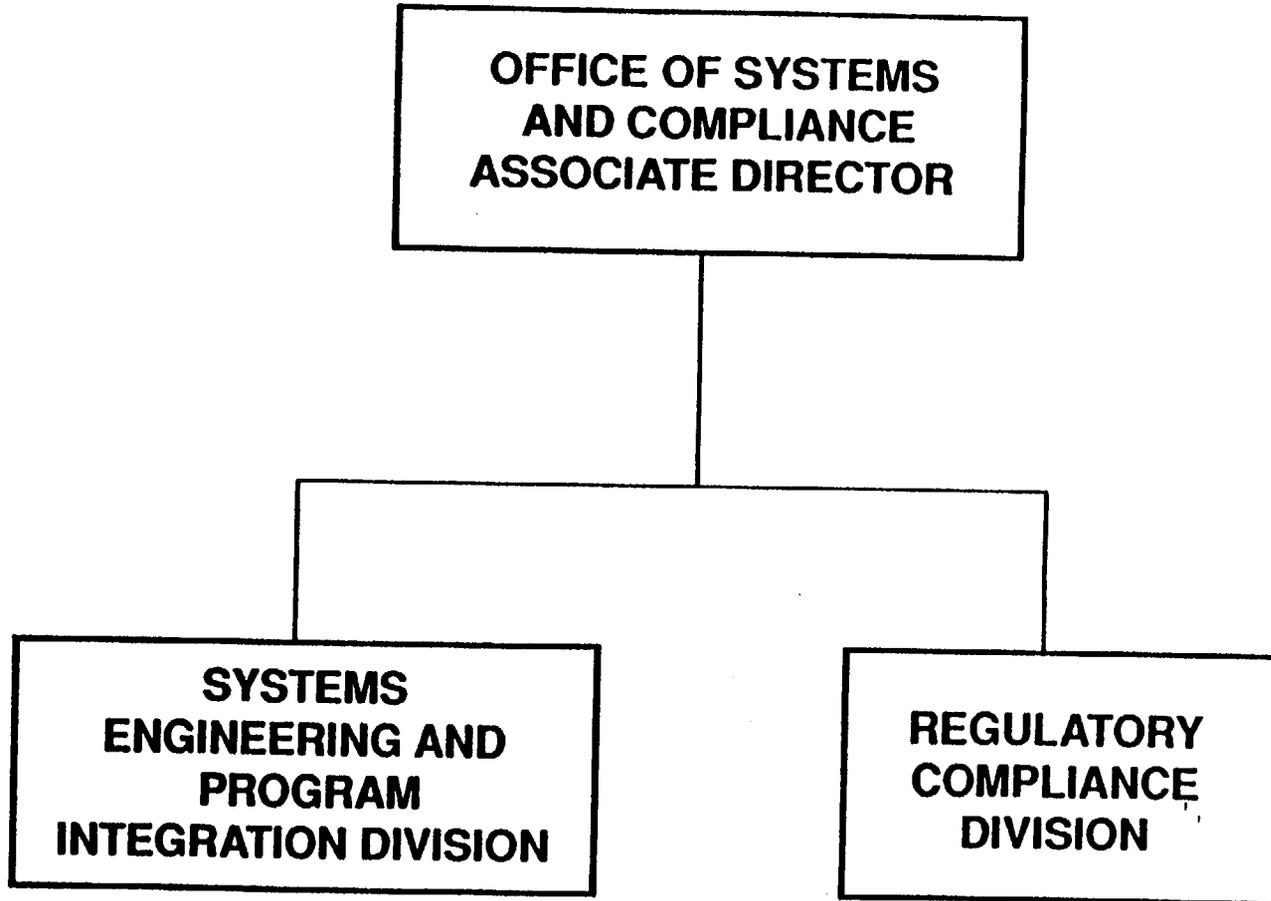
QAPD



1-23

FIGURE 1-1D. OFFICE OF EXTERNAL RELATIONS

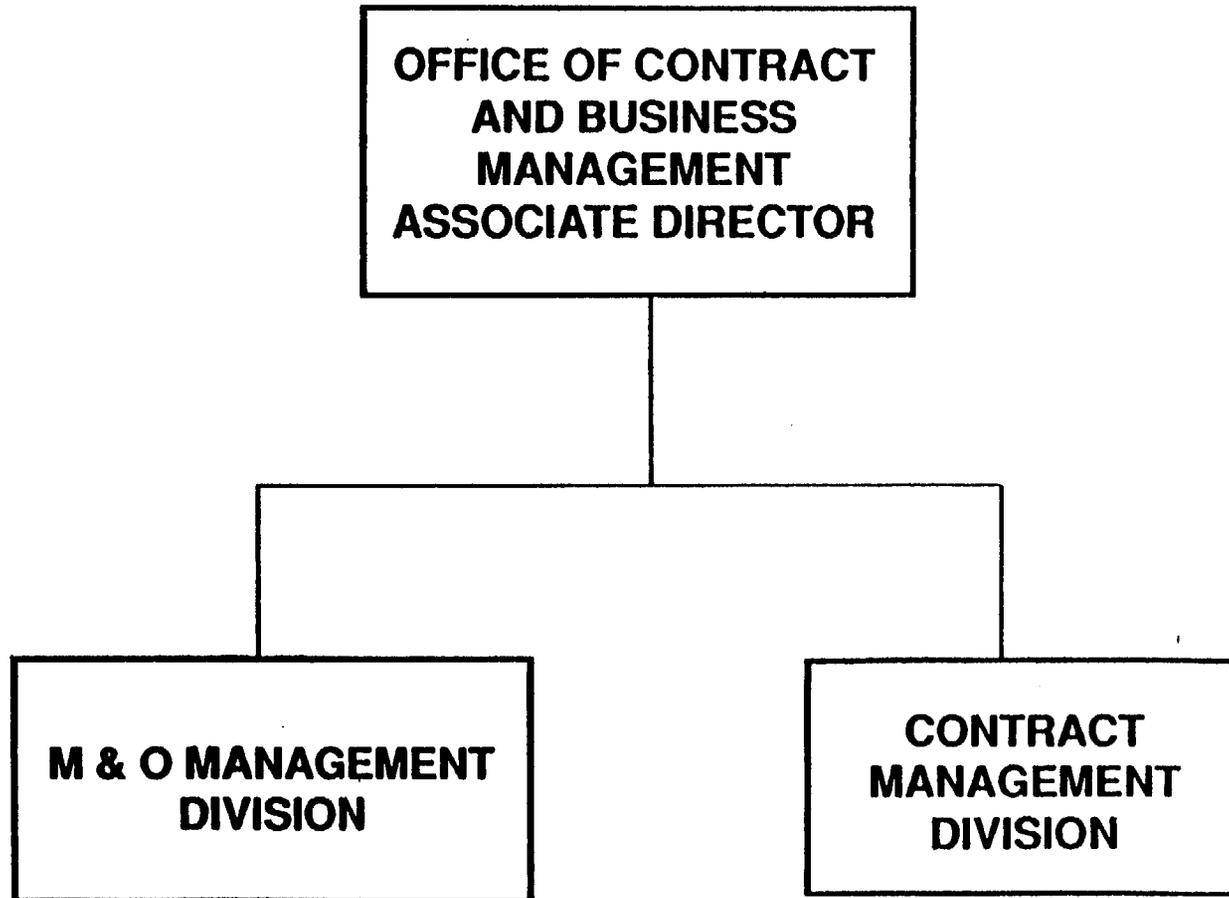
QAPD



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FIGURE 1-1E. OFFICE OF SYSTEMS AND COMPLIANCE

QAPD



1-25

FIGURE 1-1F. OFFICE OF CONTRACT AND BUSINESS MANAGEMENT

QAPD

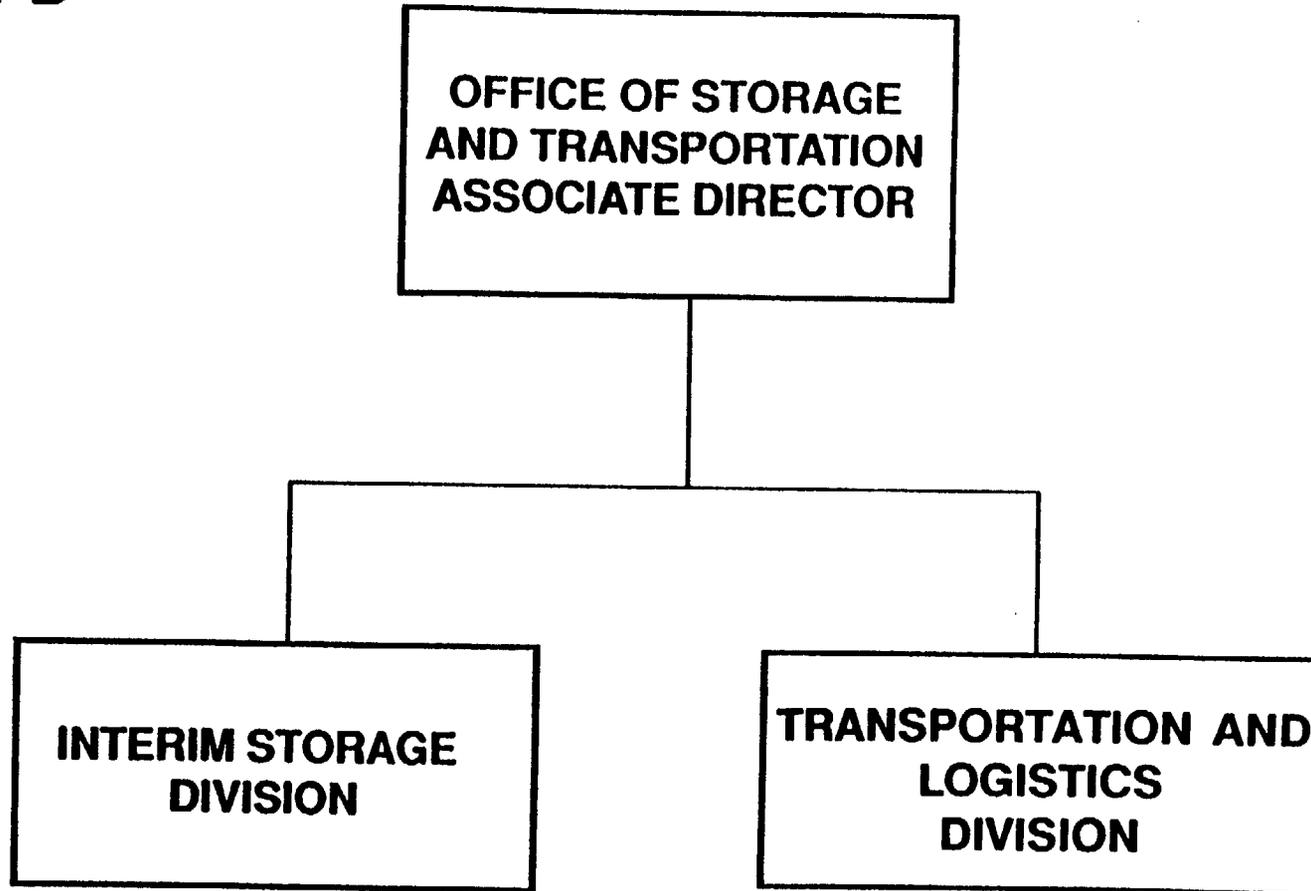
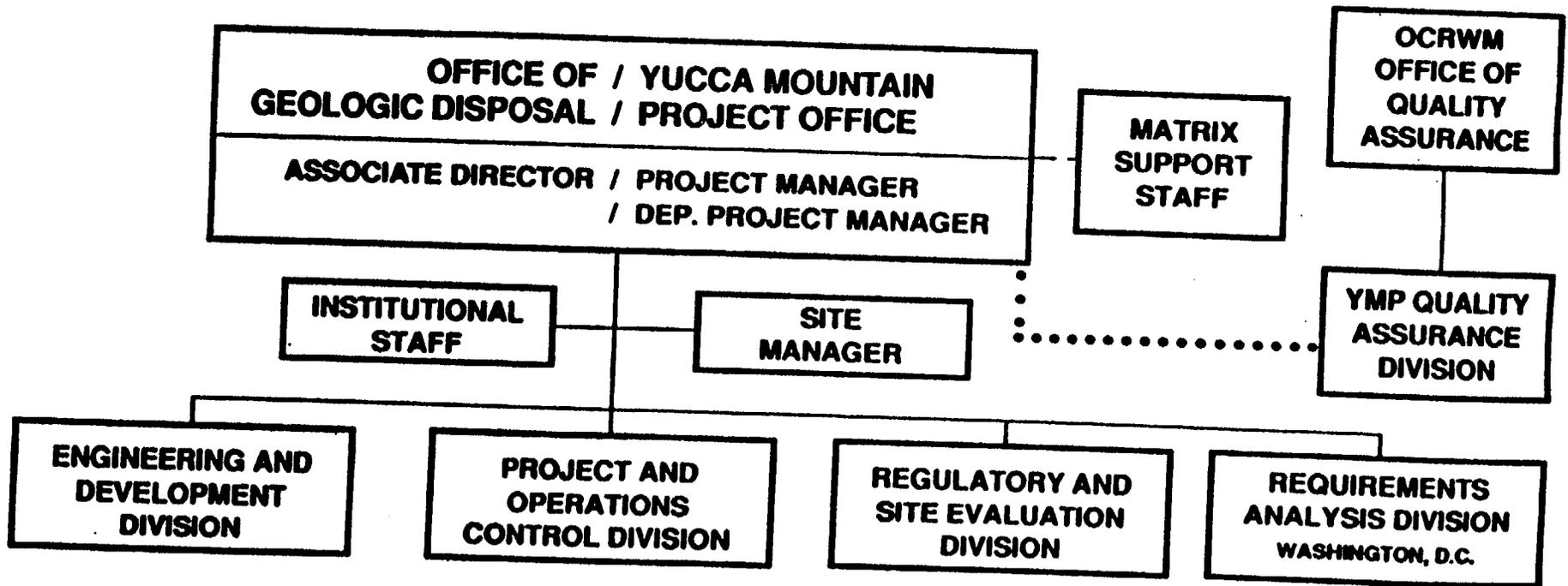


FIGURE 1-1G. OFFICE OF STORAGE AND TRANSPORTATION

QAPD



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Figure 1-1H. Office of Geologic Disposal

