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QUALITY ASSURANCE REVIEW REPORT OF THE
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM
REVIEW NO. 90-001
CONDUCTED: FEBRUARY 5-16, 1990

Prepared by: *Norman C. Frank* Date: 3/1/90
Norman C. Frank, CER Corporation
Review Team Leader

Approved by: *Dwight E. Shelor* Date: 3/1/90
Dwight E. Shelor, Acting Director
Office of Quality Assurance
DOE/OCRWM

EXECUTIVE SUMMARY

OCRWM REVIEW REPORT NO. 90-001

DOE/OCRWM

WASHINGTON, D.C.

FEBRUARY 5-16, 1990

The quality assurance (QA) program review was conducted over a two week period and covered those QA criteria applicable to the OCRWM QA program as delineated in the Quality Assurance Program Description.

It was apparent to the review team that, in general, OCRWM staff have been and are making sincere and significant efforts to implement the QA program.

The review team found that adequacy of the QA program, as currently implemented, for criteria 2 and 17 was indeterminate. For criterion 2, the QAAP for personnel qualification was not issued and review of personnel qualification and training files and records was restricted due to Privacy Act considerations. QAAP 17.1, "QA Records Management," which is a major element required for criterion 17 controls, is not yet issued.

The team found lack of compliance in most of the other areas of the QA program. Two areas of significant lack of compliance were design control and procurement control. Greater attention to assuring validity of design technical input and source documents and to controlling design interfaces is needed. Referenced design technical input and source documents must be readily available to the staff at OCRWM. The procurement controls defined in the QA program have not been implemented which is resulting in products and services of indeterminate quality.

Fifteen Deficiency Reports and twenty-seven Observations are presented for response in the full report.

The summary conclusion of the review team was that the QA program, as implemented, does not appear to be effective in preventing quality problems. Some revision to the QA program and significant improvements in compliance and implementation are necessary before the QA program should be presented to the NRC as a qualified QA program acceptable for the OCRWM/HQ support of the start of new site characterization activities. Considerable effort by all OCRWM managers is needed to identify problems in implementation and to effect corrective action.

Review Report for
OCRWM/HQ QA Program Review
February 5-16, 1990

1.0 INTRODUCTION

This report contains the results of a review of the Department of Energy, Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Program. The review was conducted at the OCRWM facilities in Washington, D.C., February 5-16, 1990. The review was conducted using QAAP 18.2, "Audit Program," as guidance.

The OCRWM staff were cooperative and well prepared for this review. The review team appreciated their efforts to help the review progress smoothly.

1.1 Objective

The objective of the review was to determine the status of the development and implementation of the OCRWM QA Program and its readiness to support start of new site characterization.

1.2 Scope

The following criteria were reviewed to assess compliance with the implementing documents:

- 1 Organization
- 2 Quality Assurance Program
- 3 Design Control
- 4 Procurement Document Control
- 5 Instructions, Procedures, and Drawings
- 6 Document Control
- 7 Control of Purchased Items and Services
- 16 Corrective Action
- 17 Quality Assurance Records
- 18 Audits

The remaining criteria (8 through 15) have been delegated to Project Offices and other PROGRAM participants.

The scope of the review included those activities related to or in support of surface-based testing and the Exploratory Shaft Facility. The review was compliance oriented rather than end-product oriented, however, several products (e.g., WMSR Management Plan) were reviewed for adequacy.

Specifically included were:

- preparation, review, and approval of the MGDS technical requirements and description (WMSR Volumes I and IV,

- WMSD, and the program SEMP)
- OCRWM review of supporting PROGRAM-participant documents (e.g., Project Office SEMP, study plans, Project Office MGDS Systems Requirements Document, ESF Subsystem Design Requirements Document)

The review team also evaluated the following technically related areas:

- qualification of technical personnel assigned to perform activities affecting quality
- adequacy of ESF and surface-based testing technical requirements
- adequacy of technical procedures

Specifically excluded were:

- study plans reviewed prior to August 1, 1989 (those were reviewed during OCRWM/HQ surveillance SR-89-003)
- readiness to start Title II ESF design (that was reviewed during OCRWM/HQ surveillance SR-89-002)

Discrepancies (Deficiency Reports and Corrective Action Reports) identified during previous internal surveillances that had OCRWM/HQ and KOH Systems listed as the "Responsible Organization" were added to the scope of the review to determine whether OCRWM has taken effective corrective actions. The corrective actions in response to the November 1986 Management Appraisal were verified during this review. There were no previous audit reports.

1.3 Review Basis

The following documents were used in developing the review checklists:

- DOE/RW-0197, OCRWM Quality Assurance Administrative Procedures
- DOE/RW-0246, OCRWM Implementing Line Procedures
- DOE/RW-0043, Program Management System Manual (PMS), Revision 3
- DOE/RW-0051, Program Systems Engineering Management Plan (SEMP), (draft, December 21, 1989)
- Program SEMP Management Plan (draft, August 25, 1989)
- WMSR Management Plan, Revision 1
- WMSD Management Plan (draft, no number, no revision number)
- DOE/RW-0223, Program Change Control Procedure, Revision 1
- Program Element Change Control Procedure (draft, July 20, 1989)

• DOE/RW-0194, Records Management Policies and Requirements, Revision 1

1.4 Review Team Members

Norman C. Frank, CER	Review Team Leader
Karl G. Sommer, DOE/OCRWM	Reviewer
I. Jake Lefman, SAIC	Reviewer
Robert M. Nilsson, CER	Reviewer
Marc J. Meyer, CER	Reviewer
Dean Stucker, DOE/OCRWM	Technical Specialist (Systems Engineer)
Carl E. Weber, Weston	Reviewer
Craig G. Walenga, CER	Reviewer
Donald E. Miller, CER	Reviewer
W. R. Marchand, Weston	Reviewer
Amelia I. Arceo, SAIC-LV	Observer
Mark Senderling, DOE/OCRWM	Observer
Bill Villanueva, DOE/OCRWM	Observer
Tim Johnson, DOE/OCRWM	Observer

1.5 Personnel Contacted

The personnel attending the pre- and post-conference meetings and those contacted during the review are listed in Attachment 1.

2.0 SUMMARY OF RESULTS

This section provides the results of the review as determined by the review team. Identified deficiencies and observations are given in Attachments 2 and 3, respectively.

2.1 QA Program Development

QA program development is not adequate to conclude that OCRWM has a fully qualified QA program at this time. However, current plans to revise the existing QA program should make it sufficient.

2.2 QA Program Compliance

There is a general lack of compliance with the QA program requirements. Greater attention to the implementation of the QA program is necessary before the QA program should be presented to the NRC as a qualified QA program acceptable for the OCRWM/HQ support of the start of new site characterization activities.

2.3 Effectiveness of QA Program Implementation

The QA program as implemented is not effective in preventing quality problems.

2.4 Technical Activities

Review of technical activities focused on the status and adequacy of technical and management plans and documents that form the basis for future work or establish additional management controls.

The review found that:

- technical inputs are not being adequately identified and controlled
- systems to control the flow of information across technical interfaces need to be defined and implemented
- reference materials that are necessary to assess the technical adequacy of documents that require OCRWM review and approval are not readily available to the OCRWM staff.

2.5 Summary of Past Deficiency Reports and Corrective Actions Reports

The results of the review/follow-up of the existing deficiencies written against DOE/OCRWM are provided in Attachment 4.

2.6 Summary of Findings

A total of 50 concerns were identified during the review. These were consolidated into 15 Deficiency Reports (DRs) and 27 observations. A synopsis of the DRs and observations noted during this review is given below.