QAPD

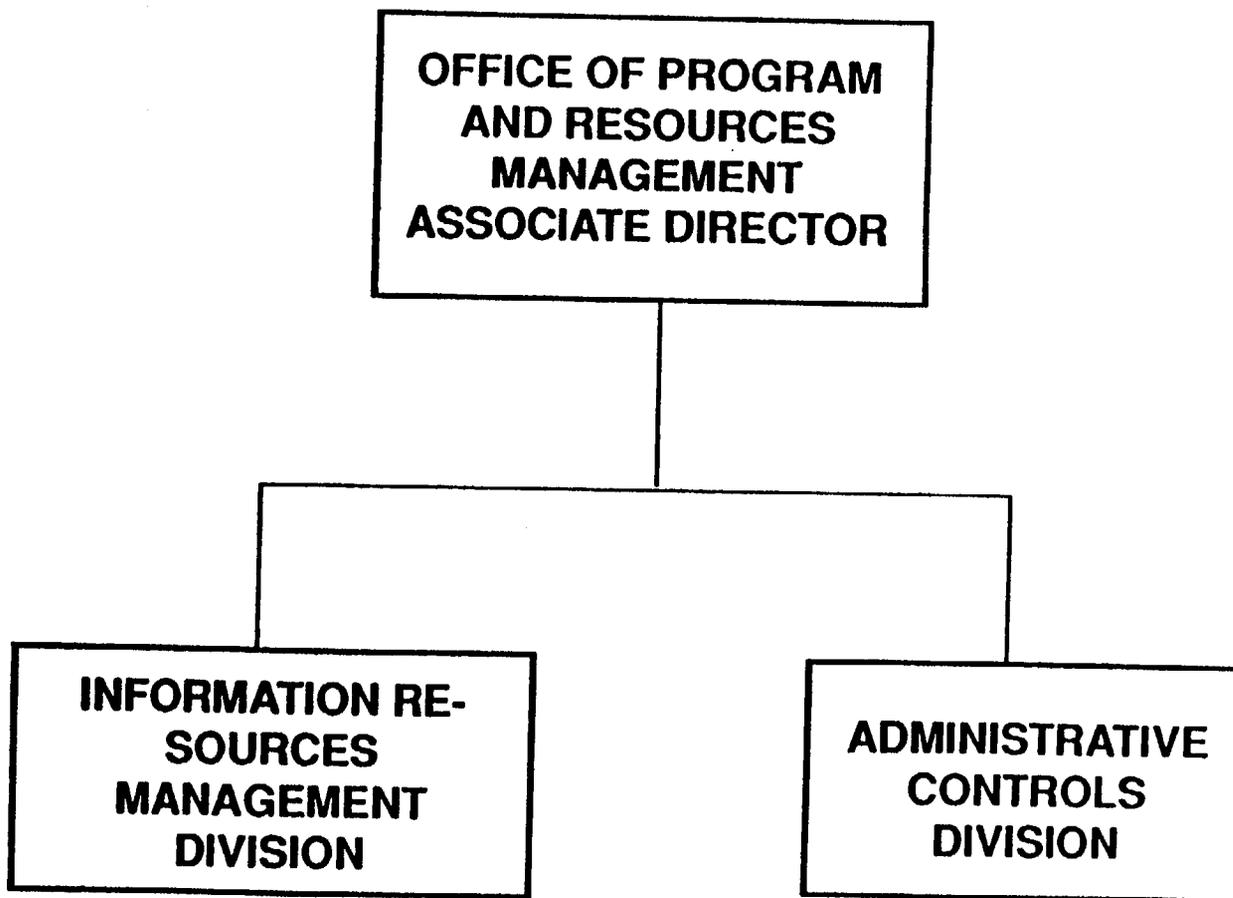


FIGURE 1-11. OFFICE OF PROGRAM AND RESOURCES MANAGEMENT

DELEGATION OF QUALITY ASSURANCE WORK

Criteria No.	Topic	OCRWM	Other Affected Organizations
1	Organization	X	X
2	Quality Assurance Program	X	X
3	Design Control (& Peer Review)	X	X
4	Procurement Document Control	X	X
5	Instructions, Procedures, and Drawings	X	X
6	Document Control	X	X
7	Control of Purchased Items & Services	X	X
8	Identification and Control of Materials, Parts, Components, and Samples.	X	X
9	Control of Processes.	D	X
10	Inspection	D	X
11	Test Control	D	X
12	Control of Measuring and Test Equipment	X	X
13	Handling, Storage, Transport, & Shipping	X	X
14	Inspection, Test, and Operating Status	D	X
15	Control of Nonconforming Items	X	X
16	Corrective Action	X	X
17	Quality Assurance Records	X	X
18	Audits	X	X
19	Computer Software	X	X

X - Means "Applicable commensurate with the Scope of Work"

D - Indicates that OCRWM delegates the work of establishing and implementing these criteria to other affected organizations. However, OCRWM retains responsibility for ensuring that these activities are established and appropriately implemented, and carries out this responsibility through audits and surveillances of the activity.

Figure 1-3. Matrix describing the delegation of quality assurance work by criteria.

SECTION 2

QUALITY ASSURANCE PROGRAM

2.0 GENERAL

OCRWM, consists of Headquarters (HQ) and the Project Offices with responsibility for Geologic Disposal(GD), Monitored Retrievable Storage (MRS), and Transportation, and has developed this Quality Assurance Program Description (QAPD) for its part of the Program. The OCRWM quality assurance program description complies with the requirements specified in the QARD that are applicable to OCRWM activities. A graded approach to the application of quality assurance requirements is used. Items and activities will be controlled to the extent required by the OCRWM quality assurance program. The OCRWM quality assurance program documents consist of this QAPD, the QARD, and OCRWM implementing line and quality assurance procedures.

This section describes provisions established by OCRWM to implement a quality assurance program to control items and activities affecting quality.

2.1 OCRWM QUALITY ASSURANCE PROGRAM

2.1.1 Quality Assurance Requirements

The quality assurance requirements for the Program are identified in DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD). The types of procedures described in the following sections are used at Headquarters and the Project Offices to ensure compliance and effective implementation of this QAPD and the QARD. A matrix, which cross-references OCRWM procedures and the QAPD to the QARD requirements, is established and maintained by the Office of Quality Assurance.

2.1.2 Quality Assurance Program Description

The QAPD describes provisions established by OCRWM to implement the applicable requirements of the QARD, the OCRWM organizational responsibilities for achieving and verifying quality, and the interfaces between OCRWM, and other affected organizations. Organizational charts are provided and the provisions that are implemented to meet each Section of the applicable requirements of the QARD are described. The QAPD is approved by the Director, OCRWM, and will be issued as a controlled document.

2.1.3 Quality Assurance Procedures

Quality assurance procedures are implemented for quality affecting activities that are performed by Headquarters and the Project Offices. Typically, Headquarters and the Project Offices work to the same procedures. However, where necessary, the Project Offices develop and implement quality assurance procedures that are specific to their scope of work. These procedures are consistent with the QARD, and this QAPD, and delineate the specific administrative and quality assurance controls or the methods used to meet requirements established in upper-level program documents.

These procedures are contained in quality assurance procedure manuals and are issued and controlled by the Office of Quality Assurance or Project document control centers, as applicable. Provisions are established for the controlled distribution of individual procedures. Preparation is assigned to the discipline or group with lead responsibility for the activity or area. Each affected discipline or group reviews the procedures to ensure appropriate requirements and interfaces are defined. The procedures are approved by the Director, OQA, or the Project Office QA organization, as applicable, and the line organization.

2.1.4 Line Procedures

Line procedures provide instructions for Headquarters and Project Office personnel performing activities affecting quality. Line procedures include technical, management, and operating instructions necessary for performing work, including implementation of the QARD requirements. Typically, Headquarters and the Project Offices work to the same line procedures. However, where necessary, the Project Offices develop and implement line procedures that are necessary for their scope of work. Line procedures are prepared, reviewed, and approved by the highest line position responsible for performing the activities. The Office of Quality Assurance and Project Office QA organizations support and assist in the development of the line procedures. The respective quality assurance organizations also review and approve the line procedures, to ensure inclusion of quality assurance program requirements.

These procedures are contained in a line procedure manual and controlled and distributed by the Office of Quality Assurance or Project Document Control centers. Provisions are established to allow for controlled distribution of individual procedures.

2.1.5 Project Office Administrative Procedures

Administrative procedures are controlled procedures that assign responsibility and coordinate interfaces for the execution of activities of Project Offices involving significant responsibilities for more than one affected organization performing work under the direction of a Project Office.

2.1.6 Quality Assurance Program Controls

Quality assurance controls are applied to items and activities affecting quality.

The quality assurance program is implemented by management, quality assurance staff, and line organization personnel at each organizational level.

The OCRWM staff evaluates the adequacy and effectiveness of programmatic systems and technical products through overview techniques such as audits, surveillances or reviews. The OCRWM staff may use the expertise of the QA organization, line organization and management personnel, other than those directly responsible for the work, in making these evaluations. The Director, OQA, in concert with the Quality Assurance Division Directors of Project Offices assist in developing and implementing the quality assurance program, provide overview to verify achievement of quality, and evaluate and report on quality assurance program compliance and implementation effectiveness.

Line organization personnel are responsible for achieving, as a minimum, the specified level of quality.

Management reviews quality assurance program status and line performance to determine acceptability of product quality, programmatic compliance, and implementation effectiveness, and to resolve quality problems.

Line managers supervising the work will ensure that specified quality is achieved by using appropriate means of management controls.

a. Internal Controls

Quality assurance controls over items and activities affecting quality are executed by QA organizations and line organizations. The extent of these controls are established jointly by the line organization and the Quality Assurance organization and described in appropriate documents.

b. Verification of the Achievement of Quality Activities

Verification of the achievement of quality is performed by personnel who are independent of the item or activity being verified.

Verification personnel have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When verification personnel are part of the line organization, the quality assurance organization oversees and monitors the verification activities by conducting independent QA audits, surveillances, or reviews.

c. Direction, Overview, and Verification of Program Participants

Direction and overview of the quality assurance activities of other affected organizations is achieved by establishing Program quality assurance requirements; declaring these requirements through controlled documents, including procurement documents; and performing overview activities, such as reviews, audits, and surveillances.

2.1.7 Readiness Reviews

OCRWM performs selected readiness reviews and participates in selected readiness reviews performed by other affected organizations. Each Associate Director maintains a list of planned readiness reviews and submits revised lists to the Director, OCRWM, semiannually. Readiness reviews are conducted at critical phases of the Program to verify accomplishment of the following activities:

- a. Work activity prerequisites have been satisfied.
- b. Implementing line, quality assurance, and administrative procedures related to the next phase of work have been developed and reviewed for adequacy and appropriateness.
- c. Personnel have been suitably trained and qualified.

2.1.8 Graded Quality Assurance

OCRWM has adopted a quality assurance approach in which the extent of quality assurance and procedural controls are selectively applied to items and activities depending on the relative importance of the item or activity to safety, waste isolation, or Program objectives. The extent of quality assurance and procedural controls to be applied to items or activities will be based on fundamental considerations such as the consequence of failure of items, degree of importance of data, complexity of design and fabrication, degree to which functional control can be demonstrated by inspection or test, quality history and economic considerations.

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The OCRWM approach to grading is delineated in approved procedures. The approach to graded quality assurance specific to MGDS activities is delineated in Section 2 of Appendix A of this document.

2.1.9 Personnel Selection, Indoctrination, Training, and Qualification

Personnel assigned to perform activities that affect the quality of an item or activity will receive appropriate indoctrination and training prior to performing work. Procedures will address the performance of indoctrination, training, and qualification activities. Training Officers, who report to the Director, OQA, or responsible Project management, are delegated responsibility and authority to implement the staff indoctrination and training program.

a. Job Evaluation

OCRWM management analyzes each job position to determine the quality-affecting task responsibilities of the position. Applicable personnel organizations establish and/or approve as applicable, position descriptions (in accordance with applicable laws and regulations) which set forth job duties that include the quality-affecting task responsibilities of the job. Minimum personnel qualification standards (including minimum education and experience requirements) for each position are established as a recognized standard for each position.

b. Personnel Selection

Personnel assigned to perform activities affecting quality are required to have education, experience, and training commensurate with the functions associated with the work. A documented evaluation is made of the candidate's qualifications against the requirements. Minimum education and experience prerequisites are verified.

c. Determination of Indoctrination and Training

A systematic approach to the determination of applicable indoctrination and training for personnel performing activities affecting quality is established. This includes training needs as identified by applicable Training Officers and the applicable manager or supervisor.

Personnel assigned responsibility for performing activities affecting quality are provided indoctrination and training as to the purpose, scope, and implementation of the QA Program, and as applicable, to the quality-affecting job function or task.

d. Training and Qualification

Training is provided if needed, to adapt to changes in technology, methods, or job responsibilities.

Classroom training is performed in accordance with documented and approved lesson plans.

Records of training are maintained. As a minimum, documentation of training includes the training objective, course content, attendees, and date of attendance.

Persons verifying activities affecting quality, such as lead auditors, auditors, and peer reviewers, are qualified in the principles, techniques, and requirements of the activity being performed. Specific qualification requirements are contained in procedures for those functions and qualification records are maintained.

For personnel performing activities not affected by qualification/certification requirements of codes or national consensus standards, qualification is taken to mean possession of education, experience (and training where applicable) commensurate with at least the minimum requirements specified. Each affected organization maintains a system for verifying pertinent education and experience evidence submitted or referenced by such individuals and shall provide certification that verification has been accomplished.

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Dec 3.1

2.1.10 Surveillance

In addition to audits described in Section 18 of this document, formal programmatic and technical surveillances are performed to provide timely, management information on Program activities affecting quality. Surveillances are performed by knowledgeable personnel on work they had no direct responsibility for performing. Surveillances are performed to written procedures, checklists, or plans and the results documented. Deficiencies identified are documented in accordance with the requirements in Sections 15 and 16, as appropriate. Deficiencies identified during the surveillance are reported to the organization responsible for the affected item or activity, for resolution. These deficiencies are tracked to verify corrective action implementation.

2.1.11 Management Assessments

An independent management assessment of the quality assurance program is conducted, at the direction of the Director, OCRWM, at least annually, by the Director, OCRWM or designees who are independent of the OCRWM QA organization.

The purpose of the independent management assessment is to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance program. Results of the independent management assessment are documented. Deficiencies identified are documented in accordance with requirements in sections 15 and 16, as appropriate.

2.1.12 Management Information Reporting and Tracking

Communication and information systems are established to ensure timely reporting, dissemination, and tracking of quality assurance management information, such as the status of quality assurance programs, status of resolution of deficiencies and conditions adverse to quality, the status of quality assurance overview results, and the status of the quality concerns program.

*Changed by 2.1.13
ICN 3.1*

SECTION 3 DESIGN CONTROL

3.0 GENERAL

Design activities are accomplished in accordance with written procedures. These procedures describe the systems engineering process by which design activities, from conceptual design through final design, are planned, controlled, and implemented; and describe the control of design inputs, interfaces, outputs, reviews, changes, and deficiencies.

This section describes provisions established by OCRWM to implement design control activities.

3.1 OCRWM CONTROL OF DESIGN ACTIVITIES

3.1.1 Systems Engineering

OCRWM uses a systems engineering approach for control and management of Program design activities. Systems engineering is used as a disciplined means of transforming Program mission requirements into a description of system performance requirements and preferred configuration. It ensures that all elements of the system are properly integrated and that the system operates effectively and protects the health and safety of the public and the environment.

Systems engineering is a structured, formal method of managing the design process to aid in ensuring that cost, schedule, and technical performance objectives are met. It specifies:

- a. The engineering process that defines the technical baseline and development of the design to that baseline. The process is iterative, cycling between the definition of requirements (design, development, siting), evaluations against the requirements, and optimization, which leads to further definition and refinement.
- b. The process for integrating the disciplines involved in design development, interfacing between the various levels of the Program, controlling revisions to the technical baseline, and periodically reviewing the design development.
- c. The documentation required to establish the technical baseline and provide a traceable record of the design and siting process.

Systems engineering is implemented at the OCRWM Program level, and at the program-element level (GD, Transportation, and MRS). Activities associated with the elements of the system are assigned to other organizations (e.g., the Project Offices and Operations Offices) in appropriate governing documents (e.g., Office Charters, Memoranda of Understanding, Contract Scopes of Work).

The systems engineering approach addresses the control of design interfaces by defining who is responsible for each element of the design, describing the process for developing an integrated design, and establishing requirements for documenting, maintaining, and controlling a technical baseline to be used. Technical and quality assurance requirements address the control of design interfaces by defining work scopes and establishing requirements for information exchange between OCRWM and other affected organizations.

3.1.2 Processing of Data

Data collection, qualification, analysis, identification, and recording activities related to design of the individual repository program elements are discussed in Appendix A of this document.

3.1.3 Design Inputs

OCRWM Headquarters identifies regulatory requirements that affect design, such as 10 CFR 60, 10 CFR 70, 10 CFR 71, environmental regulations, applicable quality standards, etc. Project Offices and other affected organizations identify any additional state and local requirements. These requirements are baselined and maintained in system and subsystem design requirements documents, that require management, technical, and quality assurance review prior to approval at a level determined by the program level of the document.

Requirements documents are developed for the overall Program mission, each system element, and other organizations responsible for parts of the system, as identified in the next higher level design document. These controlled documents are reviewed and approved at the level for which they were written and also approved at the next higher level. Requirements for baselining and controlling these documents are discussed in Section 6.0 of this QAPD. The design input for these documents prepared by OCRWM includes processed data received from other affected organizations.