Deficiency Reports

Information copies of the Deficiency Reports are provided in Attachment 2.

90-001 Training is not being completed prior to staff performing work that requires the training.

- A sample of 26 I&T matrices and reading assignment sheets were reviewed. None of the people covered had fulfilled the requirements of QAAP 2.1.

- Personnel implementing QAAP 4.2 do not appear to be fully aware of procedural requirements for the overall procurement process.
- 90-002 OQA has not established a formal system for tracking the review status of external QA program documents.
- 90-003 Management plans developed for the WMSR and WMSD fail to contain information required by Attachment II of QAAP 3.5.
- 90-004 The SEMP does not:
- identify who is responsible for each element of the design.
 - describe the process for developing an integrated design. Subsection 4.4 of the SEMP discusses interface control, however, its provisions are inadequate.
 - establish requirements for documenting, maintaining, and controlling the technical baseline to be used.
- 90-005 OSIR QA matrices do not address the preparation of system studies reports.
- The SEMP requires a System Studies Plan, However, the OSIR QA matrices state that QA does not apply.
- 90-006 There are deficiencies in the control of documents that control the design process.
- The QA Controls Matrix for OSIR states that QA does not apply to the SEMP which contradicts the QAPD
 - The SEMP Management Plan states that the SEMP is not subject to the QA program
 - Control of DOE/RW-0125 and DOE/RW-136 for waste are not discussed in the SEMP.
- 90-007 Current copies of source documents are not readily available. The Technical and Regulatory Information Management System (TRIMS) which could help alleviate this problem is not ready for use.
- The review criteria listed in the Document Review Record for the WMSR Volumes I and IV were not complete. Specifically, references to source

documents were not required to be reviewed for accuracy and appropriateness.

- 90-008 OCRWM is not fully implementing procurement controls required by a draft QA Controls Document generated in accordance with QAAP 2.3.
- 90-009 Red ink is not being used in some cases for the identification of controlled documents. This nullifies the PCCP control method for the identification of uncontrolled copies.
- 90-010 The records package for Change Proposal CP-11 that was in the process of turnover to the CRF did not contain documentation of concurrence by the Director, OQA as required by the PE-CCP.
- 90-011 The deficiency reporting system and corrective action system has not been fully implemented.
- 90-012 The record requirements of the RMPR have not been effectively implemented as evidenced by the inability to find documents in the CRF.
- 90-013 Records packages are not being suitably protected prior to transmittal to the CRF.
- 90-014 OCRWM has not performed any internal or external audits of the CRWM program.
- 90-015 One completed surveillance checklist was missing from the QA file. Surveillance reports are not always being distributed as required by QAAP 18.3.

Observations

Observations are provided in Attachment 3 of this report.

Attachment 1
Personnel Contacted
During the Review

<u>Name</u>	<u>Organization</u>	<u>Pre- Review¹</u>	<u>Contacted During Review</u>	<u>Post Review²</u>
Don Alexander	DOE/OCRWM	X	X	
Gorden Appel	DOE/OCRWM	X	X	
Lake Barrett	DOE/OCRWM	X	X	X
Alan Berusch	DOE/OCRWM	X	X	
J. A. Blair	Weston	X		
R. J. Blaney	COE/OCRWM	X	X	
Pete Bolton	Weston		X	
Harold Brandt	DOE/OCRWM	X	X	X
James Bresee	DOE/OCRWM	X	X	X
Stephan Brocoum	DOE/OCRWM	X		X
Charles E. Brooks	DOE/OCRWM	X		
Barbara Cerny	DOE/OCRWM	X	X	X
Robert Clark	DOE/OCRWM	X	X	X
B. Clemons	KOH		X	
Samuel C. Colwell	Weston	X		
Manny Comar	DOE/OCRWM	X	X	
A. S. Dam	Weston	X		
William Danker	DOE/OCRWM	X	X	X
Joe DiNuno	Weston			X
B. Easterling	DOE/OCRWM		X	
Gary Faust	Weston		X	X
Barry Gale	DOE/OCRWM		X	
Robert Gamble	Weston		X	X
G. Gardner	DOE/OCRWM		X	
Stanley Goldsmith	Weston	X		X
Steve Gomberg	DOE/OCRWM	X	X	
Jane Hadden	KOH		X	
J. J. Hale	DOE/OCRWM	X		
Charles Head	DOE/OCRWM	X	X	X
Carol Hofmann	DOE/OCRWM	X	X	
E. P. HuangFu	DOE/OCRWM	X	X	
Cecil Hughey	CER	X	X	X

¹ A pre-review conference was held with the Director, OCRWM and the OCRWM staff at 10:00 a.m. on February 5, 1990 in Room 6E-069 of the Forrestal Building. The purpose, scope, and proposed agenda and schedule for the review were discussed and the review team was presented.

² A post-review conference was held with the Director, OCRWM and the OCRWM staff at 10:00 a.m. on February 16, 1990 in Room 6E-069 of the Forrestal Building. A summary of the review conduct and review findings was presented.

Darvi Hull	Weston		X	
P. Hunt	DOE/OCRWM		X	
J. Hyde	DOE/OCRWM		X	
Tom Isaacs	DOE/OCRWM	X	X	
Robert Jackson	Weston	X		X
Margaret Jennings	DOE/OCRWM		X	
Deborah Jerez	Weston			X
Tim Johnson	DOE/OCRWM		X	X
Jay Jones	DOE/OCRWM	X	X	
John Kasprovicz	DOE/Chicago		X	
Jeff Kimball	DOE/OCRWM	X	X	X
Ginger King	DOE/OCRWM		X	
Christopher Kouts	DOE/OCRWM	X	X	
Ram Lahoti	DOE/OCRWM		X	X
J. Lowery	DOE/OCRWM		X	
Karen Manion	CER		X	
A. W. Marchand	Weston	X	X	X
Raymond A. Mele	Weston	X		
R. Milner	DOE/OCRWM	X		
Rich Minning	DOE/OCRWM		X	X
K. Mutreja	DOE/OCRWM	X		
C. Nye	KOH		X	
Mary Lee Payton	DOE/OCRWM	X	X	X
Franklin Peters	DOE/OCRWM	X	X	X
Robert Philpott	DOE/OCRWM	X	X	
Tom Pollog	DOE/OCRWM		X	
David Rasmusson	Weston	X		
Ginger Roccaprora	DOE/OCRWM	X		
Samuel Rousso	DOE/OCRWM	X	X	X
Mark Senderling	DOE/OCRWM	X	X	X
R. Sharma	DOE/OCRWM		X	
Dwight E. Shelor	DOE/OCRWM	X	X	X
David Siefken	Weston	X		X
Sharon Skuchko	DOE/OCRWM		X	X
A. Lowell Snow	Weston			X
Karl Sommer	DOE/OCRWM	X	X	X
Ralph Stein	DOE/OCRWM	X	X	
W. A. Stringfield	DOE/OCRWM	X		
Eric Svenson	DOE/OCRWM		X	
Kathy Thompson	DOE/OCRWM		X	
Vic Trebules	DOE/OCRWM	X		
Trieu Truong	Weston		X	
Deborah Valentine	DOE/OCRWM	X	X	
B. Villanueva	DOE/OCRWM	X	X	X
Ray Wallace	DOE/OCRWM			X
Edwin Wilmot	DOE/YMPO			X
William E. Wowak	Weston	X		X
D. Youngberg	DOE/OCRWM		X	X

Attachment 2
Information Copies of Deficiency Reports
Written from this Review

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WASHINGTON, D.C.**

SHEET 1 OF 2
WBS NO. 6.0 (1)
DR. NO. 90-001 (2)
REVISION NO. 0 (3)

DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001	RESPONSIBLE ORGANIZATION (5) RW-1 (lead), affects all	REFERENCE DOCUMENTS (6) QAAP 2.1, Rev. 0
REQUIREMENTS (7) See attached.		
DESCRIPTION OF CONDITION (8) See attached.		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) See attached.		
ORIGINATOR (10) <u>Donald E. Miller</u> Signature Date <u>3/1/90</u>		BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)		CAR NO. (14)
(15) RESPONSE DUE	(16) OQA _____ Signature Date	(17) DIRECTOR, OQA _____ Signature Date
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date
RESPONSE [] ACCEPT (23) * [] REJECT	OQA SIGNATURE (24) _____ Signature Date	DIRECTOR, OQA (25) _____ Signature Date
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature Date
OQA VERIFICATION (29) [] SATISFACTORY * [] UNSATISFACTORY	OQA (30) _____ Signature Date	DIRECTOR, OQA (31) _____ Signature Date

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET

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WBS NO. 6.0

DEFICIENCY REPORT (continuation sheet)

DR. NO. 90-001

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DATE 3/1/90

Requirement (7)

Para. 5.1.1 "Individuals performing activities affecting quality shall be indoctrinated and trained as appropriate, to assure a thorough understanding of the OCRWM QA Program and implementing procedures."

Conditions (8)

- 1) Twenty-six (26) I&T Matrices were reviewed. The sample was random and included personnel from RW-1, 3, 10, 20, 30, and 40. In all 26 cases, personnel indoctrination (either classroom instruction or reading) required by the I&T Matrix and the required indoctrination had not been completed.
- 2) Personnel in RW-20, 30, and 40 were interviewed who had completed required reading and classroom instruction on QAAPs 4.1, 4.2 and 7.1. However, based on interviews, the personnel did not appear to be fully aware of the following QAAP requirements.
 - o the need to include QAAP 7.1 requirements in contracts.
 - o responsibilities for initiating, QAAP 4.1 procurement document reviews
 - o QAAP 4.2 requirements for procurement QA specifications and associated basis sheets.

Recommended Actions

- 1) Complete required indoctrination
- 2) Action to be determined by responsible organizations

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WBS NO. 6.0 (1)
DR. NO. 90-002 (2)
REVISION NO. 0 (3)

DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) <u>Review 90-001</u>	RESPONSIBLE ORGANIZATION (5) <u>RW-3</u>	REFERENCE DOCUMENTS (6) <u>QAAP 2.5</u>
REQUIREMENTS (7) QAAP 2.5 section 4.3 states "The Director, OQA or designee is responsible for: ...maintaining and tracking QA program document review status."		
DESCRIPTION OF CONDITION (8) OQA has not established a formal system for tracking the review status of external QA Program documents.		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) <p align="center"><u>See Page 2</u></p>		
ORIGINATOR (10) <u>Craig E. Walery</u> Signature	<u>3/1/90</u> Date	BRANCH/DIVISION/OFFICE (11) <u>RW-3, OQA</u>
YES <input type="checkbox"/> NO <input type="checkbox"/> SIGNIFICANT (12) REPETITIVE (13)		CAR NO. (14)
(15) RESPONSE DUE	(16) OQA _____ Signature	(17) DIRECTOR, OQA _____ Signature
	_____ Date	_____ Date
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature
	_____ Date	_____ Date
RESPONSE (23) <input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT	OQA SIGNATURE (24) _____ Signature	DIRECTOR, OQA (25) _____ Signature
	_____ Date	_____ Date
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature	PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature
	_____ Date	_____ Date
OQA VERIFICATION (29) <input type="checkbox"/> SATISFACTORY * <input type="checkbox"/> UNSATISFACTORY	OQA (30) _____ Signature	DIRECTOR, OQA (31) _____ Signature
	_____ Date	_____ Date

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Block 9:

Develop a formal tracking system (e.g., topical files or log sheets) for tracking QA Program document review status. Consider including, within the tracking system, a system for identifying the scope of work for which the document has been approved. Such a system would be an aid in procurement process, similar to a qualified supplier list.

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Management Plans developed for the WMSR and WMSD fail to contain information required by Attachment II of QAAP 3.5. For example, Management Plans fail to contain criteria for identifying applicable source documents, methods for approving input sources and verifying the validity of information used as input, and criteria for translating source information into a form suitable for use in a technical document.

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SHEET 1 OF 3
WBS NO. 6.0 (1)
DR. NO. 90-004 (2)
REVISION NO. 0 (3)

DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001	RESPONSIBLE ORGANIZATION (5) RW-30	REFERENCE DOCUMENTS (6) QAPD, Para. 3.1.4
REQUIREMENTS (7) QAPD, Para. 3.1.4, says "SEMPs will address 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 the technical baseline to be used."		
DESCRIPTION OF CONDITION (8) used. See attached		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) Revise SEMP and, if appropriate, QA Controls Matrices		
ORIGINATOR (10)  Signature	<u>3/1/90</u> Date	BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)		CAR NO. (14)
(15) RESPONSE DUE	(16) OQA _____ Signature _____ Date	(17) DIRECTOR, OQA _____ Signature _____ Date
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature _____ Date	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature _____ Date
RESPONSE (23) [] ACCEPT *[] REJECT	OQA SIGNATURE (24) _____ Signature _____ Date	DIRECTOR, OQA (25) _____ Signature _____ Date
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature _____ Date	PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature _____ Date
OQA VERIFICATION (29) [] SATISFACTORY * [] UNSATISFACTORY	OQA (30) _____ Signature _____ Date	DIRECTOR, OQA (31) _____ Signature _____ Date

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET

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Description of Condition

- 1) The SEMP does not identify who is responsible for each element of the design. For example, Subsection 5.3 contains ten pages of text describing the MGDS design process. Nowhere in Subsection 5.3 is OSIR's responsibility for MGDS design activities mentioned. According to the PMS Manual, OSIR is responsible for numerous documents containing technical, regulatory, environmental and licensing requirements applicable to the MGDS. OSIR is responsible for assessing the adequacy of the MGDS design from a risk, safety, performance, environmental, and regulatory standpoint. Unless OSIR has a role in the development of the design, it cannot fulfill these responsibilities.
- 2) The SEMP does not describe the process for developing an integrated design. Subsection 4.4 of the SEMP discusses interface control, however, its provisions are inadequate. Deficiencies are as follows:
 - a) The SEMP states interfaces are identified and described in the WMSR and WMSD. The WMSD incorporates and expands on interface information in the WMSR. The SEMP states interfaces will be controlled in accordance with interface-control documents developed by IWGs (Interface Working Groups). The SEMP states the IWGs will develop procedures for controlling the interface-control documents and that IWGs will be appointed by "the Cognizant Associate Director or Project Manager." QA Control Matrices (QAAP 2.3) fail to discuss activities related to the establishment of IWGs, development of interface-control documents and development of procedures to control interface-control documents.