3.1.4 Design Process

Design activities are conducted primarily by program participants and other affected organizations. Computer programs used in design are developed and controlled in accordance with Section 19 of this document. Organizations responsible for design engineering within the Program are required (1) to prescribe

their design processes at the level of detail necessary to permit the design to be carried out in a correct manner; and (2) to ensure that such activities are documented in a timely manner and in sufficient detail to support facility design, construction, and operation; and (3) to permit verification that the design meets the established requirements.

Design processes are required to provide for planned, documented, controlled analyses, and to include the following features:

- a. Legible analysis documents in a form suitable for reproduction, filing, and retrieval.
- b. Sufficient detail as to purpose, method, assumptions, design input, references, and units to enable an individual technically qualified in the subject to review and understand the analysis and verify adequacy of the results without recourse to the originator.
- c. Provisions for ensuring that calculations are identifiable for retrieval (e.g., by subject, originator, reviewer, and date; or by other uniquely identifying data).

3.1.5 Readiness Reviews for Design Activities

Readiness reviews are conducted at established hold points in the design. Readiness reviews are performed to confirm, as a minimum, the following elements:

- a. Required systems engineering approach to design development has been factored into design schedules and related planning documents.
- b. Applicable regulatory requirements, codes, standards, and controls have been identified. Implementing line procedures and procurement documents reflect these required design inputs.
- c. Design responsibilities and interface responsibilities are defined in procedures and procurement documents.
- d. Design schedules identify milestone design reviews.
- e. Procedures exist for baselining design documents and controlling subsequent changes.

3.1.6 Technical Reviews

The adequacy and correctness of OCRWM-generated technical documents are verified by technical review prior to approval and issuance. In this application, the review considerations include inputs and sources, assumptions, prescribed processes where applicable, and compatibility with established Program objectives and approaches. Technical reviews are performed by any competent individual(s) or group(s) other than those who prepared the technical document but who may be from the same organization.

Selected major designs are also subjected to OCRWM technical review. In this application, the reviews will evaluate compatibility of design and design approach with established Program design objectives and constraints and with the prescribed systems engineering requirements.

3.1.7 Design Verification

Design verification for Program-element designs is delegated to the responsible design organizations.

3.1.8 Design Change Control

Changes to OCRWM originated design-related documents, including design input documents, are justified and processed using the same methods applied to the preparation of the original document. Changes, with the exception of minor changes as described in Section 6.0, are reviewed and approved by the organizations that reviewed and approved the original design document except where an organization was originally responsible for approving the design document is no longer responsible. In these cases, OCRWM will designate a new responsible organization to review the document changes.

The impact of design changes on procedures and training are evaluated.

3.1.9 Design Deficiency Control

Deficiencies in approved design-related documents generated by OCRWM and in design information used by OCRWM are controlled and resolved in accordance with Section 16. The impact of such design document deficiencies on work previously performed using the affected document, is evaluated and corrective measures, if necessary, are applied.

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SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

This section describes provisions to implement procurement document control activities. Procurement by OCRWM is accomplished in accordance with written procedures. These procedures describe the process by which procurement planning is accomplished; the process by which procurement documents and revisions are prepared, reviewed, approved, and controlled; the contents of procurement packages; and the responsibilities for executing procurement document control activities. In addition, these procedures describe involvement of the quality assurance staff.

4.1 PROCUREMENT DOCUMENT PLANNING, PREPARATION, REVISION, REVIEW, AND APPROVAL

Procedures are established and implemented for the control of procurement documents. The procedures define the methods and responsibilities for procurement planning and for preparation, review, and approval of procurement documents and changes thereto. Procurement planning includes identifying the need for a specific service, determining the specific work to be accomplished, identifying appropriate technical and quality requirements, and identifying sources for the work.

4.2 PROCUREMENT DOCUMENT CONTENT

The OCRWM quality assurance program requires that organizations initiating a procurement include the following, as appropriate, in the procurement document "package":

- 4.2.1 A statement of the scope of work to be performed by the supplier.
- 4.2.2 Technical requirements:
 - a. Reference to, and/or inclusion of, specific plans, drawings, specifications, codes, standards, regulations, procedures, or instructions that describe the services to be furnished.
 - b. Identification of acceptance requirements for monitoring and evaluation of supplier performance.
 - c. Technical acceptance/rejection criteria.

4.2.3 Quality assurance program requirements:

- a. Quality assurance requirements addressing applicable elements of the program, commensurate with the scope, complexity, and safety implications of the work, as determined by the procurement requestor.
- b. Permission for the supplier to work under the umbrella of the purchaser's quality assurance program, at purchaser option, when appropriate to the nature of the procurement, provided that the scope of the activity is adequately addressed therein. When these circumstances apply, the procurement documents will specify which parts of the purchaser's QA program are applicable to the supplier's work efforts.
- c. Requirement for the supplier to incorporate appropriate provisions of the quality assurance program in subtier procurement documents,

4.2.4 At each tier of procurement, the right of purchaser or designated or authorized parties, access to supplier facilities and records for verification, such as inspection and/or audit.

4.2.5 Documentation required of the supplier, including submittal of schedules, nature of documentation (i.e., information, review, or approval) and as appropriate, designation of retention times and disposition requirements for those records maintained by the supplier.

4.2.6 As applicable, the participant's requirements for reporting and review or approval of nonconformance dispositions.

4.3 PROCUREMENT DOCUMENT REVIEW

4.3.1 Organizations executing procurement document control activities, provide for documented technical and quality assurance review of procurement document packages to ensure that the documents include all necessary requirements and provisions. These reviews are performed by qualified QA and technical personnel who have access to pertinent information.

4.3.2 Procurement documents and changes are reviewed to verify that the procurement documents:

- a. Have been prepared in accordance with applicable procedural requirements.
- b. Reflect adequate and appropriate quality assurance requirements.
- c. Include applicable regulatory, design basis, and related technical information, and that these requirements are correctly stated.

4.3.3 Organizations are also required to include provisions in their applicable procedures for analysis of exceptions requested or specified by the supplier, in order to assess potential impact of such exceptions on intent of the procurement documents or on quality of the service.

4.4 PROCUREMENT DOCUMENT CHANGES

Changes to procurement documents, other than minor changes as described in Section 6, receive the same degree of control as utilized for the original documents.

SECTION 5

PLANS, PROCEDURES, INSTRUCTIONS, AND DRAWINGS

5.0 GENERAL

OCRWM activities affecting quality are prescribed by, and controlled in accordance with, plans, procedures, and instructions. Plans, procedures, and instructions include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Planning, preparation, and issuance of plans, procedures, and instructions is accomplished prior to the start of activities affecting quality.

This section describes provisions established by OCRWM to control the performance of activities affecting quality.

5.1 OCRWM PLANS, PROCEDURES, INSTRUCTIONS, AND DRAWINGS

Procedures are developed and implemented to ensure that methods to be used for performance of activities affecting quality are prescribed in documented plans, procedures, and instructions. Activities affecting quality are performed in accordance with these documents.

OCRWM delegates preparation and control of design drawings.

SECTION 6

DOCUMENT CONTROL

6.0 GENERAL

OCRWM develops and implements procedures that ensure that Program documents affecting quality are prepared, reviewed, approved, issued and revised in a prescribed and controlled manner.

This section describes provisions established by OCRWM to control the preparation, revision, review, approval, and issuance of documents affecting quality.

6.1 OCRWM DOCUMENT CONTROL

6.1.1 Document Preparation, Review, Approval, and Revision

Documents that specify quality and/or technical requirements or prescribe activities affecting quality are prepared; reviewed for adequacy, completeness, and correctness; approved; and released for issuance and distribution and revised in accordance with written procedures. Procedures for preparation and revision of plans, manuals, procedures, instructions, and other documents address, as a minimum, the following requirements:

- a. Identification of the individuals or organizations responsible for the preparation, revision, review, approval, and release of the document. The QA organization reviews and where applicable, concurs with controlled documents that contain quality assurance requirements.
- b. Review of documents affecting quality by individuals or organizational elements with responsibility for implementation.
- c. Review of documents affecting quality by individuals other than the preparer of the document.
- d. Access by reviewing organizations to pertinent background data or information to assure a complete review.
- e. Resolution of review comments for which resolutions are considered mandatory by the reviewing organization, prior to approval and issuance of the document. Review comments and resolutions are to be documented and maintained in accordance with approved procedures.

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document.

Minor changes to documents, such as inconsequential editorial corrections or clarifications, are not subject to the same review and approval as the original documents. To avoid possible omission of a required review, the types of minor changes that are not subject to such review and approval, and the authority for such a decision, is clearly delineated in approved procedures.

6.1.2 Issuance and Distribution

Document issuance and distribution are controlled to ensure that correct, applicable, and current documents are available to the personnel performing prescribed activities, prior to commencing work and at the location where work is performed. Approved procedures delineate the responsibility and authority for such releases. Documents which require verification and are released prior to verification are identified as such and controlled and authorized for release by signature approval, with the described bases for release.

Document control procedures include the following provisions:

- a. Identification and marking of documents, including documents released prior to completion of the approval process.
- b. Use of receipt acknowledgment document transmittal forms.
- c. Maintenance of controlled document distribution lists.
- d. Marking, removal, or destruction of obsolete or superseded controlled documents.
- e. Maintenance of an index (controlled document list) giving revision status for controlled documents.

Controlled document recipients are responsible for acknowledging document receipt; ensuring that the latest authorized documents are in use; and that obsolete or superseded documents are so identified, destroyed, or returned.

Program-level controlled documents (including technical baseline documents), other than the QARD and QAPD and associated procedures, that address OCRWM activities subject to quality assurance program requirements, are handled in accordance with the Program Change Control Procedure (DOE/RW-0223). These controlled documents are listed in a controlled documents register. The register is

issued as changes or revisions occur to assist recipients in maintaining up-to-date files.

Requirements for program-element and project level, controlled documents, other than quality assurance program procedures, are delineated in program-element and project level change control procedures.

Descriptions and responsibility assignments for development of program, program-element and project level controlled documents, including the technical baseline documents are described in DOE/RW-0043, OCRWM Program Management Systems Manual.

SECTION 7

CONTROL OF PURCHASED ITEMS, AND SERVICES

7.0 GENERAL

OCRWM develops and implements procedures that ensure that purchased services are controlled in accordance with specified requirements. The control of items is not performed by OCRWM, but delegated to other affected organizations.

7.1 OCRWM CONTROL OF PURCHASED SERVICES

Procedures are established to control purchased services. The system for control of purchased services includes:

a. Procurement planning

Procurement planning is accomplished and documented as early as practicable to provide appropriate interface compatibility and to ensure a systematic approach to the procurement process. Planning is performed to determine what is to be accomplished; how is it to be accomplished; when is it to be accomplished; and who is to accomplish it. Requirements for supplier quality assurance programs are specified in the solicitation package.

b. Supplier selection

Contracting Officers solicit bids and award contracts. Source selection officials are responsible for evaluating bid offers or proposals.

For procurements subject to the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR), the contract documents are prepared and contracts placed by the cognizant government procurement organization. Supplier's quality assurance programs are evaluated either before or after contract placement and any quality deficiencies are corrected prior to initiating quality-affecting work.

c. Bid Evaluation

OCRWM's bid evaluation process determines the extent of the supplier's ability to meet the procurement document requirements. Based on the type of procurement, bid evaluations consider the following subjects:

- Technical considerations.
- Quality assurance requirements.
- Personnel of potential supplier.
- Past performance of potential supplier.

d. Supplier performance evaluation

Methods and criteria for evaluating supplier performance for OCRWM procurement activities are delineated in approved procedures.

Interfaces with the supplier are established as necessary to ensure that the performance measurement methods are appropriate, adequate, and understood by each involved organization. The methods used include establishment and evaluation of performance objectives; review of supplier's records and nonconformance controls; and performance of reviews, audits, and surveillances. This documentation is evaluated to determine the supplier's quality assurance program effectiveness.

e. Supplier generated document control

Supplier generated documents are submitted in accordance with the requirements delineated in the procurement documents. OCRWM receives, reviews, and evaluates these documents, as necessary, to ensure conformance to the procurement requirements. As a minimum, OCRWM ensures the supplier provides documentation that identifies the procurement requirements met, as well as documentation identifying procurement requirements that have not been met.

f. Change control

Changes to procurement documents of purchased services are evaluated in the same manner and with the same criteria as the original procurement documents.

g. Acceptance of services

When required by procurement documents, suppliers' QA Programs are reviewed and accepted prior to initiation of activities affected by the quality assurance program.

Services are accepted by one or more of the following methods:

1. Results of audits or surveillances, as appropriate.
 2. Technical verification of data produced.
 3. Review of objective evidence for conformance to the procurement document requirements.
 4. Evaluation of suppliers certificates of conformance for services to ensure validity and documentation of results.
- h. Control of Nonconformances

OCRWM establishes and documents methods for disposition of services not meeting procurement document requirements, through approved procedures. These procedures include provisions for: evaluation of the nonconforming condition; submittal of the nonconformance document to OCRWM by the supplier, as directed by OCRWM; OCRWM disposition of the supplier's recommendation of corrective action; verification of the implementation of the disposition; and maintenance of supplier submitted nonconformance documents.

SECTION 8

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS,
AND SAMPLES

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8.0 GENERAL

The identification and control of materials, parts, components, and samples are delineated in Section 8 of Appendix A.

SECTION 9
CONTROL OF PROCESSES

9.0 GENERAL

Process control is applicable to scientific investigations and engineered items. Control of special processes is applicable to engineered items. OCRWM does not perform activities related to processes or special processes; therefore, the QARD requirements for control of these activities do not apply to this QAPD.

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September 17, 1990
Revision 3

SECTION 10

INSPECTION

10.0 GENERAL

OCRWM performs no inspection activities. Therefore, the inspection requirements delineated in the QARD do not apply to this QAPD.

SECTION 11
TEST CONTROL

11.0 GENERAL

OCRWM performs no test control activities, other than the computer software test control requirements. Application of these computer software requirements is addressed in Section 19 of this QAPD.

SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

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ICW 3.1

12.0 GENERAL

M&TE activities performed by OCRWM apply to the MGDS. The application of requirements for M&TE activities is described in Section 12 of Appendix A of this QAPD.

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SECTION 13
HANDLING, STORAGE, AND SHIPPING

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ICN 3.1

13.0 GENERAL

OCRWM activities relative to handling, storage, and shipping activities apply to MGDS. The application for these activities is described in Section 13 of Appendix A of this QAPD.

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- 13.2.3
- 13.2.4
- 13.2.5

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

OCRWM performs no inspection, test, and operating status activities. Therefore, the inspection, test, and operating status requirements of the QARD do not apply to this QAPD.

SECTION 15

CONTROL OF NONCONFORMING ITEMS

15.0 GENERAL

Control of nonconforming items is in accordance with written procedures which are reviewed and concurrence with by the QA organization. These procedures describe the methods used to identify, document, track, segregate, review, disposition, and notify affected organizations of nonconforming or defective items.

Nonconforming items are those items (i.e., material, equipment, system, structure, or component) that do not comply with established requirements, such as in drawings specifications, and procurement documents. The description of a nonconforming item is documented on a nonconformance report.

Personnel assigned approval authority for dispositions of nonconforming items are identified and the quality assurance organization responsibilities are described in these procedures. The procedures associated with control of nonconforming items are prepared and controlled by Project Offices or headquarters.

Nonconforming items are evaluated to determine the degree of significance. If conditions are determined to be significant, by the criteria provided in Section 16, these conditions will be processed as significant conditions adverse to quality and documented in corrective action reports in accordance with Section 16.

15.1 IDENTIFICATION OF NONCONFORMING REPORTS

Nonconforming items are identified by marking, tagging, or other methods that do not adversely affect the end use of the item. Identification is legible, recognizable, and includes the nonconformance report number. When identification of each nonconforming item is not practical, the receptacle or segregated storage area is identified. The authority for application and removal of the nonconformance status indicator is specified in approved procedures.

NOTE: When items of nonconformances are identified by OCRWM personnel at other affected organizations' facilities, these conditions are documented in accordance with QA program requirements and brought to the attention of that organization's management or Project Office management.

Typically, use or installation of nonconforming items may not proceed until the nonconforming condition is dispositioned and the specified actions are completed. If

only a specific part of the item is in nonconformance, that specific part is identified and work may proceed on the remaining non-affected parts. In certain cases, it is anticipated that use or installation of nonconforming items will need to continue prior to implementation of the disposition. In such cases, the approval and justification for use or continuance of installation as delineated in approved procedures, are obtained.

15.2 SEGREGATION

Nonconforming items are segregated by placement in designated hold areas until dispositioned. When segregation is impractical, due to physical configuration, other precautions are employed to preclude inadvertent use.

15.3 DISPOSITION OF NONCONFORMING ITEMS

15.3.1 Control

Nonconformance characteristics are reviewed and subsequent dispositions of nonconforming items are proposed and approved in accordance with documented procedures. The processing, delivery, installation, or use of nonconforming items are controlled, pending evaluation and approved disposition, by authorized personnel. Nonconformance documentation is distributed to affected organizations.

15.3.2 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items are procedurally defined.

15.3.3 Personnel

Individuals performing evaluations to determine a disposition have competence in the specific area being evaluated, a sufficient understanding of requirements, and access to pertinent background information to make a proper evaluation.

15.4 DISPOSITION

The organization responsible for dispositioning the nonconforming item ensures that the disposition identifies and documents the correction as repair, rework, use-as-is, or reject. In the case of use-as-is or repair dispositions, technical justification is required. Nonconformances affecting design requirements are subject to the same design controls as those applied to the original design. The design documentation (i.e., as-built records), if required, reflect the accepted deviation.

15.5 REPAIRED OR REWORKED ITEMS

Repaired or reworked items are reexamined in accordance with the original acceptance criteria unless the disposition has established other acceptance criteria.

15.6 CORRECTIVE ACTION

The action to correct the nonconforming condition is verified and documented in a timely manner. The QA organization concurs with the corrective action to ensure applicable QA requirements are satisfied and verifies proper implementation and closeout of the corrective action by signatory concurrence on the nonconformance report.

SECTION 16

CORRECTIVE ACTION

16.0 GENERAL

Conditions adverse to quality are identified promptly, documented, and corrected as soon as practical. Approved procedures which are reviewed and concurred by with the QA organization, describe the methods used to identify, document, track, review, disposition, and notify affected organizations of conditions adverse to quality.

Examples of conditions adverse to quality are those programmatic deficiencies such as defective software, procedures, records, activities, or such actions which result in failure to comply with procedures, plans, and other established requirements. Items identified as nonconforming are identified and processed in accordance with Section 15.

16.1 IDENTIFICATION OF CONDITIONS ADVERSE TO QUALITY

Conditions adverse to quality are documented and the documented deficiency receives a unique report number.

16.2 EVALUATION

Conditions adverse to quality are evaluated to determine the degree of significance. If the condition is determined to be significant, it is identified and processed in accordance with the requirements of A Significant Condition Adverse to Quality described in this section.

16.3 CORRECTIVE ACTION

After a condition adverse to quality is identified, corrective action is documented and initiated to preclude recurrence. The QA organization concurs with the corrective action to assure QA requirements are satisfied.

16.4 CORRECTIVE ACTION COMPLETION

The QA organization follows up on the corrective action to verify proper implementation and to closeout the corrective action.

16.5 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

Significant Conditions Adverse to Quality (SCAQs) are those conditions determined to be repetitive in nature, or any condition adverse to quality that, were it to remain

uncorrected, could adversely affect safety or waste isolation. SCAQs will be promptly identified and corrected in accordance with written procedures. These procedures which are reviewed and concurred by the QA organization, describe the process by which SCAQs are identified and evaluated to determine cause, generic implications to the Program, corrective action, and action to preclude recurrence. Provisions for reporting SCAQs to the cognizant directorate or affected QA organization are also prescribed.

16.5.1 Corrective Action of SCAQs

SCAQs cited within OCRWM are reported to cognizant management and the appropriate OCRWM QA organization. A corrective action report is issued for SCAQs. Evaluations of identified nonconforming items (as identified per section 15 of this document), or conditions adverse to quality may result in escalating the deficiency to a SCAQ.

Cognizant managers are responsible for determining the cause of the condition, the generic implications to the Program, the corrective action including the action to be taken to preclude repetition. The determinations made and corrective actions taken are documented and reported to the cognizant directorate or Project Office, and the applicable QA organization.,

The OCRWM QA organization is responsible for concurrence with the proposed corrective action, verification of the implementation, and closeout of the corrective action by signatory concurrence on the corrective action report.

Conditions adverse to quality and SCAQs identified by OCRWM personnel at other affected organizations' facilities are documented in accordance with QA program requirements and brought to the attention of that organization's management or Project Office management.

16.6 CONTROL OF DEFICIENCIES

Methods and responsibilities for the analysis for trends; processing, control, and resolution of deficiencies (both items and conditions adverse to quality); and handling of significant conditions adverse to quality are established.

16.7 TREND ANALYSIS

Information derived from evaluation and verification activities such as audit, surveillance, review and assessment, are analyzed to show quality trends and help identify root cause by OQA for Headquarters and by the Project Offices. Affected organizations and OCRWM analyses are reviewed by OQA to determine trends that are Program wide. Results of trend analysis are reported to upper management.

The trend analysis program is described in procedures and considers the following attributes, as a minimum:

- a. The quality indicators to be trended.
- b. The methods of data handling such as gathering, collecting, sorting, grouping, and coding.
- c. The statistical processes to be used such as type of charts, normalizing to remove bias, weighting, and control limits.
- d. The methods to be used in analyzing data and trend determination.
- e. The actions to be taken when an adverse trend is identified.
- f. The type, distribution, and frequency of issue of trend results reporting.

SECTION 17

QUALITY ASSURANCE RECORDS

17.0 GENERAL

The quality assurance (QA) records program for the OCRWM is accomplished in accordance with written plans and procedures. These documents describe the integrated set of activities for creating, identifying, collecting, controlling, processing, organizing, distributing, storing, preserving, retrieving, and disposing of Program QA records. These documents identify responsibilities of the Quality Assurance organization and other organizations.

This section describes provisions established by OCRWM to implement QA records program activities.

17.1 OCRWM QA RECORDS SYSTEM

The OCRWM records management system is decentralized in that Central Records Facilities (CRFs) are established at Headquarters, the Project Offices, and the Operations Offices. OCRWM also establishes local records centers (LRCs) that serve as record collection centers. Typically, record-initiating organizations submit documents to the LRC for subsequent turnover to the CRF. The CRFs and LRCs are established in accordance with DOE/RW-0194, Records Management Policies and Requirements, (RMPR) and are described and operated in accordance with approved procedures.

The QA records system is a subset of the overall records management system. Headquarters prepares and issues the RMPR, and retains responsibility for the total QA records system, while delegating records management for work performed by Project Offices to the Project Offices. This delegation includes collection of records from affected organizations.

Control and maintenance of QA records are delegated to the records management contractor for those QA records generated or received by Headquarters. Control and maintenance of QA records generated or received by Project Offices are retained by the Project Offices. Project Office and Operations Office CRFs, as applicable, submit microfilm of completed records to the Headquarters records-management contractor. Controlled documents and technical baseline documents, as appropriate, specify records to be generated, supplied, or maintained.

17.2 RECORD DEFINITION

OCRWM quality assurance and implementing line procedures, and program plans, define minimum QA records generated as a result of implementation. In general, the following documents are considered QA records:

- a. Individual documents that have been executed, completed, and approved that furnish evidence of the quality and completeness of data (including raw data) and activities affecting quality.
- b. Documents prepared and maintained to demonstrate implementation of quality assurance programs.
- c. Procurement documents subject to quality assurance controls.
- d. Other documents, such as plans, drawings, correspondence, specifications, technical data, books, maps, papers, photographs, and data sheets subject to quality assurance controls.
- e. Other materials that provide data and document quality, regardless of physical form or characteristic including magnetic media.

A complete record is a document that will either receive no more entries or whose revision would normally consist of the reissue of the document; and when applicable is signed and dated by the originator and by personnel authorized to approve the document.

17.3 RECORD GENERATION

The applicable design specifications, procurement documents, and other documents specify the records to be generated, supplied, or maintained by OCRWM.

Documents designated to become records are to be legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished. Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. These records may be originals or reproduced copies. Authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.

OCRWM maintains lists that contain the signatures and initials of personnel authorized to authenticate records.

Complete records are suitably protected by the record initiator prior to turnover.

17.4 RECEIPT OF RECORDS

The receipt of records is applicable to LRCs and the CRFs.

A receipt-control system is established that is structured to permit a current and accurate assessment of the status of records.

The organization responsible for receiving the records provides for protection from damage, deterioration, or loss, during the time that the records are in their possession.

17.5 RECORD IDENTIFICATION

Records or indexing systems provide sufficient information to permit identification between the record and its applicable items or activities.

The records are indexed and the indexing system or systems include the location of the record within the records system or systems.

17.6 RECORDS STORAGE AND RETRIEVAL

Records are controlled from time of completion until the time of storage in a permanent storage facility. When necessary, records are controlled from when they are initiated to protect their integrity. Temporary storage, preservation, safekeeping, and retrievability of completed records is performed in accordance with requirements applicable to the storage of records delineated in the QARD.

17.7 RECORDS CLASSIFICATION

All of OCRWM's quality assurance records are classified as lifetime records.

17.8 CORRECTED RECORDS

Records are corrected in accordance with approved procedures. These procedures provide for review or approval by the record-originating organization. Corrections to records include dates and identifications of the persons authorized to make such corrections.

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SECTION 18

AUDITS

18.0 GENERAL

OCRWM has established requirements for a quality assurance audit program to provide independent verification of the status, adequacy, compliance, and implementation effectiveness of the quality assurance program and its elements. This section describes provisions for implementing the quality assurance audit program.

18.1 AUDIT PROGRAM IMPLEMENTATION

Procedures describe the methods and responsibilities applicable to audit activities to determine compliance with requirements and to assess programmatic compliance and implementation effectiveness of OCRWM and other affected organizations' quality assurance programs. The audit program includes technical and programmatic verifications.

The Director, OQA, is responsible for the development, implementation, and maintenance of the OCRWM QA audit program. The OCRWM QA organization plans and conducts audits of the affected organization activities as well as activities performed by OCRWM staff.

18.1.1 Audit Process

Procedures for audit activities address accomplishment of the planning and scheduling of audit activities to ensure that Program-deliverable products and processes are evaluated commensurate with importance in achieving mission objectives and schedule completion dates assigned to the products or processes. Internal audits are scheduled to ensure that all applicable elements of the QA program are audited at least once a year.

18.2 AUDIT SCHEDULING

OCRWM develops, maintains, and implements an audit schedule for Headquarters and the Project Office that covers applicable quality assurance program elements.

After award of a contract by OCRWM, external audits are scheduled as appropriate.

Suppliers' quality assurance programs are evaluated on at least an annual basis. Supplier audits are performed on a triennial basis, unless the annual evaluation indicates the need for an audit prior to the end of a triennial period. The need for audit of a supplier is also evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first audit, if the scope and conduct of the preaward survey addresses contract requirements.

OCRWM audits implementation of affected organizations' quality assurance programs on at least an annual basis. Audit schedules are adjusted in the event of significant changes in personnel, organization, or quality assurance program.

18.3 AUDIT TEAMS

Audit team leaders are required to be certified, lead auditors. Lead auditor qualifications comply with requirements of the QARD.

Members of the audit team are independent with respect to activities they will audit (i.e., no audit team member audits an activity for which he or she was directly responsible). Management personnel of audited activities are prohibited from participating in the selection of audit team members who will audit their activities.

Audit team members, collectively, have the necessary programmatic and technical expertise in the work being audited, by virtue of prior experience and/or specific, documented orientation or training.

Audit teams normally include members from appropriate technical disciplines, who will verify adequacy of technical processes employed to ensure the validity and correctness of technical work.

OCRWM auditor and lead auditor training and qualification programs are administered by the appropriate QA organization. Lead auditors are certified under the appropriate QA program.

18.4 AUDIT PREPARATION

As a minimum, preparation for individual audits includes: preparation of an audit plan and an audit checklist or procedure; study of auditee procedures applicable to the activities to be audited; evaluation of relevant surveillance results; results of previous audits of the same activities; relevant corrective action history; review of trend data; and review of the current status of the work.

The scope of each audit is based on an evaluation of the activities to be audited. The evaluation considers:

- a. Results of previous audits.
- b. Impact of significant changes in personnel, organization, or quality assurance program.

The scope of an audit may include verification of product quality and technical adequacy of work being done, as well as programmatic compliance and implementation effectiveness. Personnel with appropriate technical knowledge are assigned as audit team members to evaluate technical aspects of processes and acceptability of the quality of products resulting from the processes. Technical requirements are selected for audit verification from the governing technical requirements documents and are included in audit checklists.

18.5 AUDIT PERFORMANCE

Audit team members perform document reviews, interviews, and other activities described in the audit checklist or procedure under the direction of the audit team leader. Audit team members regularly communicate the status of assigned activities, as well as problems and potential problems to the audit team leader. The audit team leader ensures problems that require immediate attention are relayed to the audited organization's representatives in a timely manner. Regular discussions with the audited organization's representatives are held to provide the status of audit activities and promote effective communications between auditor and auditee. Audit performance includes documentation of the evidence examined and conditions observed, so that a sound basis exists for reported conclusions.

Results of the audit are presented to the audited organization's representatives by the audit team leader (and team members), in a post audit.

18.6 AUDIT REPORTING

The audit report includes the following information, as appropriate:

- a. A description of the audit scope.
- b. Identification of audit team members.
- c. Identification of personnel contacted during the audit.
- d. A summary of audit results, including a statement describing the effectiveness of the quality elements audited.

- e. A clear description of each audit finding that will allow the audited organization to understand the finding and take corrective action.

The audit report is signed by the audit team leader and approved by the Director, OQA, or Project Office QA organization, as appropriate, prior to transmittal and distribution. The audit report is issued to the audited organization for review, assessment, and appropriate action. Copies of the audit report are also distributed to other affected organizations as well as the management of the auditing organization. Deficiencies require responses from the designated representative(s) of the affected organization, with specified action dates.

18.7 POST-REPORT ACTION

Management of the audited organization investigates audit findings, schedules corrective action, and notifies the auditing organization in writing of actions planned or taken.

Management of the cognizant organizational elements of the auditing organization, including QA and the audit team leader, review the audit response to determine:

- a. Adequacy of cause determinations.
- b. Acceptability of commitments for correcting the deficient (and similar) conditions (past and present).
- c. Acceptability of committed actions to preclude recurrence of the deficient conditions, and of the schedule for completing such actions.
- d. Adequacy of the evaluation of impact of the deficient work performed and the generic implications on the Program.
- e. Appropriateness of corrective action responsibility assignments.

Follow-up is performed by the auditing organization, to verify satisfactory implementation of corrective and preventive actions taken to resolve audit findings. Verification of corrective and preventive action implementation is documented to support close-out of findings.

SECTION 19
COMPUTER SOFTWARE

19.0 COMPUTER SOFTWARE DESIGN AND CONTROL

Requirements for design and control of computer software are delineated in Section 19 and Section 19 of Appendix A of the QARD. OCRWM describes application of those requirements in a Software Quality Assurance Plan or approved procedures.

APPENDIX A

AMPLIFICATIONS TO THE QUALITY ASSURANCE PROGRAM DESCRIPTION FOR MINED GEOLOGIC DISPOSAL SYSTEM ACTIVITIES

GENERAL

The purpose of this appendix is to amplify the Quality Assurance Program Description (QAPD) for Mined Geologic Disposal System (MGDS) activities. OCRWM performs activities related to the MGDS in accordance with Sections 1 through 19 of the QAPD. Specific amplifications to those requirements are provided below, as related to major, numbered QAPD sections except Section 20 of this Appendix, which is unique to scientific investigation. Where a QAPD section does not require amplification, the section reference is omitted from this appendix.