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- b) The SEMP does not establish requirements for controlling administrative interfaces, only physical interfaces. For example, the WMSD and WMSR identify no interfaces affecting either the "Store Waste" or "Isolate Waste" function, thus, no interface control would be required when developing either requirements or design documents associated with these functions.
- 3) The SEMP does not establish requirements for documenting, maintaining and controlling the technical baseline to be used. Deficiencies are as follows:
- a) Rather than containing "stand-alone" requirements, the technical baseline usually refers to requirements contained in other documents. Those that must comply with these documents are often not told what version to use, e.g., latest version or version in effect at the time the baseline document was issued. (Where OCRWM documents are referenced they are dated.)
- b) The SEMP allows requirement documents such as the WMSR to make blanket reference to "requirements" in other OCRWM documents. It does not require that documents referenced be baselined and controlled in the same manner as other OCRWM technical documents. OCRWM documents referenced in Vol. 1 of the WMSR, per the PMS Manual, are not subject to formal review, approval or controlled distribution. Accordingly, those holding a controlled copy of Vol. I of the WMSR have, in effect, a controlled "index" to requirement documents rather than controlled copies of OCRWM documents containing requirements.

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REFERENCE DOCUMENTS (6) and REQUIREMENTS (7)

QAPD, Para. 3.1.4 "Applicable design input, such as design bases, performance requirements, regulatory requirements, codes, and standards will be identified and controlled."

SEMP, Para. 4.2.1 "System studies... provide input for the resolution of key issues concerning system configuration, system performance, function allocations, or major design parameters. The information resulting from these studies will provide one of the bases for making system decisions to meet the overall Program Objectives."

QAAP 3.1, Section 2.0 "This procedure address technical documents prepared by OCRWM... for review, acceptance and release by OCRWM".

QAAP 3.5, Section 2.0 "This procedure shall be implemented for the preparation of technical documents..." Para. 6.2.1 "The technical document shall be prepared in accordance with the approved technical document management plans." Para. 5.1 "The technical document management plan shall incorporate the requirements set forth in Section 6.0 and Attachment I."

DESCRIPTION OF CONDITION (8)

- 1) OSIR (RW-30) QA Matrices do not address the preparation of system studies reports. Task 4.2.1.2; however, does address the review of system study reports. It says the QAR, QAPD, QAAPs and all other Program requirements are "not applicable."

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- 2) Para. 4.2.6.1 of the SEMP requires the development of a System Studies Plan whose purpose is to "resolve technical issues" and "present a process for supporting an information base that will provide a common and consistent set of information to be used for comparative analyses throughout the Program." Task 4.1.2 and 4.2.1.2 of OSIR QA Matrices cover the preparation and review of this plan. The Matrices state that the QAR, QAPD, and QAAPs do not apply to this plan.

[Note: Though the QA Control Matrix indicates System Study Plans will be controlled in accordance with the PMS Manual, the PMS Manual does not contain requirements for controlling System Study Plans.]

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REFERENCE DOCUMENTS (6) AND REQUIREMENTS (7)

QAAP 2.3, Subsection 5.2, "As a minimum the following OCRWM work shall be subject to QARD requirements... work that is direct input to the license application or the radiological safety sections of the environmental impact statement or indirectly supports technical arguments in the license application or the radiological safety sections of the environmental impact statement or indirectly supports technical arguments in the license application or the radiological safety sections of the environmental impact statement."

QAAP 3.1 Section 2.0 "This procedure addresses technical documents prepared by OCRWM --- for review, acceptance and release by OCRWM." Para. 3.2.6 "Technical Document -- A document that specifies scientific or engineering requirements, presents scientific or engineering information or data, or describes scientific or engineering processes."

DESCRIPTION OF CONDITION:

- 1) Paragraph 3.1.1 of the QAPD references the SEMP to control the design process. The SEMP invokes baselining requirements and Para. 3.1.1 of the QAPD states, "Compliance with SEMPs and other Program requirements will be assured through surveillances and audits of the design process."

Tasks 4.1.2 and 4.2.1.2 or OSIR's (RW-30) QA Controls Matrix covers preparation, review, approval and distribution of the SEMP. These Matrices state that the QAPD [and QAR and QAAPs] do not apply to the SEMP.

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- 2) The SEMP Management Plan, dated 08/30/89, states the SEMP does not impact any design activity or site characterization work, therefore is not subject to the requirements for the OCRWM Quality Assurance Program. Para. 3.1.1 and 3.1.4 of the QAPD requires that the SEMP be part of the OCRWM Quality Assurance Program and that the SEMP control design processes associated with each system element. Para. 5.3.5 of the SEMP contains detailed requirements for managing and controlling the design of the waste package and Para. 5.3.2 contains detailed requirements for managing and controlling site characterization work.
- 3) Para 2.3.2.1 of Vol. I of the WMSR requires that defense waste meet the requirements of DOE/RW-0125 and West Valley Waste meet the requirements of DOE/RW-0136. Controls associated with developing, reviewing, approving and distributing these specifications (requirements documents) are not discussed in the SEMP. Table 2-1 of Vol. I of the WMSR allocates the development of these specifications to the transportation function which is the responsibility of OSIR. Nothing in OSIR's QA Controls Matrices (RW-30) indicates how these specifications will be controlled.

RECOMMENDED ACTIONS (9)

- 1) Revise QA Controls Matrices (RW-30)
- 2) Revise SEMP to address control of waste form production and acceptance of waste by the transportation system. Review revised SEMP in accordance with QAAP 3.1.
- 3) Revise SEMP to include Waste Acceptance Specifications in Technical Baseline.

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REVISION NO. 0 (3)

DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001	RESPONSIBLE ORGANIZATION (5) RW-30 (lead), RW-10 affected	REFERENCE DOCUMENTS (6) See attached.
REQUIREMENTS (7) See attached.		
DESCRIPTION OF CONDITION (8) See attached.		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) See attached.		
ORIGINATOR (10) <u><i>Mark Meyer</i></u> Signature	Date <u>3/1/90</u>	BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)		CAR NO. (14)
(15) RESPONSE DUE	(16) OQA Signature _____ Date _____	(17) DIRECTOR, OQA Signature _____ Date _____
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) Signature _____ Date _____	PROJECT MANAGER/ASSOCIATE DIR. (22) Signature _____ Date _____
RESPONSE (23) [] ACCEPT * [] REJECT	OQA SIGNATURE (24) Signature _____ Date _____	DIRECTOR, OQA (25) Signature _____ Date _____
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) Signature _____ Date _____	PROJECT MANAGER/ASSOCIATE DIR. (28) Signature _____ Date _____
OQA VERIFICATION (29) [] SATISFACTORY * [] UNSATISFACTORY	OQA (30) Signature _____ Date _____	DIRECTOR, OQA (31) Signature _____ Date _____

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET

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Requirements (6) and (7)

QAPD, Para. 6.1.1(d) "Procedures for the preparation and revision of plans, manuals, procedures, instructions, reports, and other documents will address --- access by reviewing organizations to pertinent background data or information to assure a complete review".

QAAP 3.5, Attachment 1, Technical Document Management Plan Content
REFERENCES Use as references existing documents, data bases, procedures, systems descriptions, specification, and standards
BACKGROUND Provide background information that will put the plan and its end products into perspective"

QAAP 3.1, Para. 5.7 "The Cognizant Associate Director, OCRWM, shall develop, maintain and provide to the designated reviewers written instructions that establish or reference appropriate review and acceptance criteria. Documents containing such criteria include but are not limited to PROGRAM and site specific requirements documents, industry codes, standards, NUREGS, Federal Regulations and interfacing technical documents."

PMS Manual, Para. 3.5.2.7 "To facilitate data management, the Director, LCD, in collaboration with the Project Manager, YMPO, and the Director, Information Resources Management Division (IRMD), OPARM, shall develop a Technical and Regulatory Information Management System (TRIMS) to provide for real-time access, at Headquarters and field locations, to the status of data, documents and regulations while the site characterization, performance assessment and design activities are in progress." Para. 3.10.1, "The Information Resources Management Program Plan (IRMPP) shall--outline strategies and tactics to be used in effectively managing the Program's information resources."