1.0 AMPLIFICATION OF QAPD SECTION 1 - ORGANIZATION

This section describes activities assigned to affected organizations performing work related to MGDS activities. These affected organizations report administratively through either an established DOE Operations Office or an HQ office to the ADGD. Figures A1-1 and A1-2 depict the MGDS organization.

The following affected organizations are assigned specific work related to MGDS activities:

- a. Battelle, Pacific Northwest Laboratories, (PNL), through the Richland Operations Office, provides performance assessment and materials characterization.
- b. Brookhaven National Laboratory (BNL), through the Chicago Operations Office, provides waste-package scientific support and preclosure risk-assessment services.
- c. Lawrence Berkeley Laboratory (LBL), through the San Francisco Operations Office, provides geoscientific support.
- d. Oak Ridge National Laboratory (ORNL), through the Oak Ridge Operations Office, provides transportation-operations planning, geosciences, shielding, and systems integration support and performs safeguards activities.
- e. Argonne National Laboratory (ANL), through the Chicago Operations Office, provides environmental, socioeconomic, and site characterization support.

- f. Lawrence Livermore National Laboratory (LLNL), through the San Francisco Operations Office, performs defense waste studies.
- g. Sandia National Laboratory (SNL) performs performance assessment activities and Los Alamos National Laboratory performs geochemical and hydrologic research through the Albuquerque Operations Office.
- h. KOH Systems, Inc. (KOH), as a Records Management Contractor, provides records management and related activities.
- i. SRA Technologies, Inc. (SRA), as a QA and Technical Support Contractor, provides technical support services in planning and scoping an Environmental Impact Statement and an implementation plan for the geologic repository.
- j. The Office of Environmental Restoration and Waste Management (EM) is responsible for the Defense Waste Processing Facility (DWPF), the West Valley Demonstration Project (WVDP), and the Hanford Waste Vitrification Project.

Yucca Mountain Project Office (YMPO)

The Yucca Mountain Project Office, hereinafter referred to as the Project Office, is headed by the Yucca Mountain Project Manager who is also the ADGD. The Project Office is made up of several entities performing GD work. The Project Office is internally made up of Project Division Directors, a Requirements Analysis Division Director located at headquarters, an institutional staff, a Site Manager, Branch Chiefs and other in-line DOE staff. This organization is depicted in Figure 1-1H in Section 1 of this document. Other entities which are external to the DOE Project Office personnel but are considered part of the Project through support functions are:

- a. DOE Nevada Operations Office (NVO) personnel. This organization provides matrix support as appropriate.
- b. Project Office Direct Support Contractors

The Project Office uses direct support contractors that provide support in program management, integration, quality assurance, technical and scientific activities as well as other activities dictated by the Project Office. These contractors are Science Applications International Corporation/Technical and Management Support Services (SAIC/T&MSS) and MAC Technical Services Company (MACTEC).

YMP-Affected Organizations

In addition to the Project Office internal staff, NVO personnel and direct support contractors, the Yucca Mountain Project (YMP) utilizes the services of scientific laboratories, engineering and construction contractors to perform geologic disposal related work. Each of these YMP program participants, including the Project Office direct support contractors, is represented in its interchanges with the YMP Manager by a Technical Project Officer (TPO). For purposes of this program, the TPO is the accountable officer of the organization being represented. These participants describe any major delegation of work involved in establishing and executing their quality assurance programs. These YMP affected organizations supporting the geologic disposal and site investigation activities are described below and in Figure A1-2.

- a. Los Alamos National Laboratory (Los Alamos) (previously LANL)
- b. Lawrence Livermore National Laboratory (LLNL)
- c. United States Geological Survey (USGS)
- d. Sandia National Laboratories (SNL)
- e. Fenix and Scisson of Nevada, Inc. (FSN)
- f. Holmes and Narver, Inc. (H&N)
- g. Reynolds Electrical and Engineering Company (REECo)
- h. SAIC/T&MSS units involved in direct performance of technical work specified by the Project Office.

Each of the above listed affected organizations' prime responsibilities, subject to Project Office management direction and guidance, are summarized herein:

Los Alamos National Laboratory (Los Alamos):

- a. The function of lead technical organization for coordination and scheduling of the exploratory shaft testing program.
- b. Nuclide migration studies.
- c. Geochemistry studies.
- d. Mineralogy and petrology studies.

- e. Design of the integrated data acquisition system for the exploratory shaft facility.

Lawrence Livermore National Laboratory (LLNL):

- a. Definition of the waste package environment.
- b. Waste package material development and testing.
- c. Waste package design, performance analysis, and testing

United States Geological Survey (USGS):

- a. Acting as lead technical participant for site characterization drilling activities.
- b. Site characterization of geology, hydrology, tectonics, volcanism, and seismicity.

Sandia National Laboratories (SNL):

- a. Repository systems development.
- b. Repository conceptual design.
- c. Data management and analysis.
- d. Systems performance assessment of the repository.
- e. Determination of thermal properties of the host rock.
- f. Repository sealing performance requirements, materials evaluation, design, and testing.
- g. Characterization of global climatology and regional climatology.

Fenix & Scisson of Nevada (FSN): Exploratory Shaft Facility (ESF) architect/engineer for drilling and mining for the Project.

- a. Exploratory shaft subsurface design.
- b. Subsurface facilities construction and testing.
- c. Field surveillance and inspection of drilling and mining.

Holmes & Narver, Inc. (H&N): Exploratory Shaft Facility architect/engineer for subsurface support systems and surface facilities.

- a. ESF subsurface support systems design
- b. ESF surface facilities.
- c. Field surveillance and inspection of construction activities.
- d. Material test laboratory support.
- e. Nondestructive examination services.
- f. Field surveying.
- g. Microfilming and archival storage of YMP Project records.

NOTE: As of fiscal year 1991, the Raytheon Company will be assuming the duties of Holmes & Narver, Inc.

Reynolds Electrical and Engineering Company (REECo): Support contractor for the site.

- a. ESF surface and subsurface construction, drilling, and mining.
- b. Operation and maintenance of site facilities, except the YMP Sample Management Facility.
- c. Procurement and logistical services for the Project as requested.

SAIC/T&MSS Primary Participant Role:

- a. Geotechnical services.
- b. Transportation, land access, and socioeconomic studies.
- c. Environmental, meteorological, and radiological monitoring, and field programs.
- d. Performance of peer reviews.
- e. Records management. ✓
- f. Such other field and study programs as directed by the Project Office.

g. Document Control

2.0 AMPLIFICATION OF QAPD SECTION 2 - QUALITY ASSURANCE PROGRAM

The QARD requirements are implemented using a graded approach and are applied to items and activities important to safety and/or waste isolation. Specifically, the quality assurance program applies to the following items and activities:

- a. Structures, systems, and components important to public radiological health and safety.
- b. Engineered items important to waste isolation.
- c. Activities that affect items important to safety or engineered items important to waste isolation.
- d. Activities that could affect natural barriers important to waste isolation or containment.
- e. Collection, reduction, and analysis of data in support of licensing.
- f. Other items or activities that are placed within the scope of the project quality assurance program by project management prerogative.

When terms such as "quality-related activities" or "quality-affecting work" are used, they refer to activities or work directly associated with (a) through (f) above.

Additional guidance related to this subject as prescribed in NUREG-1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements is delineated in Yucca Mountain Project Office Quality Assurance and Administrative Procedures.

3.0 AMPLIFICATIONS OF QAPD SECTION 3 - DESIGN CONTROL

In addition to the description in Section 3, the requirements in this appendix apply to design control

3.1 SCOPE OF PROJECT DESIGN CONTROL

Repository and exploratory shaft design are uniquely affected by considerations of the waste isolation characteristics of natural barriers and ultimately affects those barriers. Therefore, OCRWM has adopted design-related definitions specified by the Nuclear Regulatory Commission (NRC) in the NRC's Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions. The terms Design, Design Information and Design Activities are used in this program description as follows:

3.1.1 Design

Specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system, including design inputs and outputs at each stage of design development, from conceptual to final design.

3.1.2 Design Information and Design Activities

Data collection and analysis activities and computer codes used in supporting design development and verification, including:

- a. General plans and detailed procedures for data collection and analysis.
- b. Related information, such as test results and analyses.

3.1.3 Data Analysis

Data reduction, as well as broad level system analyses, such as performance assessments, which integrate analyses of individual parameters and other relevant data.

3.2 DESIGN INPUTS

Conventional design uses inputs such as applicable codes and standards, tables of material properties, etc. The Project Office requires responsible design organizations to implement procedures for selection and approval of, and changes to, inputs in that category.

3.2.1 Site Characteristics and Test Requirements Inputs

In addition to conventional design inputs, the design basis for site facilities (e.g., the Exploratory Shaft Facility) also includes site characteristics data, as well as requirements arising from site characterization testing and sampling needs. The responsible Project Office-managed scientific organizations have been charged with providing and controlling those categories of inputs.

These participants identify the best available data on relevant characteristics of the site and are required to accomplish the necessary technical and peer reviews to ensure that the data provided actually are the best available.

The responsible architect/engineering organization is then required to review such inputs and to return to the Project Office with any requests for modification.

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Data that will be needed to be qualified to support a license application and that was not collected under the controls of a QA program meeting the QA program requirements of 10 CFR 60 Subpart G or this document shall be qualified in accordance with NUREG 1298, Qualification of Existing Data for High-Level Nuclear Waste Repositories Generic Technical Position, February 27, 1988, prior to use in support of license application activities.

Methods for technical information flow to and from the Project technical data base and the Project Reference Information Base (RIB) are delineated in approved procedures.

3.2.2 Regulatory Requirements Inputs

The Yucca Mountain Project Office is responsible for identifying any unique State and local requirements that will affect design. Those requirements, together with regulatory, consensus standard, DOE, and OCRWM requirements identified at Headquarters, are baselined and maintained in system and subsystem design requirements documents, that require management, technical, and quality assurance review prior to approval.

4.0 AMPLIFICATIONS OF QAPD SECTION 4 - PROCUREMENT DOCUMENT CONTROL

4.1 PROJECT OFFICE RESPONSIBILITIES

The Project Office procurement document package is sent to the respective contracts and procurement division for processing and award in accordance with applicable laws, regulations, and requirements. Subsequent controls for procurements are addressed in Section 7 of this document.

7.0 AMPLIFICATIONS OF QAPD SECTION 7 - CONTROL OF PURCHASED ITEMS, AND SERVICES

7.1 GENERAL

In addition to applying the requirements delineated in Section 7 of this QAPD, the following clarifications are provided for YMP.

7.2 SUPPLIER SELECTION AND EVALUATION

It is recognized that some of the research and analysis required for site characterization requires the services of specialists, or of institutions or agencies whose work does not ordinarily involve formal quality assurance activities. In these instances, selection is based on technical capability, and establishment of quality assurance

7.3 BID EVALUATION

Participants using other participants to perform services or procure items do not evaluate other participants prior to award. A criteria letter is prepared and goes through the YMP to the supplier participant.

For DOE initiated procurements, the bid evaluation process is delegated to the DOE Nevada Operations Office.

7.4 ACCEPTANCE OF SERVICES

Methods for acceptance for DOE initiated procurements are established in the procurement document package.

8.0 AMPLIFICATIONS OF QAPD SECTION 8 - IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS, AND SAMPLES

8.1 SAMPLES

The OCRWM site characterization program requires full sample traceability and accountability. The Sample Management Plan specifies sample-related interfaces among participants and defines the required sample accountability system. Requirements of the plan are implemented through internal procedures of those Project Office-managed participants who will have custody of samples at any point in the life of the sample. Those procedures are required to provide for the following:

- a. Custodial accountability, including auditable records of transfers of accountability between participants, or to or from external parties.
- b. Traceability of samples to applicable documentation, such as the scientific planning document, scientific notebook or technical procedures, drilling logs, photographs (where used), test records, inspection documents, and nonconformance reports, as applicable.
- c. Verification and documentation of correct sample identification prior to the release of samples for use or analysis.
- d. Use of separate, unique identifiers for multiple, discrete samples.
- e. Identification of the individual items or portions resulting from the subdivision that are readily traceable to the original sample in situations involving subdivisions of a sample.

Except when in use for data collection or analysis, or when consumed or destroyed by the analytical process, geotechnical samples are required to be stored in the Sample Management Facility, with archival controls and protection for the period during which additional examination or analysis by OCRWM may be needed. It is recognized that provisions available within existing technology cannot fully prevent natural time-dependent deterioration processes from affecting stored samples.

Changed 12.0
By ICW 3.1

AMPLIFICATIONS OF QAPD SECTION 12 - CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

Changed 12.1
By ICW 3.1

GENERAL

This section applies the requirements necessary to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) used in Project Office activities that affect quality are properly controlled, adjusted, and calibrated at specified periods to maintain accuracy within necessary limits. The appropriate Project Office Division Director(s) are responsible for the implementation of an effective calibration program in accordance with approved procedures.

Changed 12.2
By ICW 3.1

APPLICABILITY AND SCOPE OF THE M&TE CONTROL PROGRAM

Controls noted in this section apply to tools, gages, instruments and other M&TE used primarily in the Sample Management Facility. However, controls of M&TE are also applied to activities used to calibrate, measure, gage, test, or inspect for the purpose of either: (1) controlling or acquiring data to verify conformance to a specified requirement; or (2) establishing characteristics or values not previously known. The methodology for control of M&TE is described in approved procedures.

Changed 12.3
By ICW 3.1

M&TE REQUIREMENTS

12.3.1 Selection

Selection of M&TE is controlled to ensure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Each device has a unique identification number. The type, range, accuracy and tolerance of a measuring device is specified in approved procedures. This number is recorded on the data sheet, log, or equivalent, along with the measurement taken, to ensure traceability of the measurement to the device used to take the measurement.

Changed 12.3.2
By ICW 3.1

12.3.2 Calibration

Measuring and test equipment is calibrated against certified equipment having known valid relationships to the National Institute of Standards and Technology or other nationally recognized standards and is calibrated, adjusted,

and maintained at prescribed intervals. If no nationally recognized standards exist, the acceptability of the calibration standard used is justified. Calibrating standards have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by the responsible Division Director.

Changed by 12.3.3 Control
ICW 3.1

The method and interval of calibration for each M&TE item is defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. M&TE is labeled, tagged, or otherwise documented in a manner that indicates the due date of the next calibration and provide traceability to calibration data. If M&TE is found to be out of calibration, an evaluation is made and documented on the validity of previous results obtained, on acceptability of items previously inspected or tested or on data gathered since the last calibration. Out of calibration devices require the condition be documented in accordance with Section 15 of this QAPD, tagged or segregated, and not used until they have been dispositioned and corrective action has been satisfactorily verified. If any M&TE is found to be consistently out of calibration, it is repaired or replaced. Calibration is performed when the accuracy of equipment is suspect.

Changed 12.3.4 Commercial Devices
By ICW 3.1

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

Changed by 12.3.5 Handling and Storage
ICW 3.1

M&TE is handled properly and stored to maintain accuracy in accordance with requirements specified by either the manufacturer or the respective Project Office Division Director.

Changed by 12.3.6 Records
ICW 3.1

M&TE records are maintained and identify the calibration procedure (including revision) used to perform the calibration. These records are processed in accordance with Section 17 of the QAPD.

Changed by ICN 3.1 13.0 AMPLIFICATIONS OF QAPD SECTION 13 - HANDLING, SHIPPING, AND STORAGE

Changed By ICN 3.1 13.1 GENERAL

This section applies the requirements for controlling the packaging, handling, storage, shipping, cleaning, and preservation of items or samples to prevent damage, loss, or deterioration. Handling, storage, and shipping of items (including packaging, cleaning and preservation), primarily applies to Sample Management Facility activities. However, these requirements also apply to any other quality affecting activities that fall within the scope of this criterion.

Changed By ICN 3.1 13.2 IMPLEMENTING DOCUMENTS

Handling, shipping, and storage activities are conducted in accordance with procedures, specifications, drawings, instructions, or other pertinent documents specified for use.

Changed By ICN 3.1 13.3 REQUIREMENTS

13.3.1 Special Equipment and Protective Environments

When required for particular items or samples, technical documents specify controls for use of special equipment and special environments. These documents also require special equipment and environments to be provided and existence verified.

Changed by ICN 3.1 13.3.2 Specific Procedures

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific procedures for handling, storage, packaging, shipping, and preservation are used. Where appropriate, qualification of special lifting equipment, slings, and hoists is explicitly addressed.

Changed by ICN 3.1 13.3.3 Inspection and Testing of Special Tools and Equipment

When used, special handling tools and equipment are controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals, to verify that the tools and equipment are adequately maintained.

Changed By ICN 3.1 13.3.4 Operators of Special Equipment

Operators of special handling and lifting equipment are experienced or trained to use the equipment; related training activities are conducted and documented in accordance with procedures.

Changed 13.3.5 Procedures

*By
ICW* 3.1

Procedures used for marking, labeling, packaging, shipping, handling, and storage of items or samples include provisions addressing adequate identification, maintenance, and preservation of the items, including indication of the need for special environments or the need for special controls.

20.0 SCIENTIFIC INVESTIGATION CONTROL

20.1 GENERAL

Sufficient differences exist between the objectives, methodology and controls for design, and the studies and investigations for site characterization that this separate Section 20 has been developed to address scientific investigation separately from design.

20.2 SCIENTIFIC INVESTIGATION MANAGEMENT

The YMP Manager has the management responsibility for direction, guidance and review of scientific investigations in accordance with approved procedures. The responsibility for performing scientific investigations has been delegated to affected organizations.

20.3 SCIENTIFIC INVESTIGATION PLANNING CONTROL

YMP provides direction to affected organizations to develop a scientific investigation planning document prior to initiating the scientific investigation. Site characterization activities as defined in the Nuclear Waste Policy Act (as amended) utilize study plans as the scientific investigation planning document.

20.4 PLANNING DOCUMENT REVIEW AND APPROVAL PROCESS

The planning activity is designed to ensure compatibility of scientific investigation with conceptual or mathematical models used and the validity and representativeness of collected data. Where new or modified data collection or analysis methods are to be used in lieu of methods previously established and generally accepted within the scientific community, the modification or new methods will be subjected to technical and/or peer review by the YMP prior to being used in the scientific investigation.

The individual(s) assigned the responsibility for review of the planning document ensures the technical adequacy of the document by technical and/or peer review. The results of the technical and/or peer review and the resolutions of comments are to be retained as quality assurance records.

20.4.1 Technical Review

Technical reviews are performed when:

- a. The information or document under review is within the state-of-the-art and is based on accepted standards, criteria, principals and practices.
- b. Documents, activities, material, or data require technical verification or validation for applicability, correctness, adequacy, completeness and assurance that established requirements are satisfied.

The YMP requires that when technical reviews are required the initiator provide specific review criteria. The YMP also requires that technical reviews be performed by reviewers with sufficient technical knowledge of the subject matter to be able render an informed technical opinion and who did not direct or perform the work being reviewed.

20.4.2 Peer Review

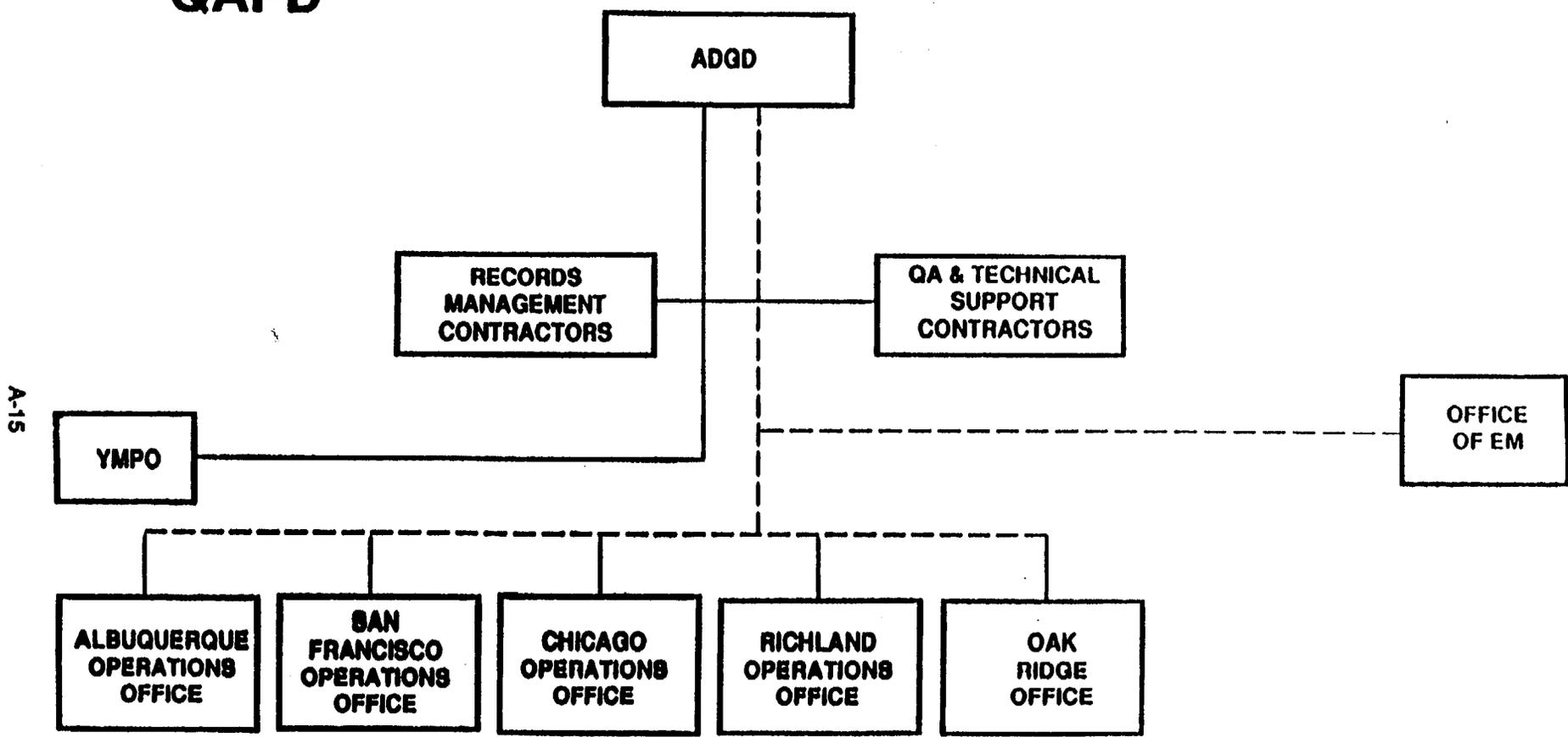
Peer reviews are required when adequacy of the information (e.g., data, interpretations, test results, design assumptions, etc.) or suitability of essential procedures and methods cannot be confirmed by testing, alternate calculations, or reference to previously established standards and practices.

The YMP establishes and implements, when appropriate, procedures that comply with the peer review requirements specified in NUREG 1297, Peer Review for High-Level Nuclear Waste Repositories.

Documents generated during the peer review process are quality assurance records.

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By
ICN 3.1

QAPD

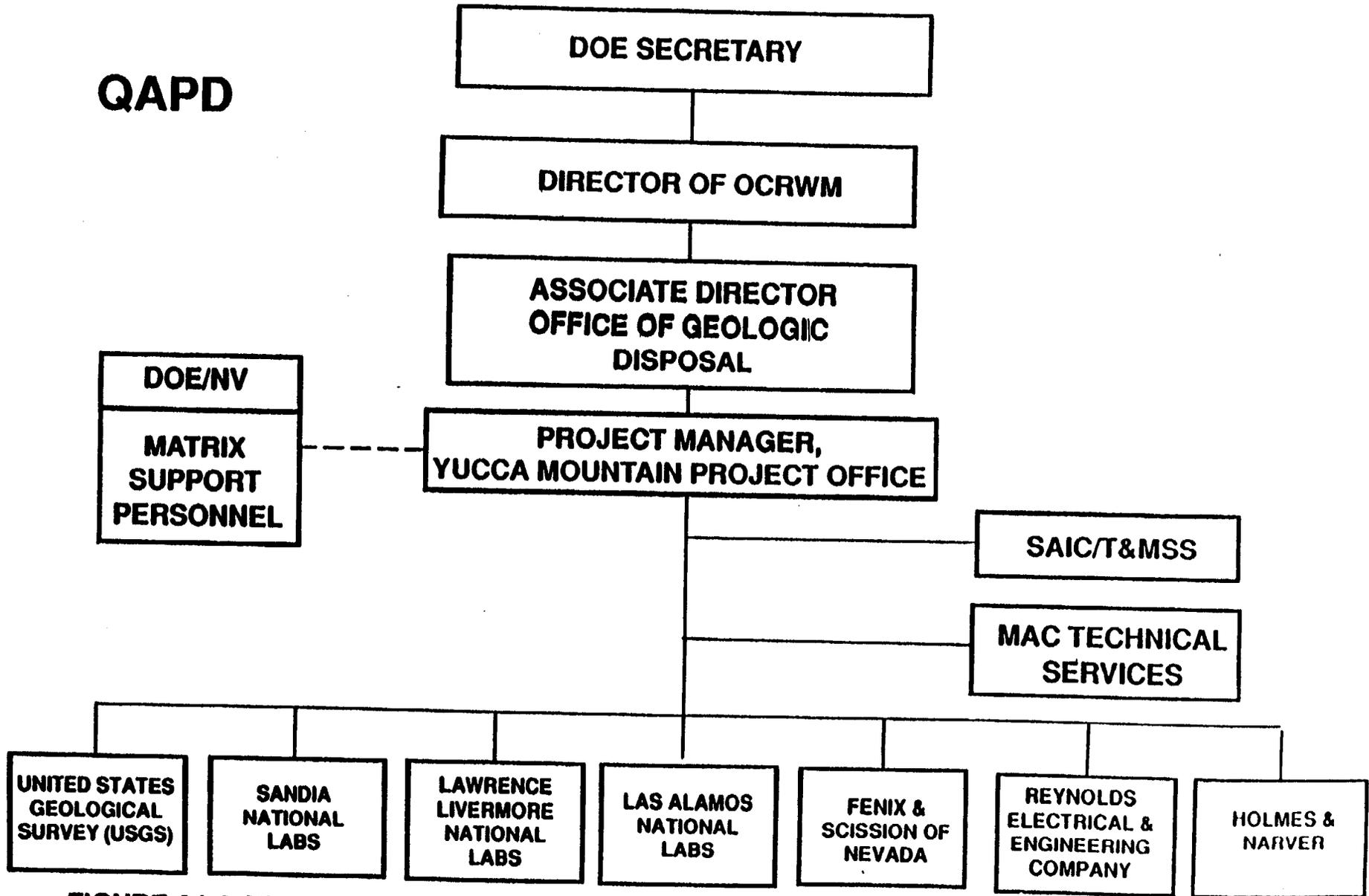


A-15

FIGURE A1-1. OCRWM GEOLOGIC DISPOSAL AFFECTED ORGANIZATIONS

YUCCA MOUNTAIN PROJECT ORGANIZATION

QAPD



A-16

QAPD
September 17, 1990
Revision 3

FIGURE A1-2. YUCCA MOUNTAIN PROJECT GEOLOGIC DISPOSAL AFFECTED ORGANIZATIONS

APPENDIX B

AMPLIFICATIONS TO THE QAPD FOR TRANSPORTATION

GENERAL

The purpose of this appendix is to amplify the QAPD for Transportation activities. OCRWM performs activities related to transportation in accordance with sections 1 through 19 of the QAPD. Specific amplifications to those requirements are provided below, as related to major numbered QAPD sections. Where a QAPD section requires no amplification, the section reference is omitted from this appendix.

Changed
By
ICW 3.1

1.0 AMPLIFICATION OF QAPD SECTION 1 - ORGANIZATION

This section describes the affected organization activities related to Transportation activities. Figure B1-1 depicts the transportation organizations.

Activities related to transportation which are performed by affected organizations include:

- a. Transportation-operations planning, shielding, and systems integration support and performing safeguards activities.
- b. Institutional planning and analysis, and management integration.
- c. Cask development.
- d. Providing records management and related activities.

The Yucca Mountain Project Office reports to and performs its transportation related activities under the direction of the Office of Geologic Disposal (OGD), coordinated with the Office of Storage and Transportation (OST), while interfacing with the Office of Systems Compliance (OSC).

Yucca Mountain Project (YMP) Office

Each YMP-managed affected organization, except YMP, is represented in its interchanges with the YMP Manager by a Technical Project Officer (TPO). For purposes of this Program, each TPO is the accountable officer of the organization being represented.

YMP direct support contractors perform activities affecting quality under controls of the OCRWM quality assurance program. YMP direct support contractor activities include, program management, technical, scientific, and quality assurance support.

YMP-Managed Participants

YMP-managed work is accomplished by scientific laboratories, engineering and construction laboratories, and engineering and construction contractors reporting to the YMP. These participants describe any major delegation of work involved in establishing and executing their quality assurance programs. Responsibilities assigned to participant organizations include:

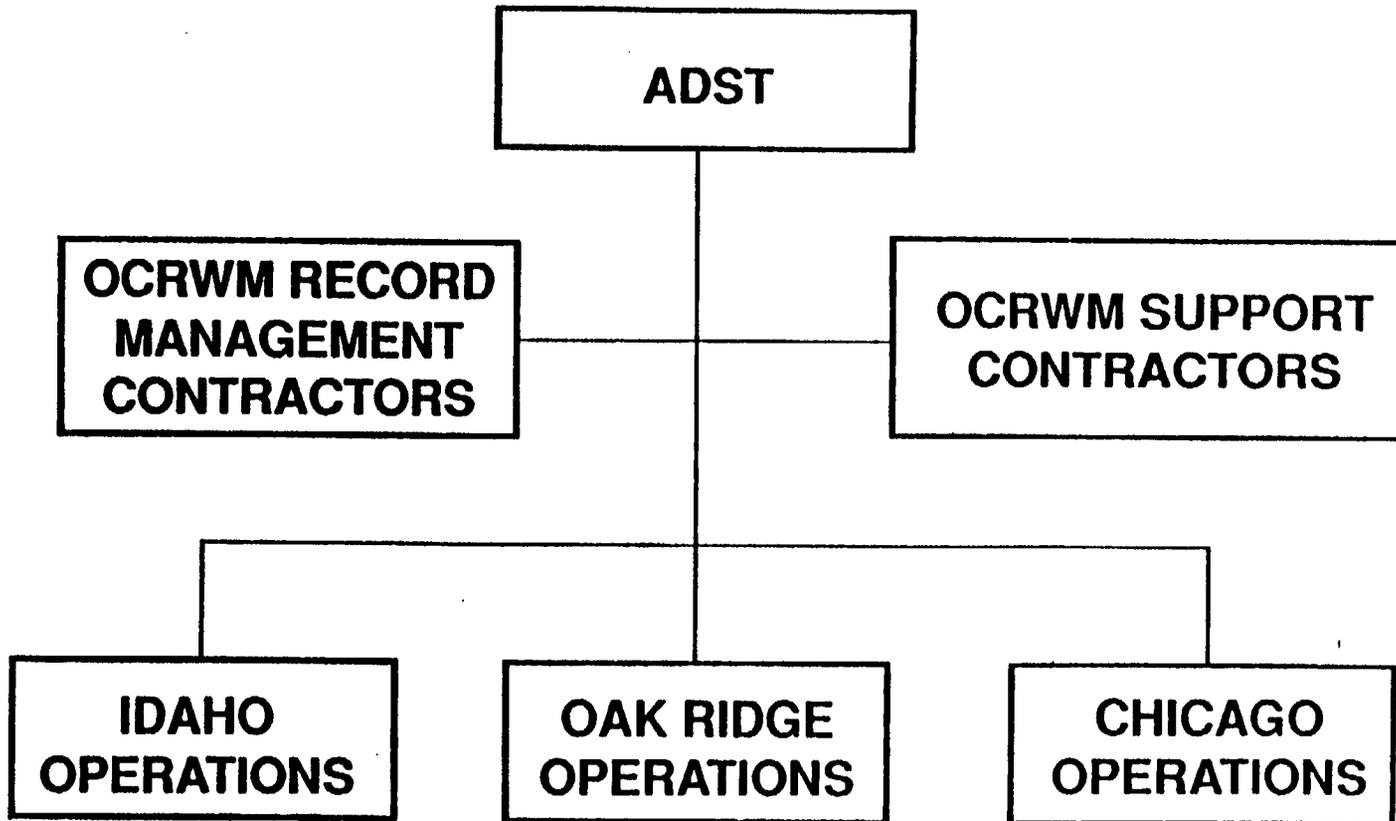
- a. Transportation, land access, and socioeconomic studies.
- b. Microfilming and archival storage of YMP records.
- c. Procurement and logistical services.