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Description of Condition (8)

- 1) DOE Headquarters does not have either TRIMS or a document control center containing current copies of project and Headquarters documents. The draft Information Resources Management Program Plan does not identify TRIMS. Libraries in the offices of those responsible for reviewing PROGRAM documents are either incomplete or contain uncontrolled copies of documents, superseded documents, or preliminary information that is not marked "preliminary".
- 2) Review criteria provided to reviewers of the WMSR, Vols I and IV and WMSD did not contain instructions for reviewing the documents against criteria contained in the WMSR and WMSD Management Plans and the SEMP. Also, criteria for reviewing the WMSD did not request that references be reviewed for accuracy and appropriateness.

Recommended Actions (9)

- 1) Revise PMS Manual to require a plan for establishing a TRIMS and an OCRWM document control center containing documents referenced in TRIMS.
- 2) Rereview WMSR, Vols. I and IV and WMSD per QAAP 3.1.

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DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001	RESPONSIBLE ORGANIZATION (5) RW-1 (lead) affects all	REFERENCE DOCUMENTS (6) DOE/RW-0214
REQUIREMENTS (7) DOE/RW-0214, QARD, Sections 7, 4, and 2 require a procurement control process to be implemented for procurements that are required to have QA controls.		
DESCRIPTION OF CONDITION (8) See attached sheets.		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) See attached sheets.		
ORIGINATOR (10) <i>Craig E. Walery</i> Signature	<u>3/1/90</u> Date	BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES [] NO [] [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)	CAR NO. (14)	
(15) RESPONSE DUE	(16) OQA _____ Signature Date	(17) DIRECTOR, OQA _____ Signature Date
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date
RESPONSE [] ACCEPT (23) * [] REJECT	OQA SIGNATURE (24) _____ Signature Date	DIRECTOR, OQA (25) _____ Signature Date
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature Date
OQA VERIFICATION (29) [] SATISFACTORY * [] UNSATISFACTORY	OQA (30) _____ Signature Date	DIRECTOR, OQA (31) _____ Signature Date

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GENERAL

OCRWM is not fully implementing procurement controls required by QAAP 4.1, "Procurement Document Review", QAAP 4.2, "Establishing Procurement Quality Assurance Controls", and QAAP 7.1, "Control of Purchased Services". First, with few exceptions, the requirements for OCRWM-managed contractor QA Programs, controls applicable to their activities, and the status of their QA Programs is indeterminate. Thus, the quality of the end products supplied by these contractors must be considered indeterminate until qualified for use.

Second, QA controls for OCRWM direct-support contractors have not been fully specified.

Specific Deficiencies

- a) QAAP 7.1, "Controlled of Purchased Services", contains specific requirements that must be included in procurement documents for total product control. These requirements have not been incorporated into previously issued procurement documents and a schedule has not been developed for reviewing and upgrading QA requirements in procurement documents.
- b) OFSD's draft program guidance letters (PGLs) contain adequate QA controls but lack supporting basis sheets required by QAAP 4.2. OSIR's issued PGLs fail to specify QA controls. Other issued and draft OSIR PGLs contain QA controls but specify controls developed outside of the QAAP 2.3 process. OPARM has not yet implemented QAAP 4.2.

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- c) Initiating Offices are not reviewing PGLs in accordance with QAAP 4.1, "Procurement Document Review".
- d) Six OCRWM-managed contractor QA Program description documents have been accepted by OCRWM. These documents were accepted prior to the issuance of the QARD and prior to the implementation of QAAPs 2.3, 4.2, and 2.5. They have not been evaluated for compliance with the QARD. ORNL QA Plan, Rev.1 (1/89) has been received by OQA but has not yet been accepted.
- e) The failure to issue a QA Controls Document in accordance with QAAP 2.3 continues to significantly affect implementation of the OCRWM procurement process.

Recommended Corrective Action

1. Issue an OCRWM QA Controls Document.
2. Incorporate required QA requirements and basis for exclusion of QA requirements in existing procurement documents requiring QA controls.
3. Conduct QAAP 4.1 reviews of procurement documents requiring revisions per Item (2) above. These reviews should address additional QAAP 7.1 requirements or controls that need to be included in procurement documents. These requirements and controls should either be established in consultation with OQA or OQA should issue a list of requirements to be included in each QAAP 4.1 review.
4. Review previously-accepted QA Plans and other contractor QA Program documents using the QAAP 2.5 review process.
5. Evaluate products delivered by OCRWM-managed contractors to determine the acceptability of product. Establish which products must be qualified for use. Consider stop work where the contractor's QA Programs are either not in place or unacceptable.

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Requirements (7)

The QAPD (Section 6.1.3), and the PCCP, DOE/RW-0223 (Rev.1, Section 2.3, 3rd Paragraph) requires that program baseline documents be controlled to ensure that the document being used is current, to preclude the use of obsolete or superseded documents.

Description of Condition (8)

The PCCP document requires that controlled documents have the control number stamped in red ink on the document to preclude use of uncontrolled documents. During this review it was observed that the control number "009" was not stamped in red ink on the controlled copy of the RMPR used during a portion of the review.

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DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001		RESPONSIBLE ORGANIZATION (5) RW-30...		REFERENCE DOCUMENTS (6) PECCP 8/89	
REQUIREMENTS (7) QAAP 6.1 references the PECCP which states in paragraph 7.5.3 that the Director of OQA shall concur in any disposition where the full PE-CCB is not involved in the review, and the CP is quality-affecting.					
DESCRIPTION OF CONDITION (8) The records package for CP-11 that was in the process of turnover to CRF, did not contain any documentation of concurrence by the Director, OQA. (See continuation)					
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) 1) Obtain concurrence of Director, OQA 2) Establish mechanisms to prevent recurrence of problem					
ORIGINATOR (10) <i>K.G. SM</i> <u>FOR I.J. LEFMAN</u> <u>3/1/90</u> Signature Date				BRANCH/DIVISION/OFFICE (11) RW-3, OQA	
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)				CAR NO. (14)	
(15) RESPONSE DUE		(16) OQA _____ Signature Date		(17) DIRECTOR, OQA _____ Signature Date	
REMEDIAL ACTIONS (18)					
EXTENT (19)					
PLANNED COMPLETION (20)		RESPONSIBLE MANAGER (21) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date	
RESPONSE [] ACCEPT (23) *[] REJECT		OQA SIGNATURE (24) _____ Signature Date		DIRECTOR, OQA (25) _____ Signature Date	
COMPLETION DATE (26)		RESPONSIBLE MANAGER (27) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature Date	
OQA VERIFICATION (29) [] SATISFACTORY *[] UNSATISFACTORY		OQA (30) _____ Signature Date		DIRECTOR, OQA (31) _____ Signature Date	

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CP-11 required an immediate revision to the SEMP (OGR/B-7). The changes were considered to be administrative/editorial in nature by the PECCB executive secretary. [Since the full PECCB was not convened to concur with this change, it was especially important that the concurrence of the Director, OQA be obtained.]

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DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001	RESPONSIBLE ORGANIZATION (5) RW-3 (lead), affects all	REFERENCE DOCUMENTS (6) QAAP 16.1
REQUIREMENTS (7) QAAP 16.1 establishes a system for identifying, tracking, and correcting conditions adverse to quality.		
DESCRIPTION OF CONDITION (8) See attached.		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) Implement QAAP 16.1		
ORIGINATOR (10) <u>Donald E Miller</u> Signature	<u>3/1/90</u> Date	BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)	CAR NO. (14)	
(15) RESPONSE DUE	(16) OQA _____ Signature Date	(17) DIRECTOR, OQA _____ Signature Date
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date
RESPONSE (23) [] ACCEPT * [] REJECT	OQA SIGNATURE (24) _____ Signature Date	DIRECTOR, OQA (25) _____ Signature Date
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OQA VERIFICATION (29) [] SATISFACTORY * [] UNSATISFACTORY	OQA (30) _____ Signature Date	DIRECTOR, OQA (31) _____ Signature Date

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Description of Conditions

1. Personnel are not initiating a DR when a deficiency is identified. For example:
 - a) the resolution of a DRR comment by Dean Stucker on WMSR Volume I was:

It is anticipated that from an audit of this review a Deficiency Report will be issued for this point. At that time, in a response to that DR, the SEMP, PMS Manual, and WMSR Volume I will [be] reviewed to determine the consistency of the documents.
 - b) Though QAAP 16.1 was issued one year ago, to date, RW-3 has been the only organization that has been identifying deficiencies.
2. DR-89-002 was replaced by CAR-89-001 and the DR was not closed-out.
3. Information in the DR/CAR tracking system is neither complete nor current.

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DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) <u>Review 90-001</u>	RESPONSIBLE ORGANIZATION (5) <u>RW-10 (lead), affects all</u>	REFERENCE DOCUMENTS (6) <u>RMPR, DOE/RW-0194, Rev. 1</u>
REQUIREMENTS (7) <u>See attached.</u>		
DESCRIPTION OF CONDITION (8) <u>See attached.</u>		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) <u>N/A</u>		
ORIGINATOR (10) <u>K.G. [Signature]</u> Signature _____ <u>3/1/90</u> Date _____	BRANCH/DIVISION/OFFICE (11) <u>RW-3, OQA</u>	
YES NO <input type="checkbox"/> <input type="checkbox"/> SIGNIFICANT (12) <input type="checkbox"/> <input type="checkbox"/> REPETITIVE (13)	CAR NO. (14)	
(15) RESPONSE DUE	(16) OQA _____ Signature _____ Date _____	(17) DIRECTOR, OQA _____ Signature _____ Date _____
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature _____ Date _____	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature _____ Date _____
RESPONSE (23) <input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT	OQA SIGNATURE (24) _____ Signature _____ Date _____	DIRECTOR, OQA (25) _____ Signature _____ Date _____
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature _____ Date _____	PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature _____ Date _____
OQA VERIFICATION (29) <input type="checkbox"/> SATISFACTORY <input checked="" type="checkbox"/> UNSATISFACTORY	OQA (30) _____ Signature _____ Date _____	DIRECTOR, OQA (31) _____ Signature _____ Date _____

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET

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Requirements (7)

The RMPR (sections 2.0, 4.1, 4.4, and A.3.0) requires controls for program-wide capturing, indexing, searching, storing, and retrieving program records, including QA records.

Description of Condition (8)

A review of the sample record search results has indicated that the record requirements of the RMPR have not been effectively implemented.

A sample group of twenty-three (23) documents were selected (by the review team) for search and retrieval in the OCRWM/HQ Central Records Facility (CRF). Search and retrieval was conducted on 2/12/90 (AM), 2/12/90(PM), 2/13/90(PM) and 2/14/90(AM).

After completing the search and retrieval process, the following conditions were noted:

- o Sixteen (16) of the documents were retrieved from the CRF.
 - o Seven (7) could not be retrieved from the CRF.
 - o Examples of QA records that could not be retrieved are;
 - 1) Transmittal of DCP-10 (RMPR) record package (11/29/89),
 - 2) Transmittal of DCP-14A (PMS) record package (11/8/89)
 - o A further search of the "QA field designation" for the group of sixteen (16) documents indicated the following:
 - o 10 documents field --- N/A (*)
 - o 2 documents field --- Blank
 - o 4 documents field --- Ind (**)
- * = not applicable
** = indeterminate

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- o It appears, based on information available, from CRF personnel interviewed, seven (7) "QA field designations" are available for use , as noted below:
 - o blank
 - o 1
 - o 2
 - o 3
 - o Ind
 - o N/A
 - o yes

- o A further search was conducted to determine the total number of QA identified records in the CRF as of 2/13/90 (PM). Tabulated results as follows:

QA Field Designation

NO. QA Records

o Blank	6,623
o 1	40
o 2	85
o 3	96
o Ind	158,786
o N/A	22,884
o Yes	1,420
o Total No. Records in CRF	189,934
o Total No. of QA Records:	40 + 85 + 96 + 1,420 or 1,641
o Total No. of QA records is less than one percent of total records in CRF.	

- o Based on the "QA Record" definition contained in the RMPR (Section 4.9), 20 of the 23 (87 percent) documents searched were QA records. Therefore, it is highly improbable that less than one percent of the documents in the CRF are QA records.

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DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001	RESPONSIBLE ORGANIZATION (5) RW-3	REFERENCE DOCUMENTS (6) QAAP 18.2
REQUIREMENTS (7) QAAP 18.2, Paragraph 5.1 states that "Audits are performed on a regular basis..."		
DESCRIPTION OF CONDITION (8) OCRWM has not performed any internal or external audits of the CRWM Program.		
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) Schedule and perform audits in accordance with QAAP 18.2.		
ORIGINATOR (10) <u>Donald E. Miller</u> Signature	<u>3/1/90</u> Date	BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES NO <input type="checkbox"/> <input type="checkbox"/> SIGNIFICANT (12) <input type="checkbox"/> <input type="checkbox"/> REPETITIVE (13)		CAR NO. (14)
(15) RESPONSE DUE	(16) OQA _____ Signature Date	(17) DIRECTOR, OQA _____ Signature Date
REMEDIAL ACTIONS (18)		
EXTENT (19)		
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date
RESPONSE <input type="checkbox"/> ACCEPT (23) * <input type="checkbox"/> REJECT	OQA SIGNATURE (24) _____ Signature Date	DIRECTOR, OQA (25) _____ Signature Date
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OQA VERIFICATION (29) <input type="checkbox"/> SATISFACTORY * <input type="checkbox"/> UNSATISFACTORY	OQA (30) _____ Signature Date	DIRECTOR, OQA (31) _____ Signature Date

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DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4) Review 90-001		RESPONSIBLE ORGANIZATION (5) RW-3		REFERENCE DOCUMENTS (6) QAAP 18.3	
REQUIREMENTS (7) See Page 2 of 3					
DESCRIPTION OF CONDITION (8) See Page 3 of 3					
RECOMMENDED ACTIONS TO CORRECT CONDITION (9) Locate the missing checklist and place it in the file for later transfer to the ORF.					
ORIGINATOR (10) <u>Donald E. Miller</u> Signature			Date <u>3/1/90</u>		BRANCH/DIVISION/OFFICE (11) RW-3, OQA
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)			CAR NO. (14)		
(15) RESPONSE DUE	(16) OQA _____ Signature		(17) DIRECTOR, OQA _____ Signature		Date
REMEDIAL ACTIONS (18)					
EXTENT (19)					
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date		
RESPONSE (23) [] ACCEPT *[] REJECT	OQA SIGNATURE (24) _____ Signature Date		DIRECTOR, OQA (25) _____ Signature Date		
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature Date		
OQA VERIFICATION (29) [] SATISFACTORY *[] UNSATISFACTORY	OQA (30) _____ Signature Date		DIRECTOR, OQA (31) _____ Signature Date		

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

SHEET 2 OF 3
WBS NO. 6.0

DEFICIENCY REPORT (continuation sheet)

DR. NO. 90-015

REVISION NO. 0

DATE 3/1790

Requirements (7) (Continued)

QAAP 18.3, Paragraph 6.3.3 states:

"Evaluation of each characteristic/attribute shall be documented. When a procedure is utilized in lieu of a checklist, a marked-up copy shall become a record."

QAAP 18.3, Paragraph 7.0 states:

"Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "QA Records Management". The attachments in Section 8.0 reflect the minimum records required, as appropriate." [Attachment I contains a "Quality Assurance Checklist"]

QAAP 18.3, Paragraph 6.4.4 requires:

"As a minimum, the Director, OQA, will distribute copies of the approved surveillance report as follows:

- a) Organization surveilled;
- b) Director, OCRWM;
- c) Affected Associate Directors;
- d) Project Manager, Yucca Mountain Project Office; and
- e) Surveillance-team members."

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SHEET 3 OF 3
WBS NO. 6.0

DEFICIENCY REPORT (continuation sheet)

DR. NO. 90-015

REVISION NO. 0

DATE 3/1/90

Description of Condition (8) (Continued)

The completed checklist for Surveillance No. 89-002 is not available in the QA office files.

Four surveillance reports were checked for distribution. Surveillance No. 89-006 was not sent to the Director, OCRWM. Surveillance No. 89-012 was not sent to the team members.

Attachment 3

Observations

- 1) No management assessments have been performed since November 1986. This has been previously identified. [RW-1]
- 2) There is no standard format for position descriptions covering personnel performing activities affecting quality. The DOE needs to develop a standard format for use within OCRWM. This could be addressed by QAAP 2.2 when it is issued. [RW-3]
- 3) QAAP 5.1 needs to be revised to remove MSSD action on distribution of documents. This has been previously identified. [RW-3]
- 4) Full implementation of the RMPR depends upon the issuance and implementation of QAAP 17.1. This QAAP needs to be completed, issued, and implemented as soon as possible. This has been previously identified. [RW-3]
- 5) The Central Records Facility (CRF) is not receiving copies of all documents as required by the "Correspondence Control and Records Management Procedures" manual. Additional training in the requirements of this manual and implementation of this manual is needed to help assure that documents are sent to the CRF. [RW-10]
- 6) DR-89-031 indicates that the process of reviewing QA program descriptions identified in QAPD, Paragraph 1.1.2(f) and QAAP-2.5, Paragraph 6.4.9 cannot be objectively evaluated. The review team identified that the process is also not being implemented for other external QA program document approvals. [RW-3]
- 7) QAPD, Figure 2-1 contains a list of planned QAAPs that are applicable to program activities. Several listed QAAPs have not been issued. The QAPD should be revised to reflect the current planned QAAPs. Justification should be provided as to why the QAAPs identified in Figure 2-1 have not been issued. [RW-3]
- 8) Paragraph 5.3.2 of the SEMP states regulatory requirements related to siting and licensing the MGDS will appear in Appendix I of WMSR, Vol. IV. Based on discussions with RW-20 and -30 management personnel, Appendix I will incorporate the requirements of DOE/RW-0101, "Issues Hierarchy for a Mined Geologic Disposal System." The WMSR Management Plan should be revised to reflect this requirement. [RW-30]

- 9) Paragraph 2.3.2.1 of Volume I of the WMSR says Defense Waste Processing Facility Waste will be controlled in accordance with DOE/RW-0125. This specification only applies to Defense High Level Waste (DHLW) stored at Savannah River. Per Paragraph 4.1.1.5 and 4.1.1.6 of the WMSD, DHLW is also stored at Hanford and INEL. How will this waste be controlled? The WMSR rationale document does nothing to clarify this matter. [RW-30]
- 10) Paragraph 2.3 of the PMS Manual mentions project charters and their control. Paragraph 1.1.9.1 of the QAPD also discusses Project Charters. Project Charters do not appear in Appendix F of the PMS Manual. The YMPO Project Charter is out of date and needs revision. The need for a revised charter is not mentioned in the PMS Implementation Plan. [RW-10]
- 11) The PMS Manual (Paragraph 3.2.1.1 and 3.2.2.2) states the SEMP will provide guidance for developing the WMSR and the WMSR will identify functional requirements needed to satisfy program objectives. Attachment A of the SEMP repeats this statement.

The SEMP does not identify program objectives that must be satisfied by functional requirements within the WMSR. Also, program objectives are not identified in the PMS Manual. [RW-30]

- 12) The PMS Manual (paragraph 3.2.1.1) and SEMP (Appendix A) state that the WMSR will specify "performance levels." The WMSR specifies "performance Criteria" vs "performance levels." Appendix A of Volume I of the WMSR defines a "performance level" as being separate and different from a "performance criterion."

Volume I of the WMSR contains 11 performance criteria, eight refer to Appendix B which states "TBD." A footnote in Appendix B gives interim criteria. One criteria concerns QA and the other two pertain to the second repository. These last two criteria appear to be "constraints" in that they do not contain any criteria on the performance of either the first or second repository. [RW-30]

- 13) Paragraph 3.2.4 of the PMS Manual requires a semiannual SCP Progress Report. The SCP was issued in December 1988. A semiannual progress report has not been issued. [RW-30]
- 14) The SEMP (Paragraph 4.1.1.1) requires, sequentially, a functional analysis, physical system descriptions and then the allocation of functional requirements to systems. The SEMP does not contain guidelines for allocating requirements or performing the functional analysis. Table 2-1 of Volume I of the WMSR contains the results of a function allocation

of requirements. The supporting Rationale Document does not discuss how requirements were allocated or reference a document that contains the functional analysis.

The allocation of Functional Requirements 2.2.1.1(1) appears incorrect. This requirement was allocated only to the transportation system; however, the requirement says waste will be accepted at storage locations. Table 2-1 allocates all requirements associated with storage to the MGDS and MRS systems. [RW-30]

- 15) Page 30 (Paragraph 5.3.4.2) of the SEMP states subsystem interfaces will be defined during Advanced Conceptual Design. Page A-4 (Item 9) states the MGDS System Requirements Document will describe the subsystem configuration and relationship between subsystem elements. Page 29 (Paragraph 5.3.4.2) states the MGDS System Requirements Document is a prerequisite to Advanced Conceptual Design. This cannot be correct as it states the MGDS System Requirements Document is a prerequisite for itself. [RW-30]
- 16) Memo from Stein dated 1/9/90 contained a plan for transition from the document hierarchy in Rev. 2 of the PMS Manual to that in Rev. 3 of the PMS Manual. Since the 1/9/90 meeting, additional agreements have been reached. A new transition plan is needed that covers what is going to happen to information in certain sections of the SCP, the Issues Hierarchy (OGR/B-10), OGR SEMP, etc. If necessary, the PMS Manual and Volume I of WMSR (Fig. C-1) should be revised to reflect this new hierarchy. The change may also effect reference to the Technical Planning Basis: Site Characterization Plan (TPBSCP) cited in Paragraph 5.3.2 of the SEMP. [RW-10]
- 17) The PMS Manual identifies an Environmental Impact Statement (EIS) Implementation Plan but not an EIS, a Safety Analysis Report (SAR), or a SAR Implementation Plan. Why? [RW-10]
- 18) The "specific program objectives" specified in the Mission Plan are to site, obtain a license for, construct, and operate geologic repositories. The WMSR Volume I specifies that the major waste management functions are to accept waste, transport waste, store waste, and dispose of waste. Where are program requirements for siting, obtaining a license, and repository construction, if they are not specified in the WMSR documents? [RW-30]
- 19) Section 3.2.3.1 of the PMS Manual identifies that "Planning for technical performance measures shall begin with the selection of technical performance parameters for tracking and testing as the key indicators of programs success. Each parameter shall be related to a specific work breakdown

structure element and identified in the SEMP. Specific test requirements and site characterization criteria mandated in the WPA as amended, 10CFR60, 10CFR960, 40CFR191, and other Federal, State, and local laws and regulations shall be included." This PMS requirement is not in the current OCRWM SEMP (February 1990) and the SEMP does not impose this requirement on Project SEMPs. [RW-30]

- 20) The Program Safety and Health Plan (draft) contains numerous policy requirements. Additionally, the current draft specifies the applicable Federal, State, and local regulations related to health and safety that apply to the Program. The majority of these regulations contain engineering requirements. Why isn't this document identified in OSIR's QA Controls Matrix? Why wasn't it prepared in accordance with QAAP 3.5 and reviewed in accordance with QAAP 3.1? Note that the OCRWM Safety Plan (DOE/RW-0119) is cited as a requirements document in Volume I of the WMSR. [RW-10]
- 21) There are four distinct and separate WMSR Volumes. Each volume has a specific function and definition. It would appear that there should either be four separate management plans to develop these important design input documents instead of only one or the existing management plan should be expanded to provide additional guidance on the scope and content for each of the volumes. [RW-30]
- 22) Appendix F of the PMS Manual lists licensing plans, regulatory compliance documents, PA management Plan, PA Strategy Plan, Technical Support Documentation Management Plan, and Environmental Regulatory Compliance Plans. These documents are not required to be controlled per PCCP or PE-CCP procedures.

The OSIR QA Controls Matrix states these documents are not subject to QAR requirements and does not require that they be distributed in accordance with QAAP-6.1, "Document Control." These documents appear to be far too important not to be subject to controlled distribution. [RW-30]

- 23) RMPR Section A.3.2b states that each record, and records package received by the CRF shall have an accession number placed on it prior to processing into the system. The OCRWM SEMP Rev. 1 dated 2/90 does not have an accession number displayed nor identified in the referenced documents as required by RMPR A.3.1e which states that all referenced material in final reports will be contained in the records system and cross-referenced to the report. [RW-10]
- 24) The QA monthly reports have not consistently been issued to appropriate levels of management. The content has not always included sufficient detail to clearly determine the status

(including responses and time extensions) of corrective actions. [RW-3]

25) The quarterly quality status summaries do not always have an executive summary and appear to have insufficient trending data and analysis. In addition, it is not clear in QAAP 2.9 who is responsible for initiating the review meeting (Paragraph 5.3 and 6.6). [RW-3]

26) Observations regarding input cited in Section 3.0 of Volume I of the WMSR are as follows:

- The title given for 40CFR191 is incorrect, 40CFR191 contains "Environmental Radiation Protection Standards" vs "Environmental Standards."
- The title given for 40CFR266 is incorrect. 40CFR266 sets standards for "hazardous waste management" vs "land disposal restrictions."
- DOE Order No. 5480.2 is cited. This Order was cancelled by DOE Notice 1321.127 on October 5, 1987. As a minimum, the Rationale Document associated with the WMSR should have identified this fact and why it was necessary to invoke requirements in a cancelled document.
- DOE/RW-0119, 0125, 0136, 0184 and 0214 all contain either preliminary information or requirements which are in the process of being revised. This fact is identified in neither the WMSR or its supporting "Rationale Document."

[RW-30]

27) OQA has not evaluated responses to DRs 89-003, -014, -024 through -031, and -036. OQA has not evaluated completion of corrective action on DRs 89-001, -003, -008, -010, -011, and -033. [RW-3]

Attachment 4

Problem Identification Documents Reviewed

	<u>Status</u>
Corrective Action Report 89-001	Response accepted 4/25/89. Based on a letter from RW-20 dated 12/14/89, the following is still needed: 1) Design Control Plan (which may be part of SEMP); forecast to be complete 4/90 2) Rev. 1 of YMPO SDRD; no forecast date given 3) A management assessment prior to ESF title II design; ESF Title II design scheduled to start 2/91. However, the current SEMP dated February 1990 calls for a readiness review prior to ESF title II design as does RW-20's 4/4/89 response which was approved on 4/25/89. The revised, 12/14/89 response was not approved or acknowledged by RW-3.

Note: Management assessments (QAAP 2.7) should be to determine the effectiveness of procedures and their implementation. Accordingly, management assessments should look at the effectiveness of readiness reviews (QAAP 2.6) rather than serve as a substitute for readiness reviews.

Deficiency Report

89-001	The response to the DR was accepted on 4/27/89 and the completion due date was indicated as 4/27/89. However, verification of corrective action has not been completed as of 2/13/90.
89-002	RW-3 accepted the response to the DR on 4/27 and sent the signed DR back to RW-20. On 9/5 RW-20 asked RW-3 to close the DR but did not send the DR to RW-3 for their signature. On 9/28/89, RW-3 told RW-20 it would close the DR but didn't have the original DR to sign. On 2/13 RW-3 asked RW-20 for original DR but they could not find it.
89-003	Response was submitted to OQA on 4/4/89 but OQA has not yet evaluated the response.
89-004	OQA extension to 1/30/90 was given on 9/28/89. OQA considers this DR to be closed but has not

verified the actions.

- 89-007 This DR was never issued.
- 89-008 Response from RW-20 was accepted on 9/8/89. Per the status memo from RW-20 dated 12/15/89 the following is still needed:
1) Jamie Binley needs to attend a QA Principles class
2) Scott Van Camp needs to attend a QA orientation class
All other RW-20 employees (a total of 33 of 35) have attended the required QAR/QAPD indoctrination classes.
- 89-009 Response to RW-3 that RW-221 considers the DR closed. Awaiting verification by OQA.
- 89-010 ILP 22.3.1 was issued and went into effect 8/1/89. A detailed review of previously reviewed study plans was completed by RW-20 on 7/31/89.
- 89-011 The response was signed on 5/25/89 and accepted on 9/11/89. Actions included, "QAAP-17.1 is currently under review and should be finalized and issued by the OQA within two months." Action was due on 11/11/89.
- 89-014 The DR response evaluation block (23) has not been completed as of 2/13/90, however a letter in the file from Director OQA to Director, YMPO indicates that the response is acceptable.
- 89-024 thru 89-029 KOH responded by 11/2/89; the responses have not yet been evaluated by OQA. KOH requested extensions for 89-026, 89-027, and 89-029 with letter dated 12/29/89 and in the same letter provided an amended response to 89-027. This letter was not acknowledged on DRs, has not been officially evaluated, and has not been responded to.
- 89-030 This was issued against the OQA on 10/26/89. OQA has never documented a response to this deficiency.
- 89-031 The response from OPARM was received 1/3/90 and has not yet been evaluated by OQA.
- 89-032 Weston response to RW-3 that they consider the DR closed.

- 89-033 A response was accepted by RW-3 on 1/12/90. On 2/13/90 during a review of documentation provided by Pete Bolton, Team B verified that approved corrective action had been implemented.
- 89-034 Weston response to RW-3 that they consider the DR closed.
- 89-035 OQA requested additional response from RW-10 on 1/12/90 with the response to be received within 15 days.
- 89-036 OQA has not evaluated the response that was signed on 11/3/89.

The following were not followed up because the action was assigned to YMP.

Corrective Action Report 89-002

Deficiency Reports

- 89-005
- 89-006
- 89-012
- 89-013
- 89-015
- 89-016
- 89-017
- 89-018
- 89-019
- 89-020
- 89-021
- 89-022
- 89-023