YMP-Managed Participant Quality Assurance Responsibilities

Each YMP-managed participant implements the following quality assurance functions as delineated in the QARD:

- a. Establishing and implementing an effective internal quality assurance program.
- b. Approving the quality assurance programs of organizations performing Program-related activities under contract to the participant.
- c. Verifying effective implementation of the participant's internal quality assurance program and of the quality assurance programs of organizations or individuals doing Program-related work under contract to, or by agreement with, the participant.

QAPD



B-3

FIGURE B1-1. OCRWM TRANSPORTATION PROGRAM ELEMENT

APPENDIX C

AMPLIFICATIONS TO THE QAPD FOR THE MONITORED RETRIEVABLE STORAGE FACILITY

GENERAL

The purpose of this appendix will be to amplify the Quality Assurance Program Description for the Monitored Retrievable Storage (MRS) Facility activities. The planned MRS organization is depicted in Figure C1-1.

QAPD

C-2

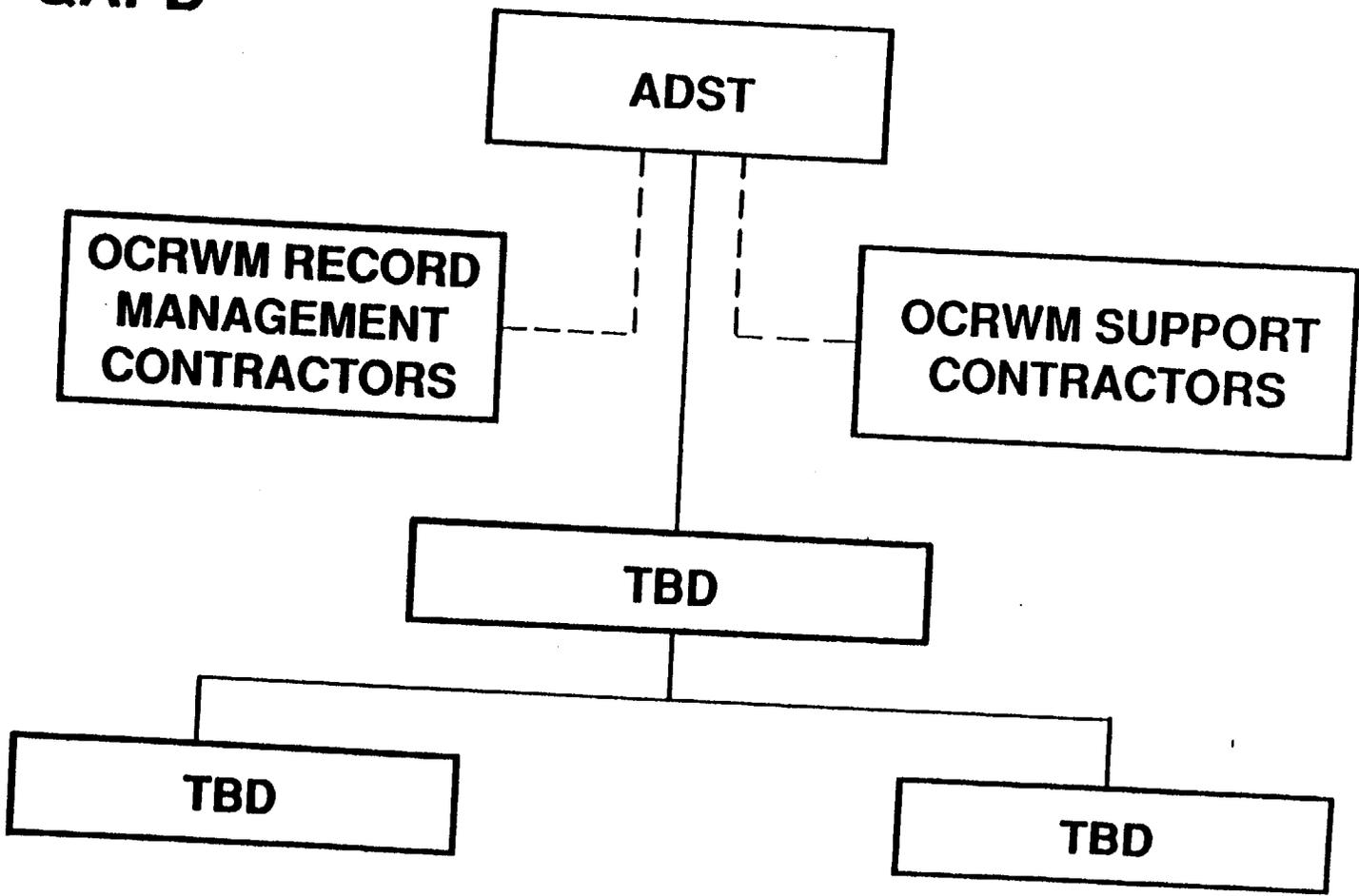


FIGURE C1-1. OCRWM MRS PROGRAM PARTICIPANTS

QUALITY ASSURANCE PROGRAM DESCRIPTION DOCUMENT
(QAPD)

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		4	1	05/17/91 ^{10/15/91}	134
RELEASE OF UNPUBLISHED INFORMATION	AP-1.6Q	0	0	06/17/88	134
WASTE MANAGEMENT PROJECT OFFICE (WMPO) ACTION ITEM TRACKING SYSTEM	AP-1.9	0	0	11/24/87	134
PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS	AP-1.10Q	4	0	07/05/91	134
DISPOSITION OF COMMENTS ON THE SITE CHARACTERIZATION PROGRAM	AP-1.14	1	0	09/18/91	134
LITIGATION DISCOVERY OF YUCCA MOUNTAIN PROJECT RECORDS	AP-1.16	0	0	08/01/89	134
		0	1	05/18/90	134
FORMS CONTROL	AP-1.17Q	1	0	02/12/91	134
		1	1	07/05/91	134
REPORTING OF UNUSUAL OCCURRENCES	AP-2.9	0	0	12/26/90	134
PROJECT COST, SCHEDULE, AND VARIANCE REPORTING	AP-2.10	1	0	12/26/90	134
		1	1	09/27/91	134
CHANGE CONTROL PROCESS	AP-3.3Q	4	0	07/15/91	134
FIELD CHANGE CONTROL PROCESS	AP-3.5Q	0	0	10/17/90	134
CONFIGURATION MANAGEMENT	AP-3.6Q	0	0	01/17/89	134
		0	1	04/24/91	134
COST AND SCHEDULE BASELINE MAINTENANCE AND CHANGE CONTROL	AP-3.7	2	0	07/30/91	134

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CONFIGURATION REVIEWS	AP-3.8	0	0	10/17/90	134
PROCUREMENT	AP-4.1Q	0	0	06/30/89	134
		0	1	10/15/90	134
		0	2	08/03/90	134
		0	3	05/01/91	134
CAPITAL EQUIPMENT PLANNING AND AUTHORIZATION	AP-4.3	0	0	10/19/90	134
CONTROL AND TRANSFER OF TECHNICAL DATA ON THE YUCCA MOUNTAIN PROJECT	AP-5.1Q	2 1	0	08/03/90 10/21/91	134 <i>REP 10/15/91</i>
TECHNICAL INFORMATION FLOW TO AND FROM THE YUCCA MOUNTAIN PROJECT	AP-5.2Q	2 1	0	08/03/90 10/21/91	134 <i>REP 10/15/91</i>
TECHNICAL DATA BASE					
INFORMATION FLOW INTO THE PROJECT REFERENCE INFORMATION BASE	AP-5.3Q	1	0	08/03/90	134
QUALIFICATION OF DATA OR DATA ANALYSES NOT DEVELOPED UNDER THE YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE PLAN	AP-5.9Q	1	0	07/05/90	134
		1	1	05/03/91	134
READINESS REVIEW	AP-5.13Q	2	0	10/26/90	134
FIELD TECHNICAL COMPLIANCE	AP-5.16Q	0	0	02/01/91	134
INTERFACE CONTROL	AP-5.19Q	2	0	09/27/91	134
		1	0	10/19/90	134
HOLD CONTROL	AP-5.20Q	0	0	05/23/89	134
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FIELD WORK ACTIVATION	AP-5.21Q	3	0	08/19/91	134

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PREPARATION AND SUBMITTAL OF AS-BUILT DRAWINGS AND SPECIFICATIONS	AP-5.24Q	0	0	02/13/91	134
SUBMITTALS CONTROL AND REVIEW	AP-5.26	0	0	01/11/91	134
CONTROL OF NONCONFORMING ITEMS	AP-5.27Q	0	0	09/05/90	134
		0	1	10/20/90	134
QUALITY ASSURANCE GRADING	AP-5.28Q	2	0	11/09/90	134
		2	1	09/27/91	134
INFORMATION RESOURCES PLANNING AND ADMINISTRATION	AP-5.31	0	0	10/13/90	134
TEST PLANNING AND IMPLEMENTATION REQUIREMENTS	AP-5.32Q	1	0	02/01/91	134
		1	1	09/06/91	134
		1	2	09/27/91	134
IMPLEMENTATION AND CONTROL OF THE PROJECT WORK BREAKDOWN STRUCTURE AND THE RESPONSIBILITY ASSIGNMENT MATRIX	AP-5.35	1	0	12/26/90	134
		1	1	06/05/91	134
		1	2	06/24/91	134
PROJECT PLANNING, BUDGETING, SCHEDULING AND WORK AUTHORIZATION SYSTEM	AP-5.36	0	0	11/05/90	134
		0	1	06/24/91	134
JOB PACKAGE ENGINEERING COST ESTIMATES	AP-5.37	0	0	02/01/91	134
PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL, AND REVISION CONTROL	AP-6.1Q	3	0	02/20/91	134
MANAGEMENT AND OPERATION OF SAMPLE HANDLING ACTIVITIES AT BOREHOLE SITES	AP-6.2Q	0	0	06/21/89	134
INTERACTION OF PARTICIPANTS AND OUTSIDE INTERESTS WITH YUCCA MOUNTAIN PROJECT SAMPLE MANAGEMENT	AP-6.3Q	0	0	06/21/89	134

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PROCEDURE FOR THE SUBMITTAL, REVIEW, AND APPROVAL OF REQUESTS FOR YUCCA MOUNTAIN PROJECT GEOLOGIC SPECIMENS	AP-6.4Q	0	0	07/28/89	134
		0	1	04/24/90	134
		0	2	10/17/90	134
FIELD COLLECTION, DOCUMENTATION, AND SPECIMEN REMOVAL OF EXPLORATORY SHAFT AND DRIFT ROCK	AP-6.6Q	0	0	06/21/89	134
		0	1	04/24/90	134
SAFETY AND HEALTH RECORDKEEPING AND REPORTING REQUIREMENTS	AP-6.12	0	0	02/01/91	134
ADMINISTRATIVE PROCEDURE: AUTHORIZATION FOR USE OF REGULATED HAZARDOUS SUBSTANCES AND MATERIALS	AP-6.13	0	0	10/19/90	134
REPORTABLE GEOLOGIC CONDITIONS	AP-6.14	0	0	02/01/91	134
DETERMINATION OF THE IMPORTANCE OF ITEMS AND ACTIVITIES	AP-6.17Q	0	0	03/19/90	134
		0	1	05/07/90	134
		0	2	08/23/90	134
RESOLUTIONS OF ENVIRONMENT, SAFETY AND HEALTH CONCERNS	AP-6.18	1	0	08/06/91	134
FIELD OPERATING INSTRUCTIONS DIRECTIVES SYSTEM	AP-6.19	0	0	01/11/91	134
ADMINISTRATIVE PROCEDURE: YUCCA MOUNTAIN PROJECT INTERACTIONS WITH THE U.S. NUCLEAR REGULATORY COMMISSION	AP-7.1	0	0	11/13/90	134
ADMINISTRATIVE PROCEDURE: PROCESS FOR REQUESTING EXEMPTIONS FROM DOE ORDERS	AP-7.2	0	0	11/13/90	134
NNWSI PROJECT PARTICIPANT AND PUBLIC INTERACTION	AP-9.1	0	0	01/15/85	134
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		2	1	05/24/91	181
STOP WORK	QMP-01-02	1	0	10/09/90	181
PROJECT OFFICE INDOCTRINATION AND QUALIFICATION TRAINING	QMP-02-01	4	0	10/15/91	181
QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL	QMP-02-02	3	0	05/31/91	181
TECHNICAL ASSESSMENT REVIEW	QMP-02-08	0	0	08/08/88	181
		0	1	02/07/89	181
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PEER REVIEWS	QMP-03-01	1	0	01/11/89	181
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PROJECT CHANGE CONTROL BOARD PROCESS	QMP-03-09	3	0	07/15/91	181
		3	1	09/16/91	181
QUALITY MANAGEMENT PROCEDURE:YUCCA MOUNTAIN PROJECT OFFICE PROCUREMENT ACTIONS	QMP-04-02	0	0	10/19/90	181

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PROJECT OFFICE DOCUMENT DEVELOPMENT, REVIEW, APPROVAL AND REVISION PROCESS	QMP-06-04	3	0	05/29/91	181
		3	1	06/03/91	181
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SUPPLIER EVALUATION/QUALIFIED SUPPLIERS LIST	QMP-07-04	1	0	10/19/90	181
		1	1	10/24/90	181
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STANDARD DEFICIENCY REPORTING SYSTEM	QMP-16-03	1	0	06/05/89	181
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		1	2	10/15/90	181
RECORDS MANAGEMENT: RECORD SOURCE IMPLEMENTATION	QMP-17-01	3	0	04/10/91	181
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SURVEILLANCES	QMP-18-02	2	0	09/27/90	181
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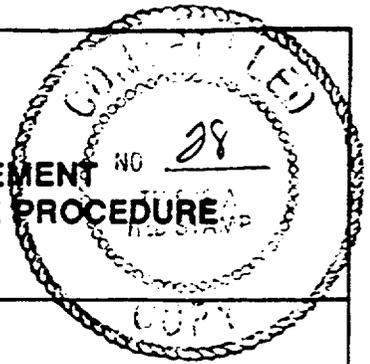
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YUCCA MOUNTAIN PROJECT OFFICE BRANCH TECHNICAL PROCEDURES FOR THE ENGINEERING & DEVELOPMENT DIVISION	BTP-EDD-002	1	0	06/24/91	43
QUALITY REVIEW BOARD	BTP-QRB-001	1	0	10/26/90	37
EVALUATION OF ONGOING ACTIVITIES	BTP-RSE-001	0	0	02/01/91	38
BRANCH TECHNICAL PROCEDURE: SAMPLE MANAGEMENT FOR THE YUCCA MOUNTAIN PROJECT OFFICE	BTP-SMF-001	1	0	10/26/90	30
BRANCH TECHNICAL PROCEDURE: TRANSPORT, RECEIPT AND ADMITTANCE FOR CURATION TO THE SMF OF BOREHOLE SAMPLES	BTP-SMF-002	2	0	08/19/91	30
BRANCH TECHNICAL PROCEDURE: EXAMINATION OF SAMPLES BY PARTICIPANTS AT THE SMF	BTP-SMF-005	2	0	06/18/91	30
BRANCH TECHNICAL PROCEDURE: REMOVAL OF WHOLE AND OTHER SPECIMENS FROM SAMPLES BY THE SMF FOR SHIPMENT, AND REMNANT RETURN	BTP-SMF-006	2	0	03/14/91	30
BRANCH TECHNICAL PROCEDURE: ACCEPTANCE FOR CURATION BY THE SMF OF SELECTED SAMPLES AND DOCUMENTATION	BTP-SMF-007	0	0	07/07/89	30
		0	2	07/01/91	30
BRANCH TECHNICAL PROCEDURE: FIELD LOGGING, HANDLING, AND DOCUMENTING BOREHOLE SAMPLES	BTP-SMF-008	2	0	07/15/91	30
BRANCH TECHNICAL PROCEDURE: GAMMA-RAY LOGGING OF YUCCA MOUNTAIN PROJECT CORE	BTP-SMF-010	0	0	03/14/91	18
STAGING, PACKAGING, DOCUMENTING NEUTRON-ACCESS BOREHOLE SAMPLES	BTP-SMF-013	0	0	09/20/91	30
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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE**



Title: **AUDIT PROGRAM**

Procedure No.:
QAAP 18.2

Revision: 4

Date: 10/11/91

Page 1 of 14

Concurrence *[Signature]* Date: 9/30/91

Approval *[Signature]* Date: 9/30/91

1.0 PURPOSE

This procedure establishes the responsibilities and methods for planning, conducting, and documenting quality assurance (QA) audits.

2.0 SCOPE

This procedure applies to internal and external QA audits conducted by or for the Office of Civilian Radioactive Waste Management (OCRWM).

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 *Quality Assurance Requirements Document (QARD), DOE/RW-0214*
- 3.1.2 *Quality Assurance Program Description Document (QAPD), DOE/RW-0215*

3.2 DEFINITIONS

- 3.2.1 Audit Team Leader (ATL) - A Lead Auditor who is designated to direct the activities of an audit team.
- 3.2.2 External Audit - An OCRWM audit of another affected organization or supplier to determine the status, adequacy, compliance to and effectiveness of the audited organization's QA program.
- 3.2.3 Internal Audit - An audit conducted by or for the OCRWM QA organization to determine the status, adequacy, compliance to, or effectiveness of the OCRWM QA program.
- 3.2.4 Lead Auditor - An individual who is certified to organize, perform, and direct a QA audit; report observed conditions adverse to quality; and evaluate related corrective actions.



3.2.5 The definitions of other quality assurance related terms are found in the Glossary contained in Reference 3.1.1.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

The Associate and Office Directors, OCRWM are responsible for providing staff to participate as technical specialists in selected audits.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for the development, implementation, and maintenance of the QA audit program including:

- 4.2.1 Preparing and maintaining this procedure;
- 4.2.2 Scheduling of audits;
- 4.2.3 Approving audit plans and issuing notification letters;
- 4.2.4 Appointing Audit Team Leaders;
- 4.2.5 Ensuring that Audit Team Leaders are properly certified; and
- 4.2.6 Approving and issuing audit reports.

4.3 AUDIT TEAM LEADER (ATL)

The ATL is responsible for:

- 4.3.1 Planning and preparing for the audit activities;
- 4.3.2 Identifying the audit team;
- 4.3.3 Developing the audit plan and audit notification letter;
- 4.3.4 Signing the audit plan;
- 4.3.5 Ensuring that the audit team is properly oriented, trained, and qualified;
- 4.3.6 Ensuring that audit team members are independent of direct responsibility for the activities that they audit;
- 4.3.7 Coordinating audit planning sessions, itineraries, and logistics;
- 4.3.8 Directing the performance of the audit;



- 4.3.9 Notifying auditees of problems requiring immediate attention;
- 4.3.10 Coordinating the preparation and issuance of the audit report;
- 4.3.11 Coordinating the preparation and issuance of Corrective Action Requests (CARs) for conditions adverse to quality identified during an audit;
- 4.3.12 Signing the audit report; and
- 4.3.13 Ensuring that audit record packages are prepared and submitted to the appropriate records center.

4.4 AUDIT TEAM MEMBERS

Audit team members are responsible for:

- 4.4.1 Preparing audit checklists or marked-up procedures as assigned;
- 4.4.2 Attending meetings scheduled by the audit team leader;
- 4.4.3 Conducting portions of the audit as assigned;
- 4.4.4 Completing assigned portions of the audit checklist or marked-up procedures;
- 4.4.5 Preparing drafts of CARs; and
- 4.4.6 Writing portions of the audit report.

5.0 GENERAL

- 5.1 A system of planned and scheduled audits are conducted to verify compliance with all aspects of the OCRWM QA program and to determine the effectiveness of the QA program.
- 5.2 Audits shall be scheduled to provide coverage and coordination with ongoing QA program requirements and at a frequency commensurate with the status and importance of the activity. Audits shall be initiated as early in the life of the activity as practical to ensure effective controls are implemented and shall be conducted at intervals consistent with the schedule for completing the specific activity. Audits of the QA program are conducted, as a minimum, once each year or at the least once during the life of an activity affecting quality, whichever is shorter.

The audit schedule shall identify the following, as a minimum:

- a) Organizations to be audited;
- b) Audit number;



- c) Location and date;
- d) ATL (tentative); and
- e) QA program elements to be audited.

6.0 PROCEDURES

6.1 SCHEDULING

- 6.1.1 The Director, OQA shall develop an audit schedule in accordance with Subsection 5.2 that identifies internal and external audits planned for the fiscal year.
- 6.1.2 The Director, OQA shall review the audit schedule at least quarterly and revise as necessary to assure adequate coverage. The transmittal of updated schedules shall identify major changes in the previously scheduled audits with appropriate justification.
- 6.1.3 Following Director, OQA approval, the audit schedule and updates shall be transmitted to the Associate and Office Directors, Participant Technical Project Officers and Quality Assurance Managers.
- 6.1.4 Regularly scheduled audits may be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

6.2 AUDIT TEAM SELECTION

- 6.2.1 The Director, OQA shall appoint an ATL for each audit and shall verify that the ATL is certified as a Lead Auditor in accordance with QAAP 18.1, *Qualification of Audit Personnel*.
- 6.2.2 The ATL shall identify the scope of the audit for inclusion in the audit plan. The scope of an audit may include evaluation of product quality and technical adequacy of work being done or completed, as appropriate, as well as programmatic compliance and implementation effectiveness. Technical requirements may be selected for audit evaluation from the governing technical requirements documents and be included in audit checklists or marked-up procedures prepared by the technical specialists.
- 6.2.3 A visit to the site of the planned audit and meetings with the organization to be audited may be considered to further define the scope and conduct of the audit.



6.2.4 The ATL shall request that Associate and Office Directors assign individuals having technical expertise to participate as technical specialists. The ATL shall select additional audit team members as needed. Prior to the audit, the qualification records of each audit team member shall be reviewed by the ATL or a DOE QA staff member to verify that the individual is qualified to conduct audits in accordance with QAAP 18.1.

6.2.5 The ATL shall ensure that audit team members are independent of direct responsibility for the activities that they audit.

6.3 PREPARATION

6.3.1 The ATL shall develop an audit plan using the format shown in Attachment I, "Audit Plan Format and Content."

6.3.2 The ATL shall sign and date the audit plan signifying that the audit team is qualified and the plan reflects the required information.

6.3.3 The ATL shall prepare an audit notification letter and forward it with the audit plan to the Director, OQA.

6.3.4 The Director, OQA shall approve and issue the audit plan and notification letter to the appropriate organization.

6.3.5 The ATL shall ensure that the audit team is prepared for the audit. Preparation shall include the following:

- a) Studying procedures that apply to the activities being audited;
- b) Evaluating previous surveillance and audit results;
- c) Evaluating relevant corrective action history;
- d) Reviewing current status of the work; and
- e) Reviewing trend data.

6.3.6 The audit team shall develop a checklist using Attachment II, "Quality Assurance Checklist" or marked-up procedures to guide their audit activities and to ensure coverage of all elements of the audit plan. Checklist questions shall be based on a review of requirements, procedures, previous audit and surveillance reports, technical documents, and other related activity reports, as applicable.



6.3.7 The ATL shall conduct a preaudit meeting with the audit team and appropriate management and staff members of the audited organization to review the audit scope, determine the status of activities to be audited, and meet counterparts. Attendance shall be documented using Attachment III, "Attendance Record."

6.4 PERFORMANCE

6.4.1 During the audit, the audit team shall:

- a) Perform reviews of documents and records to assess their adequacy and acceptability;
- b) Conduct activities in the audit checklist or marked-up procedures under the direction of the ATL;
- c) Examine objective evidence to the depth necessary to determine if the elements are being implemented effectively;
- d) Maintain a list of personnel contacted;
- e) Complete the checklist or marked-up procedures;
- f) Notify the ATL of any identified condition adverse to quality that may warrant the issuance of a CAR; and
- g) Notify the audited organization of any items identified as nonconforming.

6.4.2 The ATL shall conduct daily team meetings during the conduct of the audit to discuss conditions adverse to quality that were found during the audit. The audited organization shall be notified immediately of conditions requiring prompt corrective action.

6.4.3 The ATL shall conduct daily meetings with management of the audited organization to report the progress and status of the audit and to ensure that appropriate individuals continue to be involved in the audit.

6.4.4 The audit team shall draft CARs to document activity related conditions adverse to quality and ensure that any nonconforming items are documented as such on the audited organization's nonconformance reports. Adequacy and effectiveness statements (including technical aspects, as appropriate) shall be prepared by audit team members for the activities that they audited.

6.4.5 Prior to the postaudit meeting, or as deemed appropriate by the ATL, team members shall submit draft CARs, completed checklists, marked-up procedures, and adequacy and effectiveness statements to the ATL.



6.5 POSTAUDIT

- 6.5.1 The ATL shall conduct a postaudit meeting with the audit team and appropriate management and staff members of the audited organization to present the results of the audit. Attendance shall be documented using Attachment III.
- 6.5.2 The ATL shall process CARs in accordance with QAAP 16.1, Corrective Action.

6.6 AUDIT REPORT

- 6.6.1 The ATL shall coordinate the preparation of the audit report using the format shown in Attachment IV, "Audit Report Format and Content."
- 6.6.2 The ATL shall ensure that all relevant information from the checklist or marked-up procedures used by the audit team has been addressed in the audit report or associated CARs.
- 6.6.3 The ATL shall prepare the audit report transmittal letter.
- 6.6.4 The ATL shall sign the audit report and forward it with the transmittal letter to the Director, OQA.
- 6.6.5 The audit report and transmittal letter shall be approved by the Director, OQA and distributed to the audited organization. Copies of the audit report shall also be distributed to other affected organizations. The audit is considered closed upon issuance of the audit report.
- 6.6.6 The ATL shall assemble the completed audit record package and submit the package to the appropriate records center in accordance with Section 7.0.

7.0 RECORDS

The audit plan, notification letter, audit report, and audit schedules generated as a result of this procedure are considered QA Records and shall be collected and maintained in accordance with requirements specified in QAAP 17.1, *QA Records Management* or QMP-17-01, *Records Management: Record Source Implementation*.

Note: CAR record packages shall be maintained as QA records separately from the audit record package.



8.0 ATTACHMENTS

- 8.1 Attachment I - Audit Plan Format and Content
- 8.2 Attachment II - Quality Assurance Checklist
- 8.3 Attachment III - Attendance Record
- 8.4 Attachment IV - Audit Report Format and Content
- 8.5 Attachment V - QAAP 18.2 Flowchart



**ATTACHMENT I (Example)
AUDIT PLAN FORMAT AND CONTENT**

Audit Number: _____

Organization: _____

Location of Audit: _____

Dates of Audit: _____

Audit Team Members: _____

AUDIT SCOPE

Activities/Contracts/Tasks to be Audited: _____

Requirements/Criteria to be Audited: _____

Governing Documents: _____

PRELIMINARY AUDIT SCHEDULE

Preaudit Meeting: _____

Conduct of Audit: _____

Daily Team Debriefing Time and Location: _____

Postaudit Meeting Date, Time and Location: _____

Prepared by: _____ Date: _____

ATL

Approved by: _____ Date: _____

Director, OQA



ATTACHMENT II (Example)
QUALITY ASSURANCE CHECKLIST

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		PAGE _____ OF _____ AUDIT/SURVEILLANCE NO. _____	
		QUALITY ASSURANCE CHECKLIST	
ORGANIZATION EVALUATED	<input type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY _____ DATE _____
DATES OF EVALUATION	ACTIVITY EVALUATED		
CONTROLLING DOCUMENT (Title, Number, Revision)			
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)			

REV 0001



ATTACHMENT II (continued)
QUALITY ASSURANCE CHECKLIST

<p>OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.</p> <p>PAGE _____ OF _____ ADMINISTRATIVE PROCEDURE NO. _____</p> <p>QUALITY ASSURANCE CHECKLIST (continuation sheet)</p>	<p>CHARACTERISTIC TO BE EVALUATED</p>	<p>REMARKS Record objective evidence reviewed, method of verification, personnel contacted</p>	<p>RESULTS</p>

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ATTACHMENT IV (Example)
AUDIT REPORT FORMAT AND CONTENT

COVER SHEET

Identify audit number, primary activities evaluated, organization evaluated, and location and dates of the audit. The cover sheet should also bear the dated preparer and approval signatures of the ATL and the Director, OQA.

MAIN BODY

SECTION 1.0 EXECUTIVE SUMMARY

Describe the results of the audit in brief, concise statements addressing any corrective action required.

SECTION 2.0 SCOPE

Repeat the scope as stated in the audit plan. Identify any additions or deletions to the audit scope that occurred during the course of the audit.

SECTION 3.0 AUDIT TEAM

List the name and assigned area of responsibility of each audit team member.

SECTION 4.0 PERSONNEL CONTACTED

Identify personnel attending the preaudit and postaudit meetings and contacted during the audit. Refer to attached Attendance Records, as applicable.

SECTION 5.0 AUDIT RESULTS

Briefly discuss and reference any Corrective Action Requests, and summarize any immediate corrective actions taken. Provide the detailed description of the items and activities examined during the audit, including all relevant information from the checklist or marked-up procedures. Include a statement as to the adequacy and effectiveness of the quality assurance program elements audited.

SECTION 6.0 RECOMMENDATIONS

Identify any recommendations the audit team considers appropriate to the audit.

QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

10.2, REV. 4

The following number is for OCRWM records management purposes only and should not be used when ordering this publication.

Accession No.: HQ0.911001.0002

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

REVISION RECORD

TITLE: Audit Program	PROCEDURE NO. 18.2	REV. NO. (current) 3
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DESCRIPTION OF PROPOSED REVISION AND RATIONALE:

Revise QAAP 18.2, Revision 3 per attached draft 4A to incorporate the following changes:

1. Resolved Corrective Action Request (CAR) HQ-91-023 to eliminate conflicting requirements regarding the CAR disposition process.
2. Deleted requirement for the Audit Team Leader (ATL) to approve the audit checklist.
3. Clarified the use of marked-up procedures during an audit in lieu of a checklist.
4. Audit schedules are now revised as changes occur versus quarterly.
5. Reference to QAAP 2.9, *Quality Assurance Program Status and Trend Reporting*, has been deleted.
6. Attendance sheets are no longer considered to be QA records.
7. Information copies of the CARs and NCRs are no longer issued as an attachment to the audit report.
8. Responsibility for preparation of the audit record package has been assigned to the ATL versus the Director, OQA.
9. Included requirement for the ATL to conduct a preaudit meeting with appropriate management and staff of the audited organization.

PREPARER OF PROPOSED REVISION Richard A. Kettell DATE 06/12/91

TYPE OF REVISION (Check One): MAJOR MINOR
 SIGNATURE TO AUTHORIZE REVISION [Signature] DATE 6/20/91
N Responsible Associate or Office Director

TYPE OF REVISION (Check One): MAJOR MINOR
 CONCURRENCE SIGNATURE [Signature] DATE 6/20/91
N Director, OQA

RECOMMENDED TRAINING: READ CLASSROOM OTHER
 Classroom training for Audit personnel who have not received training to current revision. Reading for Audit personnel who have received classroom training to current revision.

[Signature] DATE 6/20/91
 RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER