

~~SECRET~~

# OAK RIDGE NATIONAL LABORATORY

## AUDIT HQ-92-02

*[Handwritten signature]*

	2500 Wilson Boulevard Suite 202 Arlington, VA 22201
EXPRESS MAIL <input type="checkbox"/> WEEKDAY DELIVERY <input type="checkbox"/> SATURDAY DELIVERY <input type="checkbox"/> _____ (Phone No.) UNITED PARCEL SERVICE <input type="checkbox"/> GROUND (REG) <input type="checkbox"/> 1ST DAY AIR <input type="checkbox"/> 2ND DAY AIR <input type="checkbox"/> 1ST CLASS <input type="checkbox"/> 3RD CLASS <input type="checkbox"/> OTHER _____ <input type="checkbox"/> _____ (Job No.)	Bill Belke Nuclear Regulatory Commission One White Flint North 11555 Rockville Pike (Corner of Rockville Pike and Marinelli Road) Rockville MD 20852  301-492-0445

*W. Belke  
Rec'd  
5:15 PM  
2/25/92*

*No letter received with this document*

### Oak Ridge, TN February 24 - 27, 1992

9204150078  
PDR WASTE  
WM-11

20220  
PDR

ADD: Bill Belke Encl. 1

*103-8  
WM-11  
NH03*

## NOTES FOR THE SCOPING VISIT OF ORNL ON FEBRUARY 4, 1992

- the audit is scheduled for February 24-27, 1992
- the OCRWM Programs group(also known as Systems Integration) at Oak Ridge has been performing two quality affecting tasks for over a year for OCRWM
- Mr. Ronald B. Pope is the ORNL Program Manager
- Mr. Tien Nguyen is the DOE Headquarters Project Manager(RW-321)
  - the Waste Characteristics Data Base task is being managed by Karl J. Notz. The Data Base is scheduled to be ready for use in the spring of this year.
  - the Waste Stream Analysis Model task is being managed by David S. Joy. This model is already being used to perform non quality affecting work.
- the December Monthly Progress Report is enclosed as Attachment 1
- Revision 1 of the ORNL QA Program Description was sent to OCRWM for approval in July of 1991. The QAPD was reviewed by OQA/CER and found to be acceptable.
- OQA conducted a surveillance on the peer review process for the Waste Characteristics Data Base on July 18-19, 1991. The team did not identify any CARs.
- this audit was originally scheduled to be performed in the fall of last year; however during the preliminary planning it was discovered that ORNL had not written any implementing procedures. A list of procedures was quickly developed and submitted to OCRWM for approval. During the procedure approval process it was learned that the majority of the work at ORNL would be transferred to the M & O at the end of Fiscal Year 1992. Due to this new information, OQA wrote a letter justifying using only eight implementing procedures instead of the original list of 19 implementing procedures(see Attachment 2).
- there are only eleven criteria applicable to the work being performed at ORNL(1,2,3,4,5,6,7,16,17,18,and 19)

- the audit team currently includes: Dennis Brown(ATL), Tom Rodgers(Auditor), Rod Schaffer(Auditor), Bob Clark(Audit Manager), and Tien Nguyen(Observer)
- observer organizations are being notified right now
- the notification letter and the audit plan will be ready for issuance at the completion of the scoping visit
- the scoping visit agenda is enclosed as Attachment 3

Mr. Ronald B. Pope  
MMES  
Manager, OCRWM Programs  
P.O. Box 2008  
105 Mitchell Road  
Mail Stop 6495  
Oak Ridge, TN 37831

**SUBJECT:** Scoping Visit for Audit of the OCRWM Programs Group at ORNL

Dear Mr. Pope:

DOE-HQ/OCRWM has scheduled a quality assurance audit of the work done by OCRWM Programs for OCRWM. This audit is presently scheduled for February 24-27, 1992. The NRC, State of Nevada, and affected counties will be invited to observe the performance of this audit.

Mr. Dennis Brown of CER Corporation has been in contact with Mr. Glen Cowart of your organization to schedule a scoping visit for February 4, 1992. Mr. Brown and Mr. Don Horton will be making this visit. Information obtained during this visit will be used to confirm the scope of the audit.

Enclosed is a brief listing of types of information we may be pursuing during the visit. It is requested that you or your staff be prepared to provide information on each of the listed topics during the scoping visit.

Robert W. Clark, Director  
Headquarters, Quality Assurance  
Division

cc:  
G. Cowart, MMES-ORNL  
R. Murthy, DOE-HQ  
C. Hampton, DOE-HQ  
R. Spence, DOE-HQ  
W. Booth, Weston

## ORNL SCOPING VISIT

1. Obtain OCRWM Program's organizational chart with names, titles, and phone numbers. ✓
2. Review OCRWM Program's organizational responsibilities and management methods of controlling work activities. ✓
3. Obtain a list of OCRWM Program's contractors and a description of the work activities they are performing. ✓
4. Discuss status of quality affecting work. Review documented evidence of whether or not QA controls are applicable to each work activity. ✓
5. Discuss transfer of all work to M & O at the end of FY 1992. ✓
6. Discuss the controls which need to remain at ORNL for FY 1993 for the ORIGEN code. ✓
7. Review interfaces between ORNL and OCRWM Headquarters. ✓
8. Review computer codes being used. Are any of them purchased? ✓
9. Confirm which programmatic criteria are applicable to OCRWM Program's activities. ✓
10. Discuss status of QA program development/implementation. ✓
11. Determine the steps necessary to comply with security requirements. ✓
12. Ensure that physical facilities and equipment will be able during the audit. ✓

available

# memorandum

DATE: FEB 10 1992

REPLY TO  
ATTN OF: RW-3

SUBJECT: Office of Civilian Radioactive Waste Management (OCRWM)  
Quality Assurance (QA) Audit HQ-92-02 of the Oak Ridge  
National Laboratory (ORNL) OCRWM Programs Group

TO: Manager, Office of Civilian Radioactive Waste Programs, ORNL  
(MMES)

Please be advised that a team from OCRWM, Office of Quality Assurance (OQA), will conduct a QA audit of the OCRWM Programs QA Program implementation during the period February 24-27, 1992. Current plans are for the audit team to hold a preaudit meeting on Monday, February 24, 1992, beginning at 8:30 a.m., at 105 Mitchell Road. Please arrange for the appropriate personnel to attend the meeting. The postaudit meeting is tentatively scheduled for 9:00 a.m. on Thursday, February 27, 1992.

A portion of this audit will be conducted at the offices of ER Johnson in Oakton, Va. on February 21, 1992, to assess implementation and effectiveness of the activities concerning the Waste Stream Analysis Model.

Refer to attached Audit Plan for details regarding audit scope.

The audit of implementation and effectiveness will be primarily based upon the current revisions of your implementing procedures and/or the procedures that were in effect when the reviewed activities were performed.

Observers representing the State of Nevada, U.S. Nuclear Regulatory Commission, and other interested parties may also be accompanying the team. You will be notified of these observers prior to the audit.

If you have any questions, please contact Bob Clark of my staff at (202) 586-5969 or Denny Brown of CER at (703) 276-9300.



For Donald G. Horton, Director  
Office of Quality Assurance

Attachment

**AUDIT PLAN**  
**AUDIT NUMBER: HQ-92-02**  
**AUDIT OF OAK RIDGE NATIONAL LABORATORY (ORNL)**

An audit of ORNL will be conducted the week of February 24-27, 1992 at Oak Ridge National Laboratory. A portion of this audit will be conducted at the offices of ER Johnson in Oakton, Va. on February 21, 1992, to assess implementation and effectiveness of the activities concerning the Waste Stream Analysis Model.

The audit will be conducted by:

R. Dennis Brown	CER Corp., Arlington, VA	Audit Team Leader
Fred Bearham	CER Corp., Arlington, VA	Auditor
Rodney Schaffer	Weston, Washington, DC	Auditor
Robert Clark	DOE, HQ	Observer (Audit Manager)
Tien Nguyen	DOE, HQ	Observer (Project Coordinator)

Observers from the State of Nevada, the NRC, the Edison Electric Institute (EEI), and other interested parties will be invited to participate.

AUDIT SCOPE

The audit scope will include the activities of the ORNL OCRWM Project Group's activities concerning the Waste Stream Analysis Model and the Waste Characteristics Data Base.

QA PROGRAM ELEMENTS

The implementation of the following criteria will be evaluated during the audit:

- 1 - Organization
- 2 - Quality Assurance Program
- 3 - Design Control (limited)
- 4 - Procurement Document Control
- 5 - Instructions, Procedures, and Drawings
- 6 - Document Control
- 7 - Control of Purchased Items and Services
- 17 - Quality Assurance Records
- 19 - Computer Software

The auditable requirements will be drawn from the DOE/RW-0214, Quality Assurance Requirements Document (QARD); QAP-X-91-WMRD-045, (ORNL) Quality Assurance Program Description; the Peer Review Plan and applicable ORNL Quality Assurance Procedures.

TECHNICAL AREAS

Technical specialists will not accompany the audit team.

Technical areas will be looked at for implementation and effectiveness of application of appropriate QA controls.

Qualification of technical personnel will be assessed.

## cc:

R. Spence, YMPO  
T. Nguyen, DOE-HQ  
G. Cowart, ORNL  
R. Loux, State of Nevada  
S. W. Zimmerman, NWPO, Carson City, NV  
K. Whipple, Lincoln County, NV  
M. Gaughman, Lincoln County, NV  
J. Bingham, Clark County, NV  
D. Betchel, Clark County, NV  
Englebrecht von Tiesenhasuen, Clark County, Las Vegas, NV  
S. Bradhurst, Nye County, NV  
P. Niedzielski-Eichner, Nye County, NV  
R. Campbell, Inyo County, CA  
R. Michener, Inyo County, NV  
G. Derby, Lander County, NV  
P. Goicoechea, Eureka, NV  
C. Schank, Churchill County, NV  
C. Jackson, Mineral County, NV  
F. Sperry, White Pine County, NV  
L. Vaughn, Esmeralda County, NV  
K. Hooks, NRC, Washington, D.C.  
W. Belke, NRC, Washington, D.C.  
F. Peters, HQ, (RW-2) FORS  
D. E. Shelor, HQ, (RW-30) FORS  
R. J. Brackett, TRW  
W. Booth, Weston

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.

PRELIMINARY AUDIT SCHEDULE

Audit Team Briefing	February 24th	8:00 am
Preaudit Meeting	February 24th	8:30 am
Conduct of Audit	February 24th	9:00 am - 4:00pm
	February 25 & 26th	8:30 am - 4:00pm
Post Audit Meeting	February 27th	9:00 am
Daily Audit Team Debriefing		4:00 pm
Daily Summary to ORNL		8:30 am

CHECKLIST/MARKED-UP PROCEDURES

The audit will be conducted using Audit Checklist HQ-92-02.

Prepared by:

JE Rodgers for  
R. Dennis Brown, CER Corporation  
Audit Team Leader

Date:

2/10/92

Approved by:

R.W. Clark  
For Donald G. Horton, Director  
Office of Quality Assurance

Date:

2/10/92

**OCRWM AUDIT HQ-92-02**  
**ATTENDING OBSERVERS**

**OCRWM**

Robert Clark  
Tien Nguyen

**NRC**

Bill Belke  
Bob Brient(Southwest Research Institute)

**TRW**

Camille Kerrigan  
Ivan Sacks(Oakton portion)

**OCRWM AUDIT HQ-92-02 TEAM ASSIGNMENTS**

Audit Team Leader: R. Dennis Brown, CER Corporation(Criteria 1, 3, 4, 7, and 16)

Auditor: Fred Bearham(Criteria 5, 6, and 17)

Auditor: Rod Schaffer(Criteria 2 and 19) *Rod*

MONDAY	TUESDAY	WEDNESDAY	THURSDAY
0830-Team and Observer Briefing	0830-ATL Brief ORNL Management  Criteria 3(Peer Review Plan), 6, 19	0830-ATL Brief ORNL Management	0900-Postaudit Meeting
0900-0930 Preaudit Meeting		Criteria 19	
0930-Commence Audit  Criteria 1, 2, 4, and 5			
1200 - 1300 Lunch			
1300  Criteria 4, 6, 7, and 19	1300  Criteria 3(Peer Review Plan), 17, 19	1300  Criteria 19	
1600 Team Debriefing	1600 Team Debriefing	1600 Team Debriefing	

OCRWM AUDIT HQ-92-02  
DAILY CAUCUS AGENDA

- 1) ATL cover items of general interest (i.e. logistics, schedule changes, etc.).
- 2) Each auditor will present:
  - a) ANY CRITERIA COMPLETED (if so, an effectiveness statement shall be prepared, read at the caucus, and given to the ATL).
  - b) POSITIVE OR NEGATIVE FINDINGS IDENTIFIED (not potential findings!) If so, the draft CAR(s) shall be prepared, read at the caucus, and given to the ATL.
  - c) POSITIVE OR NEGATIVE OBSERVATIONS (If so, the draft observation(s) shall be prepared, read at the caucus, and given to the ATL).
  - d) ANY REMEDIAL CORRECTIVE ACTIONS TAKEN IMMEDIATELY (If so, a description of the remedial actions taken shall be prepared, read at the caucus, and given to the ATL).
  - e) ITEMS REQUIRING COORDINATION WITH OTHER AUDITORS
  - f) ITEMS REQUIRING ATL ACTION
  - g) PLANS AND SCHEDULE FOR NEXT DAY

Note: We do **NOT** want to get into any philosophical discussions in the caucus!

- 3) Each observer will be given an opportunity to speak.
- 4) Adjourn!

Note: Every effort should be made to keep these meetings as short as possible consistent with covering all **necessary** information!

**OCRWM AUDIT HQ-92-02**  
**AUDITOR RESPONSIBILITIES**

1. Attendance at the preaudit and postaudit conference.
2. Start auditing each day at 0830.
3. Attend the daily team caucus at 1600.
4. Draft CARs by the morning after they are identified (prior to the daily morning briefing with ORNL management).
5. Attend the morning meeting with ORNL to explain any CARs identified.
6. Provide list of deficiencies corrected during the previous day (for morning briefing meeting).
7. Provide draft effectiveness statement for each criterion as completed.
8. Draft input to the audit report by 03/13/92.
  - who you contacted.
  - what documents you looked at.
  - narrative of what you did.
  - completed audit checklist.

OCRWM AUDIT HQ-92-02  
ORIENTATION

- 1) Status of Work Activities
  - a) Waste Characteristics Database
  - b) Waste Stream Analysis Model
  - c) ORIGEN2 computer code
- 2) Status of QA program development and implementation
  - a) History ←
  - b) New QAPD and implementing procedures
  - c) Previous internal/external verification activities
- 3) Logistics
  - a) Badging
  - b) Arrival/departure times
  - c) ORNL contacts
- 4) Audit Philosophy
  - a) Communicate
  - b) Be objective
  - c) Cover all the bases
  - d) Gain acceptance
  - \* e) Don't Preach
  - f) Encourage Remedial Action
  - \* g) Emphasis on performance/results/product rather than strictly on compliance! (i.e. ask yourself so what? What is the impact?)

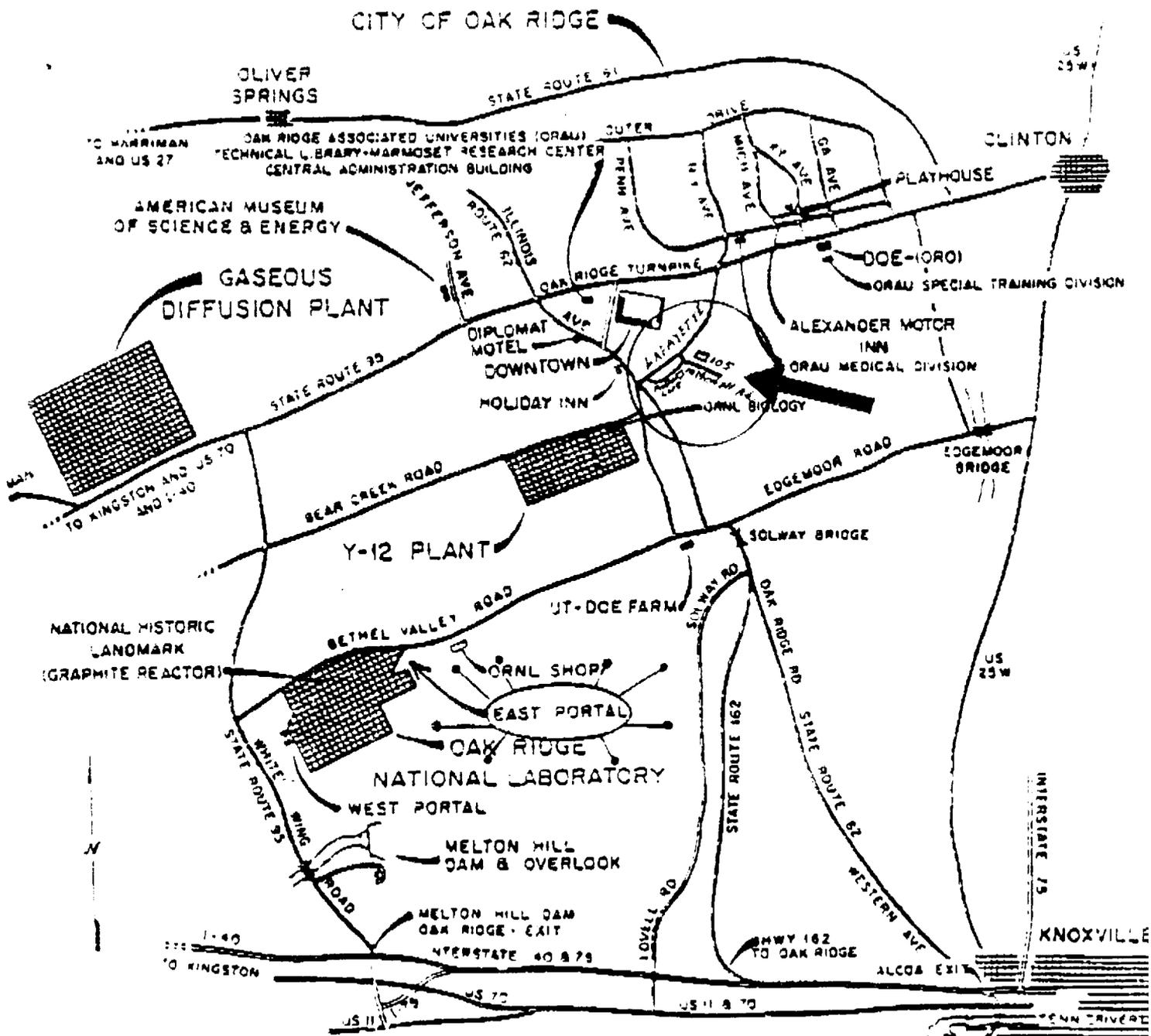
**OCRWM AUDIT HQ-92-02**  
**TEAM/CRITERION/CHECKLIST ASSIGNMENTS**

Audit Team Leader: Dennis Brown

<u>PERSONNEL</u>	<u>CRITERIA</u>	<u>QAPS/OTHER PROCEDURES</u>
Dennis Brown	1, 3, 4, 7 16	CDB Peer Review Plan QAPD
Fred Bearham	5, 6, 17	05-001; 05-002; 06-001; 17-001
Rod Schaffer	2, 19	02-001; 02-002; 19-001; 19-002; Verification Plan for WSA Model

# DOE-OAK RIDGE INSTALLATIONS AND ENVIRONS

ORNL-LR-DWG 48116A243



KNOXVILLE AIRPORT TO CITY OF KNOXVILLE	20 km
KNOXVILLE TO CITY OF OAK RIDGE	30 km
OAK RIDGE TO Y-12 PLANT	5 km
OAK RIDGE TO OAK RIDGE NATIONAL LABORATORY	20 km
OAK RIDGE TO GASEOUS DIFFUSION PLANT	15 km

NOT TO SCALE

TO ALCOA AND MARYVILLE

— BEST ROUTES

# memorandum

QA

DATE: FEB 04 1992

REPLY TO: RW-3.1  
ATTN OF:

SUBJECT: Acceptance of the OCRWM Systems Integration Support QA Program Description (QAPD), Revision 1, and the QA Requirements Matrix

TO: Chief, Systems Engineering Branch, RW-321

The Headquarters Quality Assurance Division (HQAD) has reviewed Revision 1 of the QAPD for Oak Ridge National Laboratory's (ORNL) Program, developed in support of the Systems Engineering Branch. The associated QA Requirements Matrix, completed by ORNL, was included in this review.

The HQAD considers that the ORNL QAPD adequately describes the QA Program developed for the ORNL scope of work. Consequently, the HQAD has no comments on the ORNL QAPD, Revision 1, and the QA Requirements Matrix. Acceptance of the subject QAPD is recommended.

If you have any questions, please contact me at ext. 6-1238.



Robert W. Clark, Director  
Headquarters Quality Assurance  
Division

## Attachment

### cc:

J. Roberts, RW-30  
T. Nguyen, RW-321  
D. Spence, YMPO  
W. Booth, Weston  
D. Brown, CER

# memorandum

QA Record

DATE: FEB 10 1992

REPLY TO  
ATTN OF: RW-321

SUBJECT: ORNL QA Program for Systems Engineering Support

TO: Rick Collier, DOE Oak Ridge Field Office

This is to identify priority Quality Assurance procedures which should be in place in FY92 for ORNL's OCRWM Systems Engineering support. ORNL is performing three quality-affecting tasks for OCRWM: Waste Characteristics Data Base (CDB), Waste Stream Analysis Model, and Improved Utilization of ORIGEN2. The first two tasks are scheduled to be transitioned to OCRWM's M&O contractor by the end of FY92, while the ORIGEN2 task is expected to continue at ORNL in FY93.

ORNL's Quality Assurance Program Description (QAPD) references a number of implementing procedures. In FY92, it will not be necessary for ORNL to develop all currently planned procedures. Resources should be focused on eight specific procedures which are relevant to existing tasks. The eight procedures are:

QA-SI-02-001	Establishing QA Controls
QA-SI-19-001	Computer Code Verification and Validation
QA-SI-05-001	Procedure Preparation
QA-SI-05-002	Document Reviews
QA-SI-06-001	Document Control
QA-SI-17-001	QA Records
QA-SI-19-002	Computer Code Transfer
QA-SI-02-002	Indoctrination and Training

We will evaluate the need for each of the remaining eleven procedures to determine which procedures should be developed in FY93 to support the ORIGEN2 task which will carry on through FY93. Based on input from our Office of Quality Assurance, the procedures which may be delayed and associated justification are as follows:

QA-SI-01-001    Dispute Resolution

Section 1.6 of ORNL's QAPD contains enough direction to resolve any disputes that might occur between now and September 30, 1992.

QA-SI-01-002 Stop Work

Section 1.8 contains enough instructions to stop work should the need arise between now and September 30, 1992. If additional guidance is needed, ORNL should refer to OCRWM QAAP 16.2 and request that OCRWM stop the work.

QA-SI-04-001 Procurement Document Control

No procurements are planned by ORNL for the tasks in question.

QA-SI-07-001 Control of Purchased Items and Services

No procurements are planned by ORNL for the tasks in question.

QA-SI-16-001 Occurrence Reporting

Section 16.0 contains enough information to implement DOE's Unusual Occurrence Reporting requirements.

QA-SI-16-002 Corrective Action

ORNL will report adverse conditions to OCRWM. Upon being advised of an adverse condition, OCRWM will use QAAP 16.1 to document and correct the deficiencies.

QA-SI-18-003 Surveillance

OCRWM will perform surveillance activities at ORNL for the three tasks between now and September 30, 1992.

QA-SI-18-001 QA Audits

OCRWM will perform a comprehensive QA audit of ORNL's three quality-affecting tasks during the first quarter of 1992.

QA-SI-18-002 Qualification of Audit Personnel

OCRWM, rather than ORNL, will conduct QA audits of ORNL's quality-affecting activities during this time frame.

QA-SI-06-002 Controlled Document Listing

The information will be contained either in QA-SI-06-001, QA-SI-17-001, or both.

QA-SI-02-003 Management Assessment

The tasks will be of limited duration at ORNL.

ORIGINAL  
FUNDING  
CUT

Thank you for your cooperation. If you have questions, please contact Tien Nguyen of my staff at 896-2839.

  
William A. Lemeschewsky, Chief  
Systems Engineering Branch  
Office of Civilian Radioactive  
Waste Management

cc: Robert Clark, RW-3.1  
Glenn Cowart, ORNL  
Dennis Brown, CER

WSA-VERP-1 Rev. 2

PLAN FOR THE VERIFICATION  
OF THE  
WASTE STREAM ANALYSIS PROGRAM

April 10, 1991

Approval/Signature Page

Reviewed and Approved:

William C. McClain  
System Integration Program Manager

April 16, 1991  
Date

David J. Joy  
System Integration Task Leader

April 16, 1991  
Date

C. D. Cuvatt  
ORNL QA Specialist

April 16, 1991  
Date

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## COMPUTER CODE VERIFICATION PLAN

for the

Waste Stream Analysis Program

### 1.0 PURPOSE AND SCOPE

#### 1.1 PURPOSE

The purpose of this Verification Plan is to establish specific responsibilities and methods for the verification of the Waste Stream Analysis (WSA) program in order to do quality affecting work for the support of the Office of Civilian Radioactive Waste Management (OCRWM). This verification plan implements the requirements of procedure QA-SI-19-001 and meets the intent of Section 19 Part 6 of the OCRWM QARD.

#### 1.2 SCOPE

The scope of the activities described in this plan is to verify that the WSA program correctly calculates the quantities, identity and characteristics of spent fuel and loaded fuel containers, and correctly selects both fuel and containers for all the programs major options. It has been determined that validation is not applicable to inventory and flow simulation programs such as the WSA program, this plan is limited to the verification of the WSA program. This plan may be changed during the verification process without additional approval. These changes will be made only if valid reasons are identified in the verification process. These changes will be subsequently reported in the Verification Report where they will be subject to review and approval. When the verification process is complete the program will be baselined, a configuration management procedure established, and the proper documentation produced. This documentation will assure that a generally knowledgeable user, unfamiliar with the WSA program, can prepare input and obtain output from running the WSA program using the information contained in the WSA User Manual.

## 2.0 REFERENCES

- 2.1 Quality Assurance Requirements Document (QARD), Section 19, DOE/EW-0214
- 2.2 QA-SI-19-001, Computer Code Verification and Validation.
- 2.3 QAP-X-91-WMRD-045, Quality Assurance Program Description for System Integration (Draft).
- 2.4 Final Technical Position on Documentation of Computer Codes for High-level Waste Management, NUREG-0856.

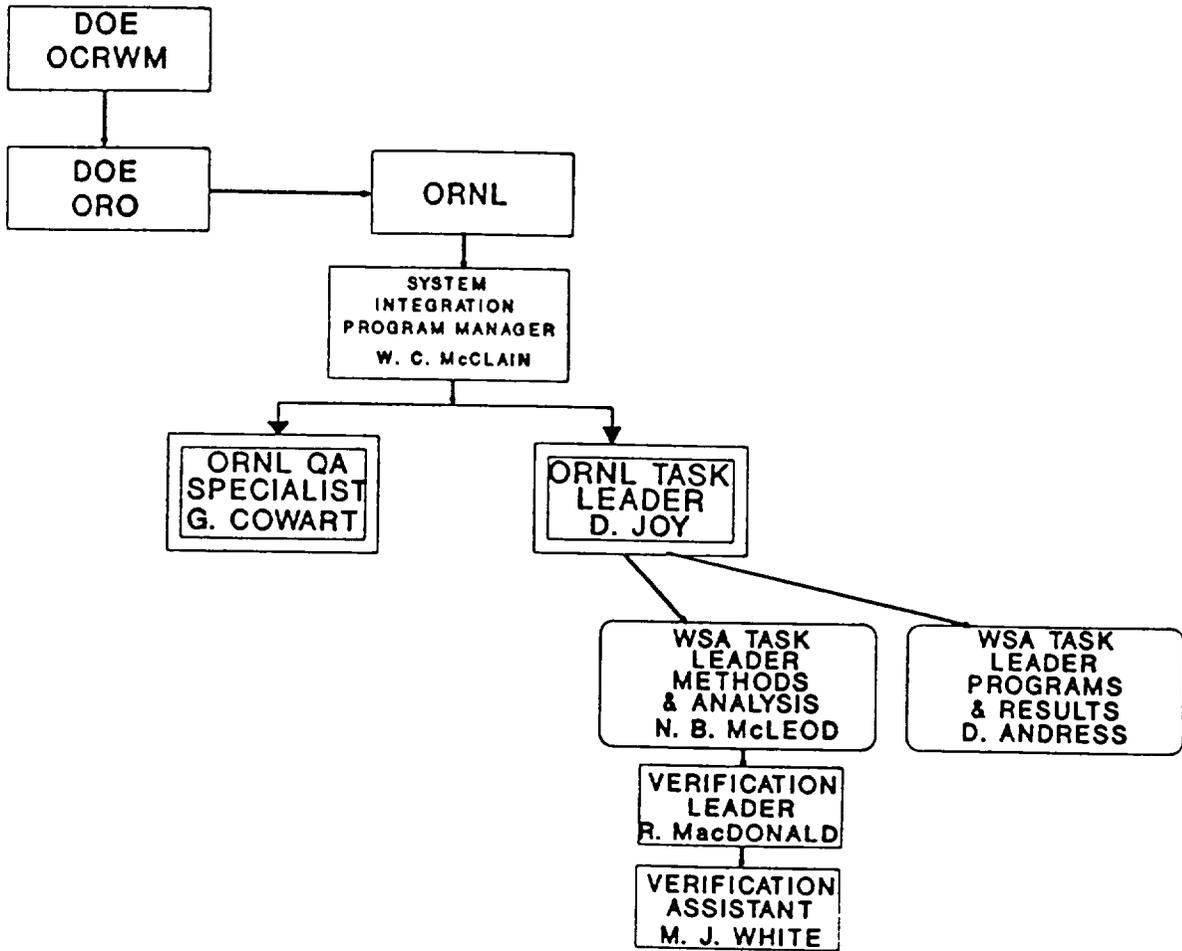
## 3.0 DEFINITIONS

- 3.1 Baseline - Collection of Configuration Items (CIs) making up a controlled and approved configuration of software and documentation.
- 3.2 Configuration Management (CM) - Formal procedures for tracking individual software and documentation elements and changes to them.
- 3.3 Data - The inputs to a system or application.
- 3.4 Database - collection of separate data structures accessible at the same time within the same software system or application.
- 3.5 Off-the-Shelf Commercial Software - packages such as dBASE, Lotus 1-2-3, SAS. Such software is sold commercially and can be used as a stand-alone application, where the user is interacting directly with the software package, or it can be embedded in an internally developed system. The quality of this software is assumed for stand-alone application and tested where embedded in system.
- 3.6 Reporting Software - any module that outputs tabular or textual report outputs (e.g., SAS report generator modules).
- 3.7 Source Code - text of instructions for a given module in a particular language.
- 3.8 User - Individual who uses systems or applications at a beginner, intermediate or expert level and may participate in the analysis and testing phases of system development, but does not participate in the design and implementation phases.

- 3.8 User Documentation - Any document that describes the details of how to use a system or application. Examples include "Tutorial Guide" and "User's Reference Manual".
- 3.9 Validation - assurance that a model, as embodied in a computer code, is a correct representation of the process or system for which it is intended.
- 3.10 Verification - assurance that a computer code correctly performs the operations specified in a numerical model.
- 3.11 Verification Report - A report which documents the results of the verification process and identified the records which were generated and retained.

#### 4.0 ORGANIZATION

The following Organization Chart shows the relationship between ORNL (including its technical direction and QA functions) and the WSA subcontractors, E. R. Johnson Associates, Inc. (JAI) and David Address & Associates, Inc. (DAA).



## 5.0 RESPONSIBILITIES

The following sections itemize the roles or functions needed on the verification task.

### 5.1 SYSTEM INTEGRATION PROGRAM MANAGER

The Program Manager is responsible for:

- 5.1.1 Reviewing and approving this Verification Plan.
- 5.1.2 Reviewing and approving all applicable documents itemized in this plan.

### 5.2 SYSTEM INTEGRATION TASK MANAGER

The Task Manager is responsible for:

- 5.2.1 Reviewing and approving this Verification Plan.
- 5.2.2 Reviewing and approving all applicable documents itemized in this plan.

### 5.3 QUALITY ASSURANCE (QA) SPECIALIST

The QA Specialist is responsible for:

- 5.3.1 Reviewing and approving this Verification Plan.
- 5.3.2 Reviewing and approving all applicable documents, in particular for their adherence to the QA procedures.
- 5.3.3 Enforcing adherence to standards.

### 5.4 WSA TASK LEADER (Methods & Analyses)

The Task Leader is responsible for:

- 5.4.1 Reviewing this Verification Plan.
- 5.4.2 Selecting Verification Staff.
- 5.4.2 Participating in review meetings scheduled during the Verification Process.

### 5.5 VERIFICATION LEADER

The Verification Leader is responsible for:

- 5.5.1 Taking the lead, in the directing of preparation and control of data sets, test case input, checking of test case results and completing

verification according to the procedures in this plan, once final approval is received.

5.5.2 Preparing the Verification Report according to the requirements of this plan.

5.5.3 Identifying and putting under control, the test results and records, as Quality Records according to the requirements of the QA procedures.

5.6 WSA TASK LEADER (Program and Results)

The Task Leader is responsible for:

5.6.1 Identifying and putting under control, the version of the WSA program to be verified and maintain this control through any revisions made during verification.

5.6.2 Supporting the Verification Leader when requested during the verification process.

5.6.3 Making any program or documentation revisions that arise out of the verification process.

5.6.4 Implementing a Configuration Management Control in accordance with the applicable QA procedures.

## 6.0 VERIFICATION PROCEDURES

The principal verification procedures will be the use of comparisons of WSA results with results developed with the independent use of supporting software (ie SAS), with other verified models, or with hand calculations. The main verification process is based on making a series of runs with the WSA code using a shortened reactor database and life history, where only a single item is changed between cases. This approach allows the verifier to easily determine whether the section of the code being tested is working correctly. Additionally, a limited number of runs will be made on the full RW-859 database for its full life history. These runs will be used to check the overall performance of the model. The details as to what is tested and how it is to be checked is described below in the Test Case Descriptions.

## 6.1 TESTING REQUIREMENTS

### Major Options To Be Tested

In general, quantities, identities and characteristics are to be verified as appropriate for the following major WSA Options:

Allocation: OFF, FCR, DECOM, User-input  
Selection: OFF, YFF5, YFF14, CFF

Cask Selection: With and without dose rate functions

Waste Package Selection: With and without heat functions

Configuration: No-MRS  
MRS FIFO  
MRS LIFO  
MRS, removal for blending  
MRS with consolidation, packaging

Certain combinations of above scenarios.

Specific Items To Be Verified: The following specific quantities, identities and characteristics are to be verified within the context of the specific cases that are described later in the Test Case Descriptions.

### Quantities

#### Fuel:

- Inventories at individual reactors, in storage, and in the repository(s)
- Flows
  - in/out of utility and DOE storage
  - from-reactor and from-MRS transport
  - consolidation at utility and DOE facilities
  - waste packaging
  - disposal

#### Fuel containers loaded/unloaded:

- consolidated SNF canisters at utility and DOE facilities
- at-reactor and at-DOE dry storage casks
- from-reactor and from-MRS transport casks
- waste packages

Identities and Characteristics

Fuel: Reactor No., type, burnup, age, enrichment in:

- at reactor inventories, in-pool, consolidated, dry-stored
- at time of acceptance by DOE
- at time of storage by DOE
- at time of waste packaging by DOE
- at time of emplacement by DOE

Loaded Fuel Containers: Batch no., etc. for:

- consolidated canisters at utilities and DOE
- loaded casks -- external dose and heat
- loaded waste packages -- heat, integrated heat and isotopes at emplacement

## 6.2 TESTING AND EVALUATION METHODS AND CRITERIA

The compiled WSA source code will be tested to verify that the developed software correctly executes the designed system. The Test Case Descriptions include general guidelines for conducting each type of test, specific items to be tested in the Test Criteria, and the specific lists to be used to record the results.

All tests will be documented, so that is easy to see that all capabilities have been addressed and that all tests have been executed. The computer output, hand calculations, as well as the listings of test data sets, and other materials will become Quality Records.

### 6.3 TEST CASE DESCRIPTIONS

The approach to the verification of the WSA program is through the use of a series of test cases, described in detail in the following. Test Cases 1-7 and their sub-cases are based on selected reactors to provide a wide range of options. Test case 8 and its sub-cases, are based on the complete 1989 RW-859 Database.

Test Case 1 OFF/OFF, No MRS, No Cask Rounding

#### Description of Case -

Case 1 will be the test case upon which a large percentage of the verification activities will be performed. This case will test whether the oldest fuel first allocation and selection criteria work. This test case consists of four reactors which have a large history of discharges. All shipments will be sent to the repository where the assemblies will be packaged into a canister and emplaced in the rock formation. This case will test the report programs which calculate the various physical, thermal and radiological properties.

Allocation/Selection - OFF/OFF

#### Reactor Base -

A test case will be constructed based on four reactors with sufficient and varied discharges to demonstrate the system. The reactors will be a mix of PWR/BWR, Truck/Rail and Small/Large Pool capacity.

#### Acceptance Rate -

The acceptance of fuel will be modelled for a ten year period. The acceptance rate will ramp up to a rate greater than the combined discharge rate of all reactors in the case.

#### Cask Rounding - None

This test will consider only the number of assemblies moved, not the number of cask loads required to perform the movements.

#### Configuration -

All shipments go directly to the repository. The assemblies will be packaged at the repository. In this case the packages will be loaded to full capacity. The heat content of each emplacement package will also be calculated and verified.

#### Test Criteria -

A table of fuel discharge dates at the time of fuel acceptance will be used to determine whether the OFF/OFF logic

is giving the proper results. The heat content at the time of emplacement will also be reported as basic output for this case. This data will be checked by hand calculations.

The following additional information will be tested in this case:

1. The various report programs will be run to calculate the thermal and radiological properties, heat, integral heat at 150 years, gamma radiation, and neutron radiation.
2. The following report programs which summarize data will be verified by SAS runs or hand calculations.

Reports to be Tested:

1. ARCON - Case 1h
2. AREATEMP - Case 1
3. ARINVEN - Case 1
4. AVGBHR - Case 1
5. AVGBHRT - Case 1
6. AVGCMP - Case 1 & 1d
7. AVGDISCH - Case 1
8. AVGMNMX - Case 1
9. AVGWART - Case 1
10. BURNAGE - Case 1
11. BURNTBL - Case 1
12. DECOM - Case 1
13. HEAT - Case 1
14. PCKUPAGE - Case 1
15. PERCENT - Case 1
16. PLOTAGE - Case 1
17. RCTTBLE - Case 1
18. TASK8 - Case 1
19. TYPTBLE - Case 1
20. WP2KW - Case 1 & 1c
21. WP4B3P - Case 1 & 1c

Case Perturbations:

1. Case 1a OFF/OFF Cask Roundup
2. Case 1b OFF/OFF Cask Rounddown
3. Case 1c OFF/OFF Partial Loaded Cask
4. Case 1d OFF/YFF5
5. Case 1e OFF/YFF14
6. Case 1f OFF/CFF
7. Case 1g OFF/HFF
8. Case 1h OFF/OUFF With Reactor Consolidation >5yr. 2:1 Fuel, 10:1 Hardware

Test Case 2 OFF/OFF, No MRS, Cask Design Curves - Averaged

Description of Case -

Case 2 will test the cask design curves phase of the program.

Allocation/Selection - OFF/OFF

Reactor Base - Same as Test Case 1  
Acceptance Rate - Same as Test Case 1

Cask Rounding - None

Configuration - Same as Test Case 1

Test Criteria - Lower priority casks are selected when external doses are too high for the higher priority casks. The following report programs which summarize data will be verified by SAS runs or by hand calculations.

Reports to be Tested:

1. DOSE - Case 2 & 2a

Case Perturbations:

1. 2a OFF/OFF Cask Design Curves - Peak

Test Case 3 OFF/OFF, With MRS FIFO, No Cask Rounding,  
No Unit Train

Description of Case -

Case 3 will test the model with a MRS. All shipment will be sent to the MRS where the assemblies will be packaged into the from MRS Transport Cask and sent to the Repository.

Allocation/Selection - OFF/OFF

Reactor Base - Same as Test Case 1

Acceptance Rate - Same as Test Case 1

Cask Rounding - None

Configuration -

All shipments go directly to the MRS and then to the repository which is delayed from its startup in test case 1. The assemblies will be packaged at the repository. In this case the transporter will be loaded to full capacity with no cask rounding or unit trains.

Test Criteria -

Correctness of the shipments and inventories with an MRS in the system will be checked, as well as the increased fuel age and reduced heat at the repository. The correctness of the fuel selection and the from-MRS cask loadings will be checked by SAS runs or by hand calculations.

Reports to be Tested:

1. HARDWARE - Case 3b
2. NUMCASKS - Case 3

Case Perturbations:

1. Case 3a OFF/OFF with MRS LIFO Unit Train
2. Case 3b OFF/OFF with MRS FIFO with 90% Consolidation

Test Case 4 OFF/OFF in Pool, No MRS, No Cask Rounding,  
With Dry Storage

Description of Case -

Case 4 will test pick up from reactors that have dry storage.

Allocation/Selection - OFF/OFF

Reactor Base - Same as Test Case 1

Acceptance Rate - Same as Test Case 1

Cask Rounding - None

Configuration - Same as Test Case 1

Test Criteria -

The correctness of fuel selection from the pool, when the oldest fuel has been put into dry storage will be checked by SAS runs or by hand calculations.

Reports to be Tested:

1. DRYCASK - Case 4 & 4a
2. DRYTBLE - Case 4 & 4a
3. DRYTBLE1 - Case 4 & 4a
4. POOLPIC - Case 4

Case Perturbations:

1. Case 4a OFF/YFF5 in pool, Dry Storage

**Test Case 5 FCR-OFF/OFF, No MRS, No Cask Rounding**

**Description of Case -**

Case 5 will be the test case to check the FCR allocation procedures.

**Allocation/Selection - OFF/OFF**

**Reactor Base - Same as Test Case 1**

**Acceptance Rate - Same as Test Case 1**

**Cask Rounding - None**

**Configuration - Same as Test Case 1**

**Test Criteria -**

Priority allocation of acceptance rights to reactors losing Full Core Reserve will be checked by SAS runs or by hand calculations.

**Reports to be Tested:**

1. DECOM - Case 5

**Test Case 6 DEC-OFF/OFF, No MRS, No Cask Rounding**

**Description of Case -**

Case 6 will be the test case to check the DEC allocation

**Allocation/Selection - OFF/OFF**

**Reactor Base - Same as Test Case 1**

**Acceptance Rate - Same as Test Case 1**

**Cask Rounding - None**

**Configuration - Same as Test Case 1**

**Test Criteria -**

Priority allocation of acceptance rights to shutdown reactors with fuel of >5 years of age will be checked by SAS runs or by hand calculations.

**Reports to be Tested**

1. DECOM - Case 6
2. DCOMA - Case 6

**Test Case 7 User Input, No MRS, No Cask Round**

**Description of Case -**

**Case 7 will test the User Input allocation phase of the program.**

**Allocation/Selection - User/OFF**

**Reactor Base - Same as Test Case 1**

**Acceptance Rate - Same as Test Case 1**

**Cask Rounding - None**

**Configuration - Same as Test Case 1**

**Test Criteria -**

**Priority allocation based on user input priority will be checked by SAS runs or by hand calculations.**

**Reports to be Tested: None**

Test Case 8 - OFF/OFF, No MRS, No Cask Rounding, Full RW-859 Database

Description of Case -

Case 8 will be a full 1989 RW-859 case. It will be used to perform general verification activities and to check overall model performance. This case will test whether the oldest fuel first allocation and selection criteria work. All shipment will be sent to the repository where the assemblies will be packaged into a canister and emplaced in the rock formation. This case will test the report programs which calculate the various physical and radiological properties.

Allocation/Selection - OFF/OFF

Reactor Base - 1989 RW-859

Acceptance Rate -

The acceptance of fuel will be the Mission Plan rate for the first repository.

Cask Rounding - None

Configuration -

All shipments go directly to the repository. The assemblies will be packaged at the repository. In this case the packages will be loaded to full capacity.

Test Criteria -

The Aggregate totals will be checked against the totals from the RW-859 Database, each years totals will be checked against the waste acceptance rate, the life history of 3 reactors will be checked against the totals from the RW-859 database, and the pick up sequence for one reactor will be checked to determine whether the OFF/OFF logic is giving the proper results. This data will be checked by hand calculations and independent SAS runs to get target number to test against.

The following report programs which summarize data will be verified as to aggregate values of age and burnup. Since these report programs use a off-the-shelf commercial program, SAS, it is assumed that SAS performs its internal functions correctly and the verification will involve only those items of calculation, interpolation, and labelling.

Reports to be Tested:

1. ASMBLEN
2. AVGBH
3. AVGBHR
4. AVGBHRT

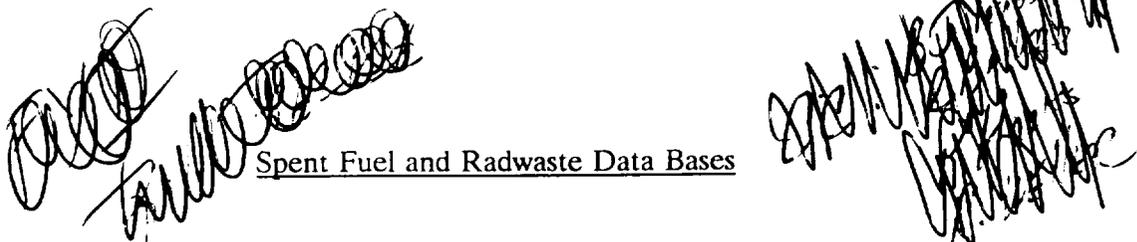
5. LASTSHIP
6. NUMCASKS
7. TBLE859
8. WP4B3P

Case Perturbations: (Will test only the variants from case 8)

1. Case 8a FCR/OFF, Dry Storage, No Cask Roundup
2. Case 8b OFF/YFF14, Waste Package Heat derating, No Cask Roundup

## 7.0 DOCUMENTATION AND QA RECORDS REQUIREMENTS

The documentation that will be entered as quality records includes: 1) The Verification Plan. 2) The Verification Report. 3) The computer output, hand calculations, as well as the listing of the test data sets, and other material. and 4) The User Manuals. The documentation will follow guidance from NUREG-0856 Final Technical Position on Documentation of Computer Codes for High-level Waste Management and meet the requirements defined in QA-SI-19-001. The Quality Records Requirements for documenting the verification of WSA are defined in QA-SI-19-001 and will be followed in this process.



Spent Fuel and Radwaste Data Bases

The U.S. Department of Energy (DOE) will eventually be directly responsible for all of the nation's spent nuclear fuel and already has jurisdiction over high-level waste, transuranic waste, remedial action waste, and much of the low-level waste. The ready availability of comprehensive and self-consistent data on inventories, projections, and characteristics of these materials is clearly an essential component of all aspects of dealing with these materials. Included are storage, transportation, and final disposal, as well as the strategic planning and systems analyses that must precede and accompany the actual physical operations. Toward this objective, the DOE has funded the creation of two major data bases, the so-called Integrated Data Base and Characteristics Data Base. Both were conceived within the Chemical Technology Division and implemented by Chem Tech staff. Both draw extensively on data sources external to ORNL and depend strongly on cooperative interaction with other national laboratories and other DOE organizations. Both have acquired a well-deserved reputation for thoroughness and integrity of technical data. Both are highly regarded by their many users. Each is described briefly in the following paragraphs.

The Integrated Data Base, referred to as the IDB, provides domestic spent fuel and radioactive waste inventories, projections, and characteristics of spent fuel, high-level waste, TRU waste, low-level waste, remedial action waste, mill tailings and mixed waste. Thus, the IDB covers all radioactive materials, which necessarily limits the level of detail. These data are assembled in a one-volume report. It was first published in its present form in 1981 and is updated annually. The latest (1991) edition is report number DOE/RW-0006, Revision 7. Along the way, a PC data base of summary data was added, using a menu-driven format written in dBASE. This was one of the first significant applications of PC technology and matching data base management software within DOE. Among its many users the IDB report is often referred-to as "the blue book" because of its blue cover.

The Characteristics Data Base, or CDB, covers only those materials that will, or may, be eventually disposed of in a geologic repository (such as Yucca Mountain). This includes light-water reactor (LWR) spent fuel, immobilized high-level waste, non-LWR spent fuel, and miscellaneous wastes (which are largely sealed isotope capsules and greater-than-Class-C low-level waste). These materials are characterized in extensive detail, including physical, chemical, radiological, and thermal properties as well as inventories and projections. The CDB was first issued in 1987-1988 as eight volumes plus five PC menu-driven data bases covering LWR quantities, assemblies, hardware, and radiological properties and high-level waste. The first revision will be released in 1992 as report number DOE/RW-0184, Revision 1, and has an additional PC data base, on LWR assembly serial numbers.

Both developments were lead by Karl Notz. The original IDB staff included Herschel Godbee, Lloyd Carter, Arlene Kibbe, Chuck Alexander, Charles Forsberg, and Wayne Morrison. The original CDB staff included Royes Salmon, Al Irvine, Tim Welch, and Scott Moore (a local consultant from Automated Sciences Group) plus dBASE programmers.

CDB PEER REVIEW # STATUS (Continued)  
February 18, 1992

	<u>Certifications Received</u>	<u>Mail Out</u>	<u>Comments (Due) and Received</u>	<u>Response By Authors (Due) and Received</u>		<u>Reviewers Final Response</u>
				<u>KJ Notz</u>	<u>Others</u>	
<u>NFA Hardware</u>		(Sept. 27)	(Oct. 21)			
Andy Luksic	April 25	Dec. 20				
<u>James Wheeler</u> PRIVATE CONSULTANT	July 29	Dec. 20	Jan. 22			
Michael White	July 22	Dec. 20				
<u>Non-LWR Spent Fuel</u>			(Sept. 27)			
Douglas Rickard	July 22	August 2	Nov. 22	Dec. 17	Dec. 17	Dec. 30
Lee Bendixsen	May 31	August 2	Sept. 4 (1)	N/A	N/A	N/A
✓ <u>Matthew Beckum</u> SPAN RIV	Sept. 4	August 20	Sept. 18	Oct. 23	Oct. 23	Nov. 18
Ray Pearson	Sept. 5	August 20	Sept. 10 (2)	Oct. 16 (2)	Oct. 16 (2)	Oct. 16 (2)
<u>Miscellaneous Wastes</u>		(Sept. 5)	(Sept. 30)			
Meraj Rahimi	Sept. 23	Sept. 4	Sept. 27	Dec. 2	Dec. 2	Dec. 16
<u>Mary Magleby</u> EGFC	Oct. 7	Sept. 4	Oct. 22	Nov. 11	Nov. 11	Dec. 10
Roger Piscitella	Sept. 23	Sept. 4	Oct. 22	Nov. 11	Nov. 11	Dec. 10

(1) Reviewer had no comments.

(2) Reviewer's comments for the addition of Section 4.4 are still in process.

Note: Areas highlighted are overdue or need to be scheduled

	Certifications Received	Comments (Due) and Received	Response By Authors (Due) and Received		Reviewers Final Response
			KJ Notz	Others	
<u>High Level Waste</u>		(April 8)	(June 14)	(June 27)	(Sept. 5)
Michael Crony <i>WEST HAMPER</i>	May 14	May 14	June 14	July 24	Sept. 3
Herschel Godbee	April 24	May 15	June 14	July 29	Sept. 3
Lee Bendixsen	May 31	May 28	June 14	August 2	Sept. 18
Rob Palmer	April 25	April 25	June 14	August 2	August 5
John Plodinec	March 28	April 8	June 14	August 2	August 14
Bob Watrous <i>WEST. HAMP</i>	July 12	June 7	June 14	August 1	Sept. 18
<u>LWR Spent Fuel</u>		(April 22)	(Aug. 30)	(Sept. 18)	(Oct. 1)
Billy Cole	April 1	April 23	Dec. 11	Dec. 11	Dec. 31
Ray Lambert	April 30	April 30	Nov. 27	Nov. 27	Feb. 4
Herman Leider <i>LCNL</i>	April 5	April 15	Nov. 25	Nov. 25	Jan. 13
Andy Luksic	April 25	May 9	Dec. 12	Dec. 12	
John Mendel <i>PNL</i>	April 8	April 25	Dec. 17	Dec. 17	
<u>ORIGEN2</u>		(April 29)	(June 21)	(June 28)	
David Andress	April 9	May 6	June 21	N/A	July 24
Barrie McLeod	April 30	April 30	June 21	N/A	July 24
Marvin Smith <i>VIRGINIA POWER (PARTIAL REVIEW, 7/2)</i>	April 4	April 25	June 24	N/A	Partial
<u>Summary and Overall</u>		(May 15)	(Sept. 6)	(Sept. 27)	(Oct. 18)
Bob Ehle	Sept. 4	August 12	Dec. 11	Dec. 11	Jan. 24
Rhane Harrison-Giesler <i>DOE/MP</i>	April 30	October 7	Nov. 25	Nov. 25	Jan. 2
Camille Kerrigan	July 12	July 15	Nov. 25	Nov. 25	Dec. 23
Ivan Sacks	July 23	July 22	Nov. 20	Nov. 20	Dec. 16
Helmut Worts <i>EE 16</i>	April 16	May 21	Nov. 18	Nov. 18	Jan. 2

# Comments MLS-002, 004, 011, 022, 024 and 025 were returned to the reviewer for resolution after modification of the author's response.

Note: Areas highlighted are overdue or need to be scheduled

**RTIN MARIETTA ENERGY SYSTEMS, INC.**

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January 13, 1992

Distribution

Systems Integration December Monthly Progress Report

Enclosed is the December monthly report. If there are any questions, please call  
FTS (624-7471).



R. B. Pope, 105 Mitchell. Rm205. MS-6495 (4-6461)

Enclosure

KJN:cmp

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T. D. Welch (ORNL)  
J. Williams (DOE/RW321)

# SYSTEMS INTEGRATION PROGRAM MONTHLY PROGRESS REPORT

December 1991

**PROJECT TITLE:** Facility Interface Capability Assessment

Project Manager: R. B. Pope

B&R No.: DB 04 02 11D

FWP No.: RWDB481

Objectives:

The task objectives are to determine existing power reactor capabilities to store, consolidate, package, and ship spent fuel and to determine where upgrading of the facilities could significantly improve spent fuel shipping and handling capabilities which could benefit the Federal Waste Management System (FWMS). The successful achievement of these objectives will provide OCRWM with some of the basic technical data needed for design and construction of the FWMS hardware and facilities, and for policy decisions such as the extent of OCRWM support of desirable modifications at waste generator sites.

Technical Activities:

No activity.

Meetings and Trips:

None

Reports, Papers, and Publications:

None

Milestones completed:

None

Problem Areas:

None

**PROJECT TITLE:** Waste Characteristics Data Base

**Project Manager:** K. J. Notz

**B&R No.:** DB 04 02 11G

**FWP No.:** RWDB 483

**Objectives:**

This task provides the detailed technical characteristics (physical, chemical, radiological, and thermal), inventories, and projected quantities of LWR spent fuel, high-level waste (HLW), non-LWR spent fuel, and other radioactive wastes which may require long-term isolation. This information is used within Systems Integration as input to Waste Stream Analysis, Systems Operations and Logistics modeling, and other systems analyses. It is also used by other OCRWM branches responsible for storage, transportation, and isolation. The Characteristics Data Base (CDB) provides this information via hard-copy reports, user-oriented PC data bases, and mainframe back-up files. The LWR Spent Fuel and HLW sections were revised and re-issued last FY in draft format, with major revisions to the radiological data bases for LWR spent fuel and activated metal hardware in addition to updates in all areas. These drafts are now ready for formal peer review, to be done this FY. The remaining sections will be reissued in draft format and peer reviewed this FY; this includes Non-Fuel Assembly Hardware, Non-LWR Spent Fuel, and Miscellaneous Wastes. The ORIGEN2 code, which is used to calculate radiological properties, will undergo limited upgrading this FY.

**Technical Activities:**

Work continued on the Peer Review process, including response to comments and revision of the draft report. The last remaining draft section, on NFA hardware, was sent out for peer review. This task has been rescheduled, for completion the end of February. The status is as follows, for each of the seven technical areas:

**HLW Panel:** All six review completed and our responses accepted. Incorporation of the revisions is nearly completed, including moving the Sr and Cs capsules from Miscellaneous Waste to HLW under the Hanford site portion.

**LWR Spent Fuel Panel:** All five reviewer's comments received and our responses sent to all reviewers. One has accepted our response and the other four are in process.

**ORIGEN2 Panel:** Additional action is still needed to complete resolution of one reviewer's comments; the other two have been completed. Revision of the draft has been started.

**Summary and Overall Panel:** Our responses were mailed to all five reviewers, and acceptance received from two.

**Non-LWR Spent Fuel Panel:** All four reviewer's comments have been responded to. Acceptances were received from all four and revisions are about 40% completed.

**Miscellaneous Wastes Panel:** Responses were sent to all three reviewers. Two of the reviewers had extensive comments. Our responses were accepted by all reviewers and these revisions are about

40% completed.

NFA Hardware Panel: This draft was completed and mailed out to the three peer reviewers.

Meetings and Trips:

None

Reports, Papers, and Publications:

None

Milestones Completed:

None

Problem Areas:

None

**PROJECT TITLE:** System Analysis Capability Development

Project Manager: D. S. Joy

B&R No.: DB 04 02 12 O

FWP No.: RWDB472

Objectives:

The main objective of the System Analysis Capabilities Development project is to update and enhance the systems analysis models used by DOE to study various aspects of the Federal Waste Management System (FWMS). The system analysis capabilities included in this project are the Waste Stream Analysis (WSA) model and the Systems Integration Operations/Logistics Model (SOLMOD). WSA is used to simulate the movement of nuclear waste on an annual basis through the major elements of the FWMS based on a preselected set of operating rules. SOLMOD is designed to perform a detailed analysis of operations and logistics functions by tracking the movement and processing of individual waste packages. Both of these capabilities are components of the Systems Integration Modeling System (SIMS). Other modeling capabilities will be added to SIMS, as needed, to support the DOE Systems Engineering Studies.

Technical Activities:

Task 1 - Waste Stream Analysis Model

The modification to WSA for correct handling of Hottest Fuel First was run and checking has begun. The various files used for input and output of the WSA verification runs were organized for archiving and possible microfilming. Completion of the first draft verification report is anticipated in the next reporting period.

A new QA version of the WSA code with QA changes has been completed. The changes between the original QA model and the new QA model have been documented. Additional material required by NRC documentation standards is being assembled.

#### Task 2 - System Operations and Logistics Model

Work continues on the testing and correction of the model. At present the MRS and Repository sections are functioning correctly and most corrections are being made in the reporting features.

#### Meetings and Trips:

None

#### Reports, Papers, and Publications:

None

#### Problem Areas:

None

**PROJECT TITLE:** System Engineering Studies

Project Manager: D. S. Joy

B&R No.: DB 04 02 13 O

FWP No.: RWDB 473

#### Objectives:

The Systems Engineering Studies project involves the application of the Systems Integration Modeling System (SIMS) in performing system studies for DOE. These studies will analyze various aspects of the Federal Waste Management System. SIMS contains six major applications models including the Waste Stream Analysis model and the Systems Integration Operations/Logistics Model. The primary emphasis of this project will be focused on a reference system performance evaluation, an aggregate receipt study, and spent fuel selection strategies study. Other studies will be included on an as needed basis.

#### Technical Activities:

##### Task 1 - Spent Fuel Selection Strategies Study

No activity.

##### Task 2 - Reference System Performance Evaluation

No activity.

**Task 3 - Aggregate Receipt Rate Study**

No activity.

**Task 4 - Miscellaneous System Studies**

No activity.

**Meetings and Trips:**

None

**Reports, Papers, and Publications:**

None.

**Problem Areas:**

None.

SURVEILLANCE REPORT

Project No.: RD-045 Project Manager: R.B. Pope  
 Project Title : Systems Integration Program - Waste Stream Analysis (WSA) Development.  
 Requirements Document(s): OAP-X-91-WMRD-045, Rev.1  
 Activity and Purpose: To examine the WSA model verification activities underway at E.R. Johnson Associates, Inc. and assess compliance with the WSA Verification Plan, WSA-VERP-1, Rev. 2.

REQUIREMENT TO BE VERIFIED	RESULTS OF SURVEILLANCE
19. Computer Software WSA-VERP-1, Rev. 2	The surveillance was conducted at the offices of E.R. Johnson Associates, Inc. (JAI) located at 10461 White Granite Drive, Suite 204, Oakton, Virginia. Those interviewed were: the V&V Lead - Ron MacDonald, and the WSA Task Leader for Programs and Results - David Andress.
1.2 Have changes been made to the Verification Plan during the verification process? If so, how have they been documented for identification in the Verification Report?	Changes have been made during the verification. Tests 1 and 1c were determined to be duplicates therefore they were combined. Also, the test set was changed from 4 to 8 reactors. The V&V Lead is maintaining a draft V&V report on his Personal Computer which includes documentation of these changes.
5.4 Have review meetings been conducted during the verification process? If so, how were they documented and was the Task Leader for Methods and Analysis involved?	Review meetings have been conducted. Copies of meeting notes for September 23 and October 22 were examined which indicated that the Task Leader for Methods and Analysis was involved. The V&V Lead stated that other meetings had taken place and that numerous telephone conversations concerning the verification had occurred regularly.

CORRECTIVE ACTION: (Corrective action is required for each activity which does not comply with written requirements.) Is corrective action required?

No X, Yes     A Corrective Action Report and Status form (QA-WMRD-16-004) should be completed for each activity not in compliance with requirements.

FOLLOW-UP:

Is a failure report required? No X; Yes     Type: NCR    , ORS      
 Is a follow-up surveillance required? No X; Yes     Schedule: N/A

APPROVAL:

David Joy 11/24/91  
 Task Manager Date

APPROVAL:

G. Cowart 11/22/91  
 QA Specialist (WR&D Programs) Date

REQUIREMENT TO BE VERIFIEDRESULTS OF SURVEILLANCE

5.5.1 Have data sets and test case input prepared for the verification been controlled and how was this accomplished?

The WSA program was compiled on 05/06/91 for use as the verification module. The date and the Data Set Name: CN6948.DA4.LIB.OBJ are the information which uniquely identifies that code as the verification version. This data set is read only and is controlled by the V&V Lead. Each test data set is also maintained independently during the verification.

5.5.1 What evidence is there of checking test case results?

The test cases are documented in three ring binders, organized and identified by test case number. Each case has a separate SAS program developed to produce numbers for comparison to WSA outputs. The results in the notebooks also include hand written comments by the V&V Lead.

5.5.3 Are verification results being controlled for inclusion as QA records? (para. 6.2 and 7.0)

The results are being controlled for turnover as records after completion of the V&V effort. The notebooks with test case results are being controlled by the V&V Lead at the JAI offices.

5.6.1 How is the WSA version being verified, identified and controlled? How are changes made during the verification process controlled?

The base version is identified as described in 5.5.1 above. The version is protected by the V&V Lead from modification by using the IBM computer security system features. The compiled version is also maintained as a hard copy. Changes identified during the verification will be transmitted to the WSA Task Leader for Programs and Results for implementation in the verified program version.

5.6.3 How are program and documentation changes controlled?

Program and documentation changes have not yet been made since the verification is not complete. Changes will be transmitted to the Task Leader for Programs and Results when the Verification Report has been approved.

6.0 Is there documentation of comparison with SAS, other verified models, or hand calculations? If other verified models are being used, is documentation of verification available?

Documentation of comparisons with SAS results prepared and generated by the V&V Lead was available and controlled in binders by test case. No other models were used for comparison purposes therefore no additional documentation of verification is required.

REQUIREMENT TO BE VERIFIEDRESULTS OF SURVEILLANCE

6.3 Have test cases been completed in accordance with this section of the Plan? What documentation exists to support completion?

Most of the test cases are complete with the exception of case 8 and the scenario dealing with hottest fuel first. As noted above, test cases have been documented in hard copy and controlled in notebooks.

7.0 Is documentation being prepared in accordance with NUREG-0856?

This activity is not yet done, but will be accomplished at the completion of the V&V process.

In general, the V&V work was found to be proceeding in accordance with the WSA Verification Plan, and work to this point has been conducted carefully and documented appropriately.

COPY

Sandia National Laboratories, Albuquerque  
Nuclear Waste Repository Technology Department 6310  
Yucca Mountain Project

QUALITY ASSURANCE AUDIT REPORT

OAK RIDGE NATIONAL LABORATORY  
Oak Ridge, Tennessee

Audit No. ORNL-A91-1  
Conducted November 6-7, 1990

COPY

*Ante Hammer* 11/30/90  
Lead Auditor Date

*F. Richard* 12/7/90  
SNL QA Supervisor Date

File No. 90/1293/AUD/Q1 (ORNL-A91-1)

## EXECUTIVE SUMMARY

The purpose of this audit was to perform a direct evaluation of the Oak Ridge National Laboratory (ORNL) QA Program to determine its adequacy and to identify any deficiencies or concerns requiring corrective action prior to initiating any technical work. This audit, supplementing Sandia National Laboratories (SNL's) prior review and approval activities on the ORNL QA Program Plan (QAPP), is intended to satisfy the QA compliance review requirements necessary for release of the mandatory hold point referenced in Contract 35-0023 Task 1.

The evaluation identified a number of observations (i.e., potential deficiencies) requiring corrective action by ORNL and by SNL. Several of the observations had been previously identified as "open items" requiring action. The ORNL QAPP as well as the SNL contract requires some changes, none of major significance. Agreement was reached on several changes needed in the ORNL QAPP to comply with Yucca Mountain Project (YMP) QA requirements.

The most serious problems impeding further ORNL work is the acceptance of prior work proposed by ORNL letter of June 30, 1990 and the need for an ORNL software QA plan and implementing procedures. These and other observations are documented in Audit Finding/Observation Reports (AFORs) in Appendix A for tracking purposes to ensure proper resolution.

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## 1.0 INTRODUCTION

MAC Technical Services Company (MACTEC) conducted an audit on November 6-7, 1990 at Oak Ridge National Laboratory (ORNL), Oak Ridge, Tennessee for Sandia National Laboratories (SNL) Nuclear Waste Repository Technology (NWRT) Department 6310. The purpose of the audit was to evaluate the ORNL QA Program for ORIGEN-Type Code Work relative to SNL Contracts 35-0023 and 35-0047. The objective of the ORNL effort is to provide the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) with a qualified (both technically and quality-assured) radionuclide inventory generation/depletion or source term code (i.e., ORIGEN-Type) for use in the design, assessment and licensing of the high-level waste repository. Contract 35-0047 provided Project Management Support from October 1, 1989 to September 30, 1990. Contract 35-0023 provides support to SNL in the following areas:

- o Task 1 - Submission, Review and Approval of QA Program
- o Task 2 - QA Evaluation of Prior Work
- o Task 3 - Experimental Data for Code Validation
- o Task 4 - ORIGEN-Type Code Validation Review Committee

ORNL work on Task 3 will not be authorized by SNL until release of the mandatory hold point associated with Task 1 and Appendix I and the SNL approval of the applicable Work Plan and QA Grading Report. The period of performance for these tasks was planned for April 1, 1990 through December 31, 1990. Work involving further verification, enhancement, and updating of the ORIGEN2 code will be delayed until later in fiscal year (FY) 1991.

## 2.0 AUDIT SCOPE

The scope of this initial audit was an evaluation to determine the adequacy of the ORNL QA Program and to identify any deficiencies or concerns requiring correction prior to initiating any technical work. ORNL's ORIGEN-Type Code Work QA Program Plan, QAP-RD-011, R2, of September 5, 1990 was prepared under Contract 35-0047 and was approved by SNL's letter of October 5, 1990. All elements/sections of the QA Program Plan (QAPP), including those considered not applicable by ORNL (i.e., 10.0, 11.0, and 14.0) were reviewed for

consistency with SNL requirements and to ensure a common understanding on the application of these requirements to work for SNL.

ORNL completed a QA evaluation of prior work (Task 2) and submitted a letter report dated June 30, 1990 to the SNL Contract Monitor concluding that the prior work did meet the requirements of a 10CFR60 Subpart G QA program. This report is currently being reviewed at SNL.

Since no work has been performed under the new QAPP, the Audit Team performed a limited review of ORNL's activities conducted under the previous plan that are representative of those to be performed on the new QAPP. ORNL representatives advised that the primary difference between the two plans was the incorporation of unique Yucca Mountain Project (YMP) requirements.

### 3.0 AUDIT TEAM AND PERSONNEL CONTACTED

The Audit Team consisted of two MACTEC auditors, Curtis Barnes, Lead Auditor; Dave Hawkinson, Auditor; and Robert Sandoval, SNL Technical Specialist. Fred Gelbard, SNL Contract Monitor, participated as an observer and provided guidance and interpretation of SNL requirements. Appendix B lists ORNL personnel contacted during the audit.

### 4.0 PERFORMANCE OF THE AUDIT

The Audit Team held an entrance meeting on the morning of November 6, 1990 with ORNL ORIGEN-Type Code Work Project personnel to introduce the Audit Team; review the audit plan, purpose, scope and duration; agree on an agenda for the audit; establish channels of communication and set a tentative time for the close-out meeting. Mr. Scott Ludwig, Project Manager, presented a Project Overview covering program organization, description of ORIGEN2, ORIGEN history, ORIGEN revisions and updates, ORIGEN features and limitations, ORIGEN2 input data libraries, task objective and scope, justification of code selection, verification, validation, code enhancements, general uses of ORIGEN2 and other aspects of code work, including current and future activities (FY 1991 and beyond). This overview and the Technical Plan (Appendix A of the QAPP) were most helpful in understanding ORNL's technical status, project objectives for FY 1990 and proposed future work for FY 1991.

Subsequently, the Team evaluated project activities against Contract 35-0023 requirements, including the ORNL QAPP requirements and controls that were the basis for the audit checklist. While following the checklist, the Team toured the Hi Radiation Level Building 2026 containing spent fuel samples and records furnished by Battelle PNL (Materials Characterization Center) and the Maintenance Management Department containing calibration equipment and records. Selected requirements from all sections of the QAPP were reviewed and, when possible, examples of previous ORNL work were evaluated against the requirements. A number of observations/concerns were discussed and are summarized in paragraph 5.0. Those requiring corrective action are identified as observations in Audit Finding/Observation Reports (AFORs) of Appendix A. [It would be inappropriate to identify these as Findings (i.e., deficiencies) since no technical work has been performed.]

A close-out meeting was held with ORNL Project personnel during the afternoon of November 7, 1990 to present audit results, clarify any misunderstandings and to reach agreement on necessary corrective action. The Team received excellent cooperation throughout the audit and commended ORNL Project personnel for their technical capabilities and effort to incorporate YMP QA requirements in the QAPP.

## 5.0 SUMMARY OF AUDIT RESULTS

5.1 The following observations/concerns were noted with respect to compliance with the Statement of Work for Contract 35-0023:

- ORNL's QAPP has been approved by SNL. ORNL acknowledges that a software quality assurance plan and procedures are required prior to any software work. (The QAPP will require revision for this and other clarifications identified herein.)
- The SNL Contract Monitor advised that a contract change is in process to make release of the mandatory hold point contingent on SNL approval of the applicable Work Plan and QA Grading Report, not the Yucca Mountain Project office.
- The QA Grading Report, when prepared and approved by SNL, must be consistent with the QA criteria identified in the ORNL QAPP or the QAPP will require further revision.

- o Although of no immediate concern, contract and QAPP references to "QA Levels" should be changed to refer to ORNL's work in terms of importance indicated on the QA Grading Report. (Reference to QA levels was deleted in Revision 4 of the YMP QA Plan, NNWSI/88-9.)
- o ORNL has completed the Task 2 QA evaluation of prior work and has concluded that this work did meet the requirements of a 10CFR60, Subpart G QA program. ORNL's conclusion is documented in their June 30, 1990 letter report (deliverable). [SNL's letter of November 21, 1990 does not concur that the requirements for qualification of existing data are not applicable.]
- Appendix I states requirements for Deviations. The QAPP was not responsive to this requirement and does not reference a procedure for handling deviations. SNL's DOP 16-2 may be used for guidance on SNL's method of handling deviations. ORNL needs a deviation procedure to supplement the existing nonconformance procedure.
- o Appendix I states requirements for Records Preparation and Submittal. It requires preparation of records in accordance with SNL DOP 17-1. The QAPP does not refer to DOP 17-1 but does cover the two month requirement for submittal to SNL. Reference to DOP 17-1 should be deleted since ORNL has a QAPP and implementing procedures.
- o Appendix I requires ORNL personnel working on the contract to complete the YMP familiarization training program prior to beginning work. This training has not been accomplished and must be completed as soon as possible.

5.2 The following comments/observations/concerns resulted from reviews and discussions of the ORNL QAPP, applicable procedures, and project activities relevant to the audit:

- o QAPP Section 2.0 refers to quality levels in paragraph 2.3. This was appropriate since the YMP QA Plan Revision 2 established requirements for quality levels. Revision 4 of the QA Plan, issued March 19, 1990, changes "QA level" terminology to "QA controls," "quality affecting," or similar terms. When issued, the QA Grading Report required by SNL QAIP 2-10 will establish applicable QA criteria for the ORNL work. The QAPP Section 2.0, 3.0, etc. may require revision to implement the criteria specified by the QA Grading Report and should describe the importance of ORNL work with respect to the QA Grading Report statement of importance. SNL should provide directions to ORNL on action required when the QA Grading Report is issued.
- o Monthly progress reports by the QA Specialist required by QAPP Section 2.0 have been issued.

- o QAPP Section 2.0 requires regular management assessments; the last one performed was December 1988 and was reported in June 1989. The YMP QA Plan requires management assessments at least annually. The QAPP should be revised consistent with the YMP QA Plan, otherwise, SNL will expect assessments to be performed "regularly."
- o QAPP Section 2.0 requires certification of personnel qualifications which, at this time, has been documented on SNL's certification form (DOP 2-6) for the 13 ORNL personnel expected to work on the project. (Reference Fred Gelbard's SNL letter of October 26, 1990 to Scott Ludwig of ORNL.) These certificates are adequate for the present. However, ORNL has not yet documented the required position descriptions for these personnel and the position descriptions are the basis for personnel certifications. The position descriptions should be established and an ORNL certification issued for project personnel. The education and experience of project personnel has been verified and documented by ORNL.
- o Training and indoctrination required by QAPP Section 2.0 paragraph 2.5 has not yet been accomplished.
- o No activity subject to the requirements of QAPP Section 3.0 has been performed for SNL.
- o No procurement activity subject to the requirements of QAPP Sections 4.0 and 7.0 has been initiated.
- o QA procedures, both administrative and technical, identified in QAPP Appendices B-3, B-4 and B-6 are available for use. The administrative procedures, contained in the waste R&D Programs QA Manual with a table of contents date of January 1990, have not required updating to meet SNL requirements according to the QA Specialist. The adequacy of these procedures should be verified following the next revision of the QAPP.
- o QAPP Section 6.0 requires a Controlled Document Listing which is available. Proposed revision 5 of that list was reviewed and may not contain all applicable controlled documents. For example, SNL documents that prescribe requirements (e.g., the Software QA Plan) should be listed to ensure use of the correct documents. It was noted that the Controlled Document Listing did not contain the WR&D Programs QA Manual procedures which are identified in that manual. The controlled list should identify the applicable revision of that manual's table of contents. The list should identify all controlled documents, technical as well as administrative, or reference lists that do identify these documents.
- o QAPP Section 8.0 establishes requirements for items, samples and data. Sample logbooks, labeling and custody records were audited and determined acceptable. [Samples being held in Building 2026 are those provided by Battelle PNL (MCC) for work prior to the SNL contract.]
- o QAPP Section 9.0 establishes requirements for control of processes. This section does not identify ORNL special processes but the QAPP compliance checklist (pages 89-91) implies that analytical procedures (e.g., those listed in QAPP Appendix B-4) are special process procedures. The Project Manager was requested to review the YMP QA Plan requirements for special

processes, confirm that these processes are special and ensure that ORNL controls are consistent with the requirements. The QAPP should identify activities involving the use of special processes.

- o QAPP Sections 10.0 and 11.0 are not applicable to ORNL's scope of work.
- o Measuring and test equipment activities required by QAPP Section 12.0 were discussed with the Manager of the Maintenance Management Department during a tour of the calibration facilities. Examples of equipment, procedures and records appeared to be under adequate control by well qualified personnel.
- o The storage of analytical samples provided by PNL (reference PNL letter of June 15, 1989) appeared to be consistent with QAPP Section 13.0. Logbooks and work control plans reviewed maintained continuity and consistency in tracking work activities.
- o QAPP Section 14.0 is not applicable to ORNL's scope of work.
- o A review of QAPP Section 15.0 on control of nonconforming items indicates a misunderstanding of SNL disposition requirements in paragraph 15.2. "Use-as-is" and "repair" dispositions affecting SNL requirements must be submitted to SNL for obtaining approval of such dispositions. The QAPP requires revision to include this requirement which is based on the YMP QA Plan Section XV para 1.4.4 and 1.4.5.
- o Examples of corrective action documents required by QAPP Section 16.0 were reviewed and found acceptable. None of the types of corrective action documents required have been initiated on the SNL scope of work. As noted in paragraph 5.1 above, there is no provision in the QAPP for controlling activity deviations.
- o QAPP Section 17.0 requirements and controls for QA records appears to be acceptable. The requirement for records/record package submittal to SNL at least every two months is included and ORNL QA record categories for this work are identified in QAPP Appendix B-8. Review of the appendix resulted in questions as to its adequacy to satisfy SNL records requirements. For example, "Program Records" probably should be deleted; analytical procedures and technical manuals should be included. Some of the documents identified as references in the QAPP Appendix A (Technical Plan) probably should be included. The SNL Contract Monitor and ORNL Project Manager should review this list and revise it as necessary to ensure that SNL obtains needed QA records. Additionally, the retention period column on the list, if retained, applies to retention of ORNL records and is probably not needed in the QAPP.
- o The QA Specialist advised that internal audits required by QAPP Section 18.0 will be performed by the ORNL Quality Department; none have been performed on the SNL work. The last audit of project work was performed in March 1988. An audit had been expected in 1989 by DOE-HQ which would have satisfied ORNL requirements. The DOE-HQ audit was not performed.

QAPP Section 18.0 paragraph 18.3 requires revision to exclude sponsor audits as fulfilling the annual audit requirements. Unless otherwise negotiated, SNL requires each contractor responsible for executing a quality assurance program to perform internal audits at least annually or once during the life of the activity, whichever is shorter.

- 5.3 Observations requiring corrective action have been summarized in two AFORs in Appendix A; one requiring action by SNL (ORNL-A91-01) and one by ORNL (ORNL-A91-02). The ORNL Project Manager and the SNL Contract Monitor were knowledgeable of several of the observations and/or incomplete actions. Those identified during the audit are included in this report to assure proper resolution. As indicated during the close-out meeting, this audit probably did not identify all potential deficiencies. ORNL should perform further assessments of the QAPP and procedures versus SNL requirements. Due to the importance of the ORNL work, the changes in the QA program from prior work and the fact that no surveillances or audits have been performed for over a year, ORNL should perform a readiness review prior to initiating new work on the project.

**APPENDIX A**  
**AUDIT FINDING/OBSERVATION REPORTS**



Sandia  
National  
Laboratories

SNL NWRT DEPARTMENT 6310  
AUDIT FINDING/OBSERVATION REPORT

- AUDITED ORGANIZATION: ORNL ORIGEN- Type Code Work
- 2. DISCUSSED WITH: Scott Ludwig and Fred Gelbard
- 3. AFOR NO.: ORNL-A91-01
- 4. AUDITOR(S): Barnes, Hawkinson and Sandoval
- 5. FINDING  OBSERVATION
- 6. PAGE 1 OF 2
- 7. RESPONSE DUE DATE: 20 working days from transmittal
- 8. QA LEVEL: 1  2  3   
Not Applicable
- 9. REQUIREMENT: See Attached Pages
- 10. FINDING/OBSERVATION: See Attached Pages

SEE REVERSE SIDE FOR INSTRUCTIONS

11. CAUSE:

REMEDIAL CORRECTIVE ACTION AND EFFECTIVE DATE:

13. ACTION TO PRECLUDE RECURRENCE:

14. SIGNIFICANT CONDITION ADVERSE TO QUALITY: NO  YES  IF YES, CAR NO.: \_\_\_\_\_ ISSUED: NO  YES

15. COMMITMENT DATE AND RESPONSIBILITY FOR CORRECTIVE ACTION, INCLUDING CONFIRMATION TO QA COORDINATOR:

16. RESPONSIBLE MANAGER/SUPERVISOR & DATE: \_\_\_\_\_

17. EVALUATION OF CORRECTIVE ACTION STATEMENT: SATISFACTORY  UNSATISFACTORY

18. LEAD AUDITOR & DATE: \_\_\_\_\_

VERIFICATION OF ACTION TAKEN: SATISFACTORY  UNSATISFACTORY

20. LEAD AUDITOR & DATE: \_\_\_\_\_

**HOW TO ADDRESS THE CAUSE/CORRECTIVE ACTION RESPONSE  
FOR AUDIT FINDINGS/OBSERVATIONS**

**STEP 1: Root Cause Determination**

Be specific in identifying the root cause of the problem. Document response in Space 11.

**STEP 2: Remedial Corrective Action and Effective Date**

Document actions taken to correct the specific problems identified. Be specific, record items corrected and how corrected. Record in Space 12. Investigate other similar areas/items that might have similar problems. Document this activity, identify items reviewed and items corrected. Evaluate the problem impact on completed work. State result in Space 12.

**STEP 3: Actions to Preclude Recurrence**

Identify what actions have been and/or will be taken to preclude recurrence. Record specifics in Space 13.

**STEP 4: Determine significance of problem and need for a CAR to ensure appropriate management action. Record in Space 14.**

**STEP 5: Commitment Date and Responsibility for C/A, including Confirmation to QA Coordinator**

Identify who is responsible for the steps above and the date each action is to be completed; record the latest date identified for corrective action in Space 15. The identified individual is responsible for follow up to complete required actions and, for findings, to confirm and provide objective evidence to the QA Coordinator that corrective action has been accomplished as committed. Sign and date in Space 16.

**STEP 6: Transmittal**

Return this report to the QA Coordinator.

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Use additional sheets for continuation of information from the front page.

SNL NWRT DEPARTMENT 6310  
AUDIT FINDING/OBSERVATION REPORT (Continuation)

AUDITED ORGANIZATION: ORNL ORIGEN-Type Code Work  
AUDITORS: Barnes, Hawkinson and Sandoval  
AFOR NO.: ORNL-A91-01  
PAGE 2 of 2

OBSERVATIONS/CONCERNS REQUIRING SNL ACTION

1. Contract 35-0023 Task 1 requires clarification in several areas, particularly if the ORNL work is to continue in the future. The Contract Monitor advised that SNL release of the mandatory hold point will be based on SNL approval of the applicable Work Plan, QA Level Assignment (if applicable), and QA Grading Report, not the YMP Project Office. With respect to QA grading, QA Levels are no longer applicable (reference YMP QA Plan Revision 4) and when the QA Grading Report is issued, ORNL should receive direction from SNL as to its effect on the ORNL QAPP and work. The QAPP must be consistent with the QA Grading Report.
  2. Contract 35-0023 Appendix I states requirements for Records Preparation and Submittal. Reference to DOP 17-1 should be deleted and additional instructions provided related to the periodic submittal. Any necessary relevant requirements from DOP 17-1 for interfacing with the SNL records management system should be stated (e.g., record package table of contents).
- QAPP Section 17.0 refers to Appendix B-8 for identification of QA record categories. This list contains some questionable records (e.g., "Program Records") and does not contain all records needed by SNL. For example, several documents identified in the QAPP Appendix A (Technical Plan) should be included. SNL should review this list and ensure that it contains the required records.



SNL NWRT DEPARTMENT 6310
AUDIT FINDING/OBSERVATION REPORT

- AUDITED ORGANIZATION: ORNL ORIGEN- Type Code Work
2. DISCUSSED WITH: Scott Ludwig et al
3. AFOR NO.: ORNL-A91-6
4. AUDITOR(S): Barnes, Hawkinson and Sandoval
5. FINDING [ ] OBSERVATION [X]
6. PAGE 1 OF 2
7. RESPONSE DUE DATE: 20 working days from transmittal
8. QA LEVEL: 1 [ ] 2 [ ] 3 [ ] Not Applicable
9. REQUIREMENT: See Attached Pages
10. FINDING/OBSERVATION: See Attached Pages

SEE REVERSE SIDE FOR INSTRUCTIONS

11. CAUSE:

REMEDIAL CORRECTIVE ACTION AND EFFECTIVE DATE:

13. ACTION TO PRECLUDE RECURRENCE:

14. SIGNIFICANT CONDITION ADVERSE TO QUALITY: NO [ ] YES [ ] IF YES, CAR NO.: ISSUED: NO [ ] YES [ ]

15. COMMITMENT DATE AND RESPONSIBILITY FOR CORRECTIVE ACTION, INCLUDING CONFIRMATION TO QA COORDINATOR:

16. RESPONSIBLE MANAGER/SUPERVISOR & DATE:

17. EVALUATION OF CORRECTIVE ACTION STATEMENT: SATISFACTORY [ ] UNSATISFACTORY [ ]

18. LEAD AUDITOR & DATE:

19. VERIFICATION OF ACTION TAKEN: SATISFACTORY [ ] UNSATISFACTORY [ ]

20. LEAD AUDITOR & DATE:

**HOW TO ADDRESS THE CAUSE/CORRECTIVE ACTION RESPONSE  
FOR AUDIT FINDINGS/OBSERVATIONS**

**STEP 1: Root Cause Determination**

Be specific in identifying the root cause of the problem. Document response in Space 11.

**STEP 2: Remedial Corrective Action and Effective Date**

Document actions taken to correct the specific problems identified. Be specific, record items corrected and how corrected. Record in Space 12. Investigate other similar areas/items that might have similar problems. Document this activity, identify items reviewed and items corrected. Evaluate the problem impact on completed work. State result in Space 12.

**STEP 3: Actions to Preclude Recurrence**

Identify what actions have been and/or will be taken to preclude recurrence. Record specifics in Space 13.

**STEP 4: Determine significance of problem and need for a CAR to ensure appropriate management action. Record in Space 14.**

**STEP 5: Commitment Date and Responsibility for C/A, including Confirmation to QA Coordinator**

Identify who is responsible for the steps above and the date each action is to be completed; record the latest date identified for corrective action in Space 15. The identified individual is responsible for follow up to complete required actions and, for findings, to confirm and provide objective evidence to the QA Coordinator that corrective action has been accomplished as committed. Sign and date in Space 16.

**STEP 6: Transmittal**

Return this report to the QA Coordinator.

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Use additional sheets for continuation of information from the front page.

AUDIT ORGANIZATION: ORNL ORIGEN-Type Code Work  
AUDITORS: Barnes, Hawkinson and Sandoval  
DR NO: ORNL-A91-02  
PAGE 2 of 2

OBSERVATIONS/CONCERNS REQUIRING ORNL ACTION

1. The YMP QA Plan Rev. 2 Appendix H requires a software QA plan and necessary implementing procedures. The ORNL plan and procedures(s) have not been issued. SNL approval of the plan is required and the documents must be available for use prior to any software work.
2. Contract 35-0023 Appendix I cites requirements for handling activity deviations from specified SNL requirements. The QAPP does not include this requirement or measures to comply with the requirements.
3. Appendix I requires ORNL personnel working on the contract to complete the YMP familiarization training program prior to beginning work.
4. QAPP Section 2.0 requires regular management assessments. The YMP QA Plan requires assessments at least annually. If assessments are not to be performed regularly, the QAPP should be changed to the annual requirement.
5. QAPP Section 2.0 contains several requirements relating to personnel selection, indoctrination and training that have not yet been implemented. Position descriptions for each position have not been established and ORNL personnel certifications have not been issued. Training and indoctrination required by this section has yet to be accomplished.
6. The QA Specialist indicated the administrative and technical procedures cited in the QAPP were those in use on prior work and had not been updated to SNL requirements. The continued adequacy of these procedures should be verified by ORNL following the next revision of the QAPP.
7. The QAPP Section 6 does not identify documents to be controlled as required by the YMP QA Plan. Additionally, ORNL should assure that all documents requiring control, internally originated as well as external, are listed and available for use.
8. QAPP Section 9.0 does not clearly identify ORNL special processes. These should be identified and applicable controls effected. Analytical procedures may be special process procedures; these should be evaluated as to the need for special process controls or less stringent controls, if applicable.
9. QAPP Section 15.0 requires revision to require SNL disposition approval on all recommended "use-as-is" and "repair" dispositions affecting SNL requirements.
10. QAPP Section 18.0 permits sponsor (customer) audits to fulfill annual audit requirements. Unless authorized by SNL, ORNL is responsible for performance of audits.
11. ORNL submitted the required letter report (June 30, 1990) on QA evaluation of prior work required by contract Task 2. [SNL's letter of November 21, 1990 indicates that SNL does not concur with ORNL's conclusion on prior work acceptability. Resolution of this matter should be a high priority for both ORNL and SNL.]

**APPENDIX B**  
**PERSONNEL CONTACTED**

**APPENDIX B**  
**ORNL PERSONNEL CONTACTED**

<u>Name</u>	<u>Position</u>	<u>Audit Function</u> *
Glen Cowart	ORIGEN QA Specialist	1, 2, 3
Anthony Malinauskas	Waste R&D Programs, Director	2
William McClain	Systems Integration Programs, Manager (Project Planning and Future Code Work)	1, 2, 3
Scott Ludwig	ORIGEN-Type Code Work, Project Manager (Experimental Work)	1, 2, 3
Bill Roddy	ORIGEN-Type Code Work, Project Manager	1, 2, 3
Karl Notz	Systems Integration Group	1, 3
Jim Botts	Building 2026 Facility Manager	2
Don Miller	Maintenance Management Department Manager	2
Bud Cooper	Technician, Measurement Research	2

---

\* 1 Audit Entrance Meeting  
2 Assistance During Audit  
3 Audit Exit Meeting



Department of Energy  
Washington, DC 20585

WBS 6.07  
QA

SEP 9 1991

Mr. Ronald B. Pope  
Oak Ridge National Laboratories  
P.O. Box 2008  
Oak Ridge, TN 37831-2008

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)  
HEADQUARTERS (HQ) SURVEILLANCE OF THE OAKRIDGE NATIONAL  
LABORATORY (ORNL) PEER REVIEW OF THE CHARACTERISTICS DATA BASE,  
SURVEILLANCE REPORT HQ-SR-91-008

Enclosed is the report of the subject surveillance which was  
conducted by OCRWM HQ personnel at your facility during  
July 18-19, 1991.

No Corrective Action Requests resulted from this surveillance.  
However, the attached surveillance report does identify several  
minor discrepancies which must be addressed by the Peer Review  
Chairman prior to the submittal of the documentation to OCRWM.  
No formal response is required to this report.

If you have any questions, please contact Bob Clark at (202)  
586-1238.

  
Donald G. Horton, Director  
Office of Quality Assurance

Enclosure

cc:

J. Bartlett, RW-1  
F. Peters, RW-2  
J. Hale, RW-32  
D. Shelor, RW-30  
W, Lemeskewski, RW-321  
T. Nguyen, RW-321  
R. Clark, RW-3.1  
J. Arpia, RW-3.1  
R. Schaffer, Weston  
R. Thomas, CER  
K. Notz, ORNL  
C. Cowart, ORNL

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ROUTE: 100.110.24213.91.008
FILE: 100.100.104

Department of Energy  
OCRWM  
Office of Quality Assurance  
Quality Assurance Surveillance Report

1.0 Surveillance Number

OCRWM-HQ-SR-91-008

2.0 Dates of Surveillance

July 18-19, 1991

3.0 Organization and Location

Oak Ridge National Laboratories  
P.O. Box 2008  
Oak Ridge, Tennessee 37831-2008

The surveillance was conducted in its entirety at the ORNL facilities at the above address.

4.0 Surveillance Team Members

Rod Schaffer (Lead), WESTON/UE&C  
Bob Thomas (Team Member), CER  
Tien Nguyen (Observer), DOE

5.0 Personnel Contacted

R.B. Pope - ORNL  
K.J. Notz - ORNL  
C.G. Cowart - ASG  
R. Salmon - ORNL

6.0 Scope

The surveillance reviewed the implementation of the peer review process by Oak Ridge National Laboratories during the peer review of the Waste Characteristics Data Base.

7.0 Requirements

The primary reference documents that pertain to this surveillance are as follows:

- DOE/RW-0214, Quality Assurance Program Requirements Document,

- Revision 4
- DOE/RW-0215, Quality Assurance Program Description Document, Revision 3
- DOE/RW-0197, OCRWM Quality Assurance Administrative Procedures
- QAAP 3.3 - "Peer Review, Revision 0
- DOE/RW-184, Revision 1 - "Characteristics of Potential Repository Wastes (Draft)
- SI-PR-001 - Peer Review Plan for DOE/RW-0184, Revision 1

## 8.0 Results

### 8.1 Executive Summary

The surveillance was performed to determine if the implementation of the peer review process for the Characteristics Data Base (DOE/RW-184) by Oak Ridge National Laboratories was in compliance with the criteria provided by the documents identified in the "Requirements" section of this report. The surveillance was performed early in the peer review process and all documentation was not yet available for review. However, through interviews with ORNL personnel and reviews of available documentation there was sufficient objective evidence to determine that the peer review activities were being effectively implemented.

No Corrective Action Requests (CARs) resulted from the review. The surveillance team identified some instances where the documentation on file did not fully comply with requirements. Since this surveillance was performed early in the peer review process the noted discrepancies are not deficiencies requiring formal corrective action. These items do, however, have the potential to become a formal deficiency if the noted recommendations are not addressed. These minor discrepancies are further described in the "Discussion" section of the report.

### 8.2 Discussion

8.2.1 The surveillance was conducted in the early stages of the peer review process at the request of Oak Ridge National Laboratories so that any areas of non-compliance could be corrected before final documents were submitted to OCRWM. The draft Revision 1 of DOE/RW-0184 consists of six volumes that include five chapters and seventeen appendices. The documentation represents seven broad technical areas, each of which will have a technical review panel.

At the time the surveillance was performed, only five of the seven panels were formed. The NON-LWR Spent Fuel Panel and the Miscellaneous Wastes Panel were still being organized. Only two of six volumes had comments which could be reviewed, these being the comments submitted by the panel members from the ORIGEN 2 Panel and the High Level Waste Panel. The other four

volumes were still in earlier stages of the review process. The comment resolution meeting for the ORIGEN 2 Code was scheduled for July 24, which was the week following the surveillance.

The documentation reviewed during the surveillance is identified in tabular form on Attachment 1.

- 8.2.2 The surveillance team took particular note of the fact that the Chairman, Task Manager and Secretary of the Peer Review Group all seemed well acquainted with the requirements of the Peer Review Plan and the OCRWM QAAPs referenced in its introduction. When inquiries were made by the surveillance team on various matters, they were able to produce documentation to show that they were not only aware of the situation but in many cases had already taken steps to correct it. It seemed apparent that the peer review activities were being directed by knowledgeable people who were concerned about the integrity of the final product.
- 8.2.3 The following observations were noted by the surveillance team. The observations were discussed with the Peer Review Task Manager, Secretary and Chairman at the conclusion of the surveillance. Recommendations are provided for each of the observations.

Observation 1:

The review of the personnel qualification files indicated that in one instance a peer reviewer (James Wheeler) had submitted a Certification of Technical Qualification form (Table 8 of SI-PR-001) which did not have a verification signature. The Peer Review Secretary was aware of this since there was a letter in the file which requested that a signed form be resubmitted. In addition, the form did not indicate that a resume' was attached which provided the information required by the upper portion of the form.

Recommendation:

The Secretary should assure that the signed form is obtained as soon as possible and also that the blank upper portion of the form indicates that a resume' is attached.

Observation 2:

Three members of the Peer Review Group (Messrs. White, Sachs, Eble) had not provided certification prior to the start of the peer review. When questioned about this, the Task Manager of the Peer Review Group indicated he was aware of this but as of the surveillance no comments had been received from the three individuals. Moreover, he would not

entertain any of their comments until they had submitted the documents. The Secretary also provided a status sheet which confirmed that the ORNL personnel were aware that some documents had not been submitted. The documents for Mr. Eble were received later during the surveillance.

Recommendation:

The Peer Review Chairman must assure that the remaining missing documents are obtained and that none of the comments submitted by the individuals are incorporated into the final document package until the required documents are received.

Observation 3:

The peer review being conducted of DOE/RW-0184 is in response to part of a corrective action identified on CAR 90-018, which was issued as a result of a surveillance conducted during March 20-23, 1990 (OCRWM-HQ-SR-90-001). The revised response to this CAR states that the completion date for the peer review is anticipated to be September 30, 1991. Discussions with the Peer Group Review Secretary and the Task Manager indicated that the schedule had slipped and that the review will not be completed until December 1991.

Recommendation:

The Chairman of the Peer Review Group should ascertain as accurately as possible when the peer review will be completed. This information should be forwarded to OCRWM personnel in RW-30 so that a request for extension of completion of corrective action to CAR 90-018 can be submitted to OQA.

In addition, the Peer Review Plan contains a schedule of peer review milestones which should also be revised to reflect the actual completion dates. The Chairman should review the Peer Review Plan for other changes dictated by circumstances and revise the Peer Review Plan to reflect actual events. These anticipated changes to the Peer Review Plan should be reviewed by the members of the Peer Review Group, as required by QAAP 3.3.

Observation 4:

The surveillance noted that several of the comment sheets reviewed contained comments written in pencil. The comment sheets are intended to be submitted as an attachment to the final peer review report, as is indicated by the CDB Peer Review Report Annotated Outline, dated May 17, 1991. OCRWM QAAP 17.1, paragraph 6.2.4 (C-2) states that pencil is not an acceptable means for recording information on a record that is to be submitted to the QRC.

Recommendation:

The Chairman of the Peer Review Group must assure that no pencil comments are submitted with the final peer review report. The comment resolution meetings can be a convenient forum for correcting any such comment sheets with the peer reviewer who made the submittal.

No formal response to the observations is required. However, the suggested actions provided with each observation must be corrected at the time when the final peer review report is submitted to OCRWM.

9.0 Corrective Action Requests

9.1 No Corrective Action Requests were issued as a result of this surveillance.

Prepared by: Rod Schaffner August 27, 1991  
Surveillance Team Leader Date

Approved by: Alvin R. Horton 9/9/91  
Director, OQA Date

10.0 Attachments

10.1 Attachment 1 - CDB Peer Review Status.

CDB PEER REVIEW STATUS  
July 16, 1991

	<u>Certifications Received</u>	<u>Comments (Due) and Received</u>	<u>Response By Authors (Due) and Received</u>		<u>Reviewers Final Response</u>
			<u>KJ Notz</u>	<u>Others</u>	
<u>High Level Waste</u>					
		(April 8)	(June 14)	(June 27) (Salmon)	
Michael Cooney	May 14	May 14	June 14		
Herschel Godbee	April 24	May 15	June 14		
Lee Bendixen	May 31	May 28	June 14		
Ron Palmer	April 25	April 25	June 14		
John Plodinec	March 28	April 8	June 14		
Bob Watrous	July 12	June 7	June 14		
<u>LWR Spent Fuel</u>					
		(April 22)	(June 28)	(July 10) (Moore)	
Billy Cole	April 1	April 23			
Ray Lambert	April 30	April 30			
Hermann Leider	April 5	April 15			
Andy Luksic	April 25	May 9			
John Mendel	April 8	April 25			
<u>ORIGEN2</u>					
		(April 29)	(June 21)	(June 28) (Welch)	
David Andress	April 9	May 6	June 21	?	July 3
Barrie McLeod	April 30	April 30	June 21	?	July 3
Marvin Smith	April 4	April 25	June 24	?	July 3
<u>Summary and Overall</u>					
		(May 15)	(July 3)	(July 17) (All)	
Bob Eble					
Diane Harrison-Giesler	April 30				
Camille Kerrigan	July 12	July 15			
Ivan Sacks					
Helmut Worle	April 16	May 21			

Note: Areas highlighted are overdue

## CDB PEER REVIEW ATUS (Continued)

July 18, 1991

	<u>Certifications Received</u>	<u>Comments (Due) and Received</u>	<u>Response By Authors (Due) and Received</u>		<u>Reviewers Final Response</u>
			<u>KJ Notz</u>	<u>Others</u>	
<u>NFA Hardware</u>		(July 30)			
Andy Luksic	April 25				
James Wheeler	July 12 *				
Michael White					

\* Independence form only,  
Qualif. form returned for  
verification signature

*Note: Areas highlighted are overdue*

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**QUALITY ASSURANCE CHECKLIST**

ORGANIZATION EVALUATED  Oak Ridge National Laboratory	<input checked="" type="checkbox"/> EXTERNAL  <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT  <input type="checkbox"/> SURVEILLANCE  <input type="checkbox"/> INSPECTION	PREPARED BY <u>Fred Bearham</u> DATE <u>2/12/92</u>
DATES OF EVALUATION  February 24-27, 1992			

CONTROLLING DOCUMENT (Title, Number, Revision) Document Control, QA-SI-06-001, Rev. 0	ACTIVITY EVALUATED Document Control
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Verify that a Controlled Document Custodian is assigned for each Controlled Document not under the responsibility of a specific Task Manager. (Para. 6.1)		
2	Paragraph 6.2.1 requires the Task Manager to assign a Controlled Document Custodian for each Controlled Document within the Manager's Scope of Work. This requirement is not addressed in the Procedure section of QA-SI-06-001. Verify that the requirement is implemented. (Para. 6.2.1)		

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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**QUALITY ASSURANCE CHECKLIST (continuation sheet)**

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	The establishment of distribution list for documents designated in Section 7.2 is assigned to the OCRWP Manager (Paragraph 6.1.4) and the Task Manager (Paragraph 6.2.3). Verify that the list is prepared.)		
4	Verify that the Task Manager has assigned a Controlled Document Custodian for each Controlled Document within the Manager's scope of work. (Para. 6.2)		
5	Verify that the custodian maintains a Controlled Document List. (Paragraph 6.3.3)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6	Verify that Controlled Document Transmittals (CDTs) are prepared by the Task Manager and concurred with by the OCRWP Manager prior to release. (Paragraph 7.4)		
7	Verify that acknowledgement of transmittal by recipients is in accordance with this procedure. (Paragraph 7.9)		
8	Is the requirement for the QAS to perform audits and surveillances still applicable? (Paragraph 6.5.3)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	Verify that personnel are assigned to key positions (General)		
10	Verify that only controlled copies of procedures are used to perform quality affecting work and that uncontrolled copies are correctly identified. (Paragraph 7.1)		
11	Verify that an index, register or list of controlled documents is available. (Para. 7.2)		

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**QUALITY ASSURANCE CHECKLIST (continuation sheet)**

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12	Verify that the current versions of controlled documents are available at work stations. (Paragraph 7.1)		
13	Verify that individually issued documents are stamped "Controlled Copy" in red and assigned a control number. Review several procedures to ensure there is a CDT and they are included on the Controlled Document List (CDL). Who initiates and maintains the CDC? (Paragraph 7.6)		
14	Verify that controlled manuals are stamped "controlled" on the Table of Contents, and are entered on the CDT and CDL. (Para. 7.7)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
15	Verify that document copies are decontrolled for delinquent acknowledgement. (Paragraph 7.11.2)		

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ORGANIZATION EVALUATED Oak Ridge National Laboratory		<input checked="" type="checkbox"/> EXTERNAL	<input checked="" type="checkbox"/> AUDIT	PREPARED BY <u>Fred Bearham</u> DATE <u>2/12/92</u>
DATES OF EVALUATION February 24-27, 1992		<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE <input type="checkbox"/> INSPECTION	
CONTROLLING DOCUMENT (Title, Number, Revision) QA Records, QA-SI-17-001, Rev. 0			ACTIVITY EVALUATED Quality Assurance Records	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		* RESULTS
1	Clarify QA record processing requirements. The ORNL QAPD commits to NQA-1 supplement 17S-1. QA-SI-17-001 does not. (QAPD Para. 17.0)			
2	Review dual storage requirements. Verify that the QAS maintains copies at a remote location. (Para. 7.4)  Note: The QASs responsibilities are not referenced in Section 7.0.			

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	Review the controls established for transmitting record packages for completed tasks to OCRWM (Para. 7.5)		
4	Verify that records are legible, reproducible, microfilmable, and produced and signed in black ink. Review several packages. (Para. 7.1.2)		
5	Verify that record storage provides for protection from natural disasters, environmental conditions, and insect infestation. (Para. 7.1.5)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify that the construction of storage facilities meets the requirements of NQA-1 Basic Requirement 17 and Supplement 17S-1. (Para. 6.5.3)		
7	Review the process of record transmittal and storage:  a) At what point is each record assigned a unique number? Is each page of each document numbered?  b) What controls are established for the storage, retrieval and verification of record packages which develop over a long period of time and are not validated? Note: This attribute is intended to review packages which became unwieldy over time. (Para. 7.3)		

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**QUALITY ASSURANCE CHECKLIST (continuation sheet)**

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8	Paragraph 6.5.3 requires the QAS to maintain the Duplicate Records Storage Facility (DRSF). Paragraph 7.4 has the DRSF custodian performing the function. Is this a contradiction? (Para. 7.4)		
9	Review the documentation trail of several document packages for compliance with the procedure, NQA-1 and the QARD. (General)		
10	Review several packages for proper corrections to documents and arrangements for missing documents. (General).		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
11	Verify that the QAS is cognizant of the contents of QA records packages that are in the QA Records system and DRSF. (Para. 6.5.1)		
12	Review several packages for proper corrections to documents and arrangements for missing documents. (General)		
13	Review the processing of oversize, one-of-a-kind and special process records. (Para. 7.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
14	Review access control to record storage facilities. (Para. 7.3.4)		
15	Verify that responsibility for records validation prior to turnover is established. Paras. 7.5.5 and 6.1.2 have the OCRWP Manager for final reviews. Who performs for the actual validation? (Para. 7.5.5)		

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**QUALITY ASSURANCE CHECKLIST**

ORGANIZATION EVALUATED Oak Ridge National Laboratory		<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE <input type="checkbox"/> INSPECTION	PREPARED BY <u>Fred Bearham</u> DATE <u>2/12/92</u>	
DATES OF EVALUATION February 24-27, 1992					
CONTROLLING DOCUMENT (Title, Number, Revision) Procedure Preparation, QA-SI-05-001, Rev. 0			ACTIVITY EVALUATED Instructions, Procedures and Drawings		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
1	Verify that the four steps of procedure preparation followed. Review several QA-S1s for compliance with Paras. 7.1.1, 7.1.2, 7.1.3 and 7.1.4. (Para. 7.1)				
2	Verify the draft procedures are controlled. Review the process for comment resolution, incorporation and escalation of conflicts. (Para. 7.1.2)				

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Review the selection process for reviewers. Verify the independence of reviewers. (ORNL QAPD Para. 5.1)		
4	Verify that QA-SIs conform to the approved format. Review several QA-SIs and verify that they contain a minimum of 9 sections. (Para. 7.2.2).		
5	Verify that title pages contain: Title, Procedure Number, Revision Number, Effective Date, Approval/Concurrence Blocks and Page Number. (Para. 7.2.4)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6	Verify that continuation pages include the following: Title, Procedure Number, Revision Number, Page Number. (Para. 7.2.5)		
7	Verify that QA-SIs and any revisions are signed by the QAS and OCRWP Program Manager. (Paras. 7.4 and 7.5)		
8	Verify that the QAS and OCRWP Program Manager have made sure all comments are resolved prior to approving procedures. (Paras. 7.4 and 7.5)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	Verify that comments, comment resolutions, and original signed procedures are controlled documents. (Para. 8.9)		

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**QUALITY ASSURANCE CHECKLIST**

ORGANIZATION EVALUATED Oak Ridge National Laboratory	<input checked="" type="checkbox"/> EXTERNAL  <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT  <input type="checkbox"/> SURVEILLANCE  <input type="checkbox"/> INSPECTION	PREPARED BY <u>Fred Bearham</u> DATE <u>2/19/92</u>
DATES OF EVALUATION February 24-27, 1992			

CONTROLLING DOCUMENT (Title, Number, Revision) Peer Review Plan, SI-PR-001	ACTIVITY EVALUATED Peer Reviews
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1	<p>Verify that each Peer Review Plan addresses these topics. Does the plan have an index?</p> <ul style="list-style-type: none"> <li>• Organization of the peer review group, including a chairman, secretary, and technically-qualified peer review panels;</li> <li>• Identification of specialized technical areas and structure of the peer review panel;</li> <li>• Duties and qualifications of the peer review group chairman, secretary, and panel members;</li> <li>• Review criteria and methodology;</li> <li>• Submittal of comments and response;</li> <li>• Comment resolution meeting;</li> <li>• Preparation of the Peer Review final report; and</li> <li>• Schedule to be followed.</li> </ul> <p>(Para. 3)</p>		

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2	Verify that the panel members represent a spectrum of DOE contractor and utility interests. (Paragraph 5)		
3	Verify that OCRWM Task Manager conforms panel substitutions or additions. (Paragraph 5)		
4	Verify that Tables 6, 7, and 8 are completed for document independence and technical qualifications of reviewers including justification for lack of total independence. (Paragraph 5)		

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**QUALITY ASSURANCE CHECKLIST (continuation sheet)**

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5	Verify that the Chairman maintains the Peer Review Checklist with signature and dates for completed action. (Paragraph 5)		
6	Verify that each reviewer's comments are presented on a comment form (Table 10). (Paragraph 6)		
7	Verify that generic comments are made on the standard form citing multiple locations to which the same comment applies. (Paragraph 6)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify comment forms are reviewed by the Chairman, responded to by the author, and that the Chairman reviews the response. (Paragraph 7)		
9	Verify that a comment resolution meeting(s) is held to allow discussion and reach consensus. (Paragraph 8)		
10	What version of ORIGEN 2 is being used? (Paragraph 10, Reference 12)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
11	Verify that Peer Review Group members are certified per QAAP 2.2 and have received indoctrination and training per QAAP 2.1 (Table 6).		
12	Review objective evidence of completion of and compliance with Tables 4 through 11. (General)		

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**QUALITY ASSURANCE CHECKLIST**

ORGANIZATION EVALUATED Oak Ridge National Laboratory		<input checked="" type="checkbox"/> EXTERNAL  <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT  <input type="checkbox"/> SURVEILLANCE  <input type="checkbox"/> INSPECTION	PREPARED BY <u>Dennis Brown</u> DATE <u>2/18/92</u>	
DATES OF EVALUATION February 24-27, 1992					
CONTROLLING DOCUMENT (Title, Number, Revision) QAPD, QAP-X-91-WMRD-045, Rev 1			ACTIVITY EVALUATED Criteria 1,4,7 and 16 (General)		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		* RESULTS	
1	Is the organization chart in Figure 1-1 current? (Section 1.0)				
2	Has a QA Specialist (QAS) been assigned? (Section 1.0)				

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	<p>Do procurement documents for quality-affecting services contain the following, as appropriate:</p> <ul style="list-style-type: none"> <li>a) statement of the scope of work</li> <li>b) Technical and QA program requirements, including design bases and regulatory requirements</li> <li>c) statement of the applicable portions of the QAPD; sub-tier organizations must be addressed also</li> <li>d) right of access</li> <li>e) documentation required to be submitted, including a schedule (collection and maintenance of QA records must be defined also)</li> <li>f) nonconformance controls</li> <li>g) special spare/replacement parts requirements. (Section 4.1)</li> </ul>		
4	<p>Are procurement documents being reviewed (initials) by applicable QA and technical personnel? (Section 4.2)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Are changes to procurement documents receiving the same reviews as the originals? (Section 4.2)		
6	Verify that services contractors are selected by either: <ul style="list-style-type: none"> <li>• evaluating the contractor's history of providing similar services. Current capability must be evaluated, or</li> <li>• evaluating the contractor's current quality records (both quantitative and qualitative), or</li> <li>• directly evaluating the contractor's technical and quality capability at his facilities. (Section 7.2)</li> </ul>		
7	Is the bid evaluation and award process being controlled in accordance with Section 7.3?		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Are Task Managers adequately controlling the performance of their contractors by: <ul style="list-style-type: none"> <li>• requiring the contractor to identify planning techniques and processes to be utilized</li> <li>• reviewing contractor's documents which are generated for the contracts</li> <li>• identifying and processing change information</li> <li>• establishing document information exchange methods. (Section 7.4)</li> </ul>		
9	Are Task Managers giving contractor generated documents acceptance reviews. (Section 7.5)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Has ORNL had any occurrences reportable under DOE Order 5300.3A? (Section 16.0)		
11	Has ORNL had any significant conditions adverse to quality? (Section 16.1 - 16.3)		

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DATES OF EVALUATION February 24-27, 1992		<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE <input type="checkbox"/> INSPECTION		
CONTROLLING DOCUMENT (Title, Number, Revision) WSA-VERP-1, Rev. 2 Plan for the Verification of the Waste Steam Analysis Program			ACTIVITY EVALUATED Computer Software		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS	
1	Have changes been made to the Verification Plan during the verification process? If so, how have they been documented for identification in the Verification Report? (Para. 1.2)				
2	Verify that changes are recorded in the Verification Report. (Para. 1.2)				

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	<p>Verify that the following personnel are assigned:</p> <p>Systems Integration Program Manager (SIPM) Systems Integration Task Manager (SITM) Quality Assurance Specialist (QAS) WSA Task Leader (Methods &amp; Analysis) (TLMA) Verification Leader (VL) WSA Task Leader (Program and Result) (TL PR) (Para. 5.0)</p>		
4	<p>Are the verification parameters identified and controlled? Review comparisons with SAS, other verified models or hand calculations. Establish the reliability of comparison sources. (Para. 6.0)</p>		
5	<p>Major options to be tested. Review the process for selection characteristics to be verified. What is the interpretation of "general" in the first sentence and "certain combinations" in the last sentence? (Paragraph 6.1)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6	Is the SITM reviewing and approving all applicable documents itemized in this plan? (Paragraph 5.2)		
7	Does the WTPR have a process for the control of the version of the WSA program to be verified. To assure that the changes are being documented for inclusion in the verification report referenced in Paragraph 1.2. (Para. 5.6.1)		
8	Have review meetings been conducted during the verification process? If so, how were they documented and was the Task Leader for Methods and Analysis involved? (Para. 5.4.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	Verify that the specific items to be verified in Para. 6.1 are addressed. (Para. 6.1)		
10	Have test cases been completed in accordance with this section of the Plan? What documentation exists to support completion? (Para. 6.3)		
11	<p>Is documentation being prepared in accordance with NUREG-0856 (Final Technical Position on Documentation of Computer Codes for High Level Waste Management)? (Para. 7.0)</p> <p>Verify that documentation is divided into five categories:</p> <ul style="list-style-type: none"> <li>(1) Software Summary</li> <li>(2) Description of mathematical models and numerical methods</li> <li>(3) User's manual</li> <li>(4) Code assessment and support</li> <li>(5) Continuing documentation and code listings</li> </ul> <p>Verify that the five categories are addressed.</p>		

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DATES OF EVALUATION February 24-27, 1992		<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE <input type="checkbox"/> INSPECTION	
CONTROLLING DOCUMENT (Title, Number, Revision) Establishing Quality Assurance Controls, QA-SI-02-001, Rev 0 (new)			ACTIVITY EVALUATED Quality Assurance Program	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
1	<p>Subparagraphs 8.1 through 8.8 identify the procedure for processing the QA Controls Matrix. Are these requirements being implemented with regard to activities associated with the Waste Stream Analysis Model, the Waste Characteristics Data Base, and ORIGEN 2, specifically with regard to:</p> <ul style="list-style-type: none"> <li>• sign off and concurrence signatures</li> <li>• maintenance of duplicate copies</li> <li>• evidence that a duplicate copy has been forwarded to the appropriate OCRWM Program Manager?</li> </ul> <p>Review the appropriate matrices on file to verify compliance and also to determine if they reflect the requirements contained in the OCRWM QA Controls Specification included with the OCRWM guidance memorandum.</p>			

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2	Paragraph 8.2 of the procedure requires that any (all) discrepancies between the Systems Integration QA Controls Matrix and the OCRWM QA Controls Specification be identified on Attachment A of the procedure. Paragraph 8.8 then states that it be sent to the appropriate Program Manager, for information. How are these discrepancies resolved?		
3	Are the Task Managers implementing this procedure for their respective quality affecting tasks, as required by Subparagraph 5.2.1?		
4	Are the Task Managers assuring that all changes in the work are evaluated against the QAPD to determine if changes are needed in the QA controls applicable to the work, as required by Subparagraph 5.2.2 of the procedure?		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5	Paragraph 2.1.4 of the SIQAPD states that the System Integration Program will maintain QA and line procedures which provide more detail than the controls established in the QAPD. What line procedures are controlling the activities for the tasks being audited?		

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DATES OF EVALUATION February 24-27, 1992		<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE <input type="checkbox"/> INSPECTION		
CONTROLLING DOCUMENT (Title, Number, Revision) Indoctrination and Training, QA-SI-02-002, Rev 0 (new)			ACTIVITY EVALUATED Indoctrination and Training		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS	
1	Is an I&T Matrix on file for personnel who are performing quality affecting activities? (Paragraph 4.0)				
2	Subparagraph 6.2.4 requires that Task Managers assure that indoctrination and training requirements are completed in a timely manner. Is any specific time frame identified for the completion of the basic training?				

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	<p>Verify that the Task Managers are:</p> <ul style="list-style-type: none"> <li>• Determining, documenting, and approving initial and continuing indoctrination and training requirements for staff.</li> <li>• Providing approval of completed indoctrination and training.</li> <li>• Maintaining an I&amp;T Matrix for task specific technical training.</li> <li>• Selecting qualified instructors for classroom training on task specific technical topics.</li> <li>• Reviewing and updating indoctrination and training requirements when position or work duties of staff change.</li> </ul> <p>(Subparagraphs 6.2.1 through 6.2.7)</p>		
4	<p>Have appropriate staff received minimum training in the following areas:</p> <ul style="list-style-type: none"> <li>• General criteria (codes, standards, regulations) applicable to their scope of work.</li> <li>• QA Program Description and supporting procedures.</li> <li>• Program responsibilities and authority.</li> </ul> <p>(Subparagraph 7.1.4)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5	<p>Review the available lesson plans to determine if they contain the information required by Paragraph 7.3 of the procedure:</p> <ul style="list-style-type: none"> <li>• Lesson plan is identified by title and revision number, and identifies the author.</li> <li>• The plan is signed by an authorized reviewer and approved by the Task Manager or QAS, as appropriate.</li> <li>• The plan identifies course objectives, course summary, terms to be defined, documentation to be discussed, prerequisites, instructional method, course length, testing, method of evaluation, and the target audience.</li> </ul>		
6	<p>Do the training records being maintained by the Records Custodian contain the following documentation?</p> <ul style="list-style-type: none"> <li>• Completed I&amp;T forms</li> <li>• Lesson Plans</li> <li>• Classroom test results</li> <li>• Certifications</li> </ul> <p>(Paragraph 8.0)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	Is there evidence that personnel have proceeded with performing quality affecting activities prior to completing the minimum training? (OCRWM QAAP 2.1)		
8	Have position descriptions been established which set forth job duties and identify the minimum education and/or experience requirements, as required by Section 2.6 of the SIQAPD?		
9	Are internal memorandum being maintained by each organization identifying the evaluation by management that staff are qualified with the necessary education, experience, and/or training to perform their intended functions to support the Systems Integration Program? (SIQAPD, Paragraph 2.6)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
10	In addition to the items listed in Subparagraph 7.3.2.3 of this procedure, Paragraph 2.6 of the SIQAPD also requires that the training records identify attendees at Classroom training and due dates for retraining. Review the files to determine if this information is being maintained.		
11	Does the Indoctrination and Training Program appear to address the requirements established in the OCRWM QARD?		

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DATES OF EVALUATION  February 24-27, 1992	<input type="checkbox"/> INSPECTION			
CONTROLLING DOCUMENT (Title, Number, Revision) Computer Code Verification and Validation, QA-SI-19-001, Rev 0 (new)			ACTIVITY EVALUATED Computer Software	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1	Which computer codes have been designated for use on the OCRWM Project Group's activities relative to the Waste Stream Analysis Model and the Waste Characteristics Data Base?  For which of these codes has the implementation of this procedure been required? (Paragraph 2.0)			
2	Paragraph 5.1 states that the Systems Integration Program Manager is responsible to assure implementation of this procedure, when required. Are there any codes being used on OCRWM activities for which it was determined that this procedure was not required? Is there written justification for the decision?			

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	Is the scope of the V&V process identified in the V&V Plan and is the justification for the decision documented in the Plan, as required by Paragraph 7.1?		
4	Paragraph 7.3 suggests section titles and their order for the format of the V&V Plan. Are the V&V Plans organized as suggested and do the sections provide, as a minimum, the information required for each section?		
5	Has the Plan been reviewed and approved by the Task Manager, the Systems Integration Program Manager, and the QAS, as required by Paragraph 7.4?		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6	Does the V&V Report contain the suggested format as identified in Paragraph 7.6 of the procedure?		
7	Has the report been reviewed by the QAS and at least one other reviewer qualified to review the report for technical content, as required by Paragraph 7.7?		
8	Is the review of the report, including the resolution of comments, documented and being maintained as a quality assurance record, as required by Paragraph 7.8?		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	Has the report been approved by the Task Manager and the Systems Integration Program Manager, as required by Paragraph 7.9?		
10	Has the computer code been placed under configuration control, as required by Paragraph 7.10 of the procedure?		
11	Do the quality assurance record files contain, as a minimum, the documentation listed in Section 8.0 of the procedure?		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12	Is the final version of computer software to be used for a licensing activity verified and/or validated by an independent individual who did not work on the original software, as required by Paragraph 19.3 of the QAPD?		

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DATES OF EVALUATION February 24-27, 1992			

CONTROLLING DOCUMENT (Title, Number, Revision) Computer Software Transfer, QA-S1-19-002, Rev 0 (new)	ACTIVITY EVALUATED Computer Software
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Has a software custodian been assigned to control the designated software for transfer into or out of Systems Integration? (Subparagraph 6.2.2)		
2	Has a software transfer system been implemented by the custodian which meet the requirements identified in Paragraph 7.2.1 in that all requests for a software package is either in writing or has been documented by the custodian to include the name, address, and organization making the request?		

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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3	<p>Does the software transfer package assembled by the custodian include the elements identified in Paragraph 7.2.2?</p> <ul style="list-style-type: none"> <li>• Source and/or object program on appropriate media.</li> <li>• User's Manual, Guide, or other instructions appropriate for the software</li> <li>• Sample problem input and output, when appropriate</li> <li>• Other appropriate or requested information (i.e., V&amp;V Report)</li> <li>• A transfer package listing with receipt acknowledgement</li> </ul>		
4	<p>Has an appropriate disclaimer covering requester made modifications been included in the transfer package when a source program is included in the transfer package, as required by Paragraph 7.2.4?</p>		
5	<p>Does the method of shipment protect the integrity of the magnetic media, as required by Paragraph 7.2.5?</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6	<p>Are acknowledgement forms used as a condition of the transfer which comply with Subparagraphs 7.2.6 through 7.2.8?</p> <ul style="list-style-type: none"> <li>• Requestor required to return acknowledgement</li> <li>• filed in transfer files by custodian with action taken on content discrepancies of the package or perceived discrepancies with the software</li> <li>• obtaining acknowledgement from requestor if not returned</li> </ul>		
7	<p>Has any externally controlled software been identified as needed for use on a quality affecting task? (Subparagraph 7.3.1)</p>		
8	<p>Does the request for the software by the custodian contain a request for the owner to assure that the software was either developed under an OCRWM approved QA Program or has been qualified for use in quality affecting work subsequent to its development, as required by Subparagraph 7.3.2.1?</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	When received, was the software package placed in control by the software custodian, as required by Subparagraph 7.3.3?		
10	Have software packages which have been accepted by OCRWM for use in quality affecting work been placed into the Systems Integration QA Records system with evidence of that acceptability, as required by Subparagraph 7.3.3.1 of the procedure?		
11	Has the software custodian prepared a configuration management plan for the software in accordance with Section 19.6 of the Systems Integration QAPD, as required by Paragraph 7.3.3.1?		

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**QUALITY ASSURANCE CHECKLIST (continuation sheet)**

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12	Has software which has not been accepted by OCRWM been placed in a qualification process in accordance with Paragraph 7.3.3.2 and also Section 19.7 of the Systems Integration QAPD?		
13	Is the software custodian maintaining control of the software so as to comply with the requirements expressed in Paragraphs 7.3.3.2.1 and 7.3.3.2.2 of the procedure?		
14	Do the quality assurance records packages of the software contain at least the documentation identified in Section 8.0?		

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

PAGE 1 OF 3  
AUDIT/SURVEILLANCE/INSPECTION  
NO. HQ-92-02

**QUALITY ASSURANCE CHECKLIST**

<b>ORGANIZATION EVALUATED</b> Oak Ridge National Laboratory	<input checked="" type="checkbox"/> EXTERNAL  <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT  <input type="checkbox"/> SURVEILLANCE  <input type="checkbox"/> INSPECTION	<b>PREPARED BY</b> <u>Fred Bearham</u> <b>DATE</b> <u>2/12/92</u>
<b>DATES OF EVALUATION</b> February 24-27, 1992			

<b>CONTROLLING DOCUMENT (Title, Number, Revision)</b> Document Reviews, QA-SI-05-002, Rev. 0	<b>ACTIVITY EVALUATED</b> Document Control
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1	Are all quality affecting documents applicable to this procedure identified? (Para. 2.1).		
2	Verify that the QAS is included in the review process for controlled documents. (QAPD Para. 6.3)		

\* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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

SHEET 2 OF 3  
AUDIT/SURVEILLANCE INSPECTION  
NO. HQ-92-02

**QUALITY ASSURANCE CHECKLIST (continued on sheet)**

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	Verify that controls are established for controlled documents which are released prior to approval. (QAPD Para. 6.2)		
4	Verify that the QA Controls Matrix documents justification when the Task Manager assigns fewer QA requirements to a specific lower level task. (Para. 7.1.3)		
5	Verify that draft procedures are so identified, comments are submitted on a DRR and comments are resolved. (Para. 7.1.2)		

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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

SHEET 3 OF 3  
AUDIT/SURVEILLANCE/INSPECTION  
NO. HQ-92-02

QUALITY ASSURANCE CHECKLIST continuation sheet

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6	Verify DRRs and continuation sheets are properly completed. Review several records for proper sign-off, resolution of comments and documentation of conflicts. (Para. 7.2.2)		
7	Verify that DRRs and a copy of the reviewed document is maintained as a QA record. (Para. 8.0)		

FORMER U.S. DEPARTMENT OF ENERGY

2.1.4

Craig W. Legna

ATIN MARIETTA ENERGY SYSTEMS, INC.

POST OFFICE BOX 2008  
OAK RIDGE, TENNESSEE 37831

June 27, 1991

Mr. William Lemeshewsky  
U.S. Department of Energy/OCRWM  
Forrestal Building, RW 321  
1000 Independence Ave. SW  
Washington, DC 20585

Dear Bill:

Enclosed is Revision 1 of the Systems Integration Quality Assurance Program Description (QAPD) which is a thorough rewrite of the QAPD submitted to your office on January 4, 1991. This version of the QAPD is based on additional written and verbal guidance received from the Headquarters QA staff.

The QAPD is hereby submitted for review and acceptance by Headquarters, as required under the Systems Integration Quality Assurance task (DB-040215). It has been prepared in accordance with the OCRWM Quality Assurance Requirements Document (QARD), DOE/RW-0214, Rev. 4. (Please note that procedures and plans referenced in the QAPD are "to be developed".) We expect that enough detail is presented in the QAPD to allow the reviewers to evaluate the suitability of the methods ORNL intends to use to satisfy the applicable OCRWM QARD requirements. The referenced procedures will be prepared and submitted to your office for review prior to conducting any quality-affecting work in these areas.

Also enclosed is the QA Requirements Matrix required under the QA task. The procedure for establishing QA Controls for Systems Integration support at ORNL is in review and will be submitted to your office in July.

Please call me if we can assist you in obtaining approval of the QAPD.

Sincerely,



Ronald B. Pope, Manager  
Office of Civilian Radioactive  
Waste Programs

Enclosures: QA Program Description, Revision 1  
QA Requirements Matrix

cc w/o Enclosures: C. G. Cowart                      A. P. Malinauskas  
R. N. Collier                              K. J. Notz  
D. S. Joy                                      T. Nguyen

RECEIVED CER CORPORATION PROJECT OFFICE JUL 18 1991
ROUTE:
FILE:

DOCUMENT NO.: QAP-X-91-WMRD-045

Revision 1

OCRWM  
SYSTEMS INTEGRATION SUPPORT

QUALITY ASSURANCE PROGRAM DESCRIPTION

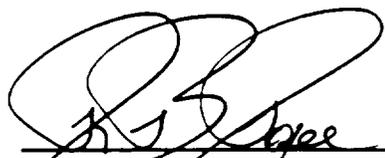
JUNE 1991

OCRWM

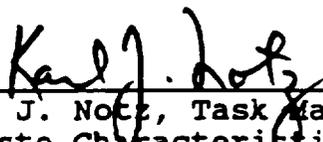
SYSTEMS INTEGRATION SUPPORT

QUALITY ASSURANCE PROGRAM DESCRIPTION

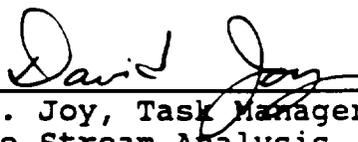
JUNE 1991



R. B. Pope, Manager, Office of  
Civilian Radioactive Waste  
Programs



K. J. Notz, Task Manager  
Waste Characteristics Database  
and ORIGEN2 Upgrade



D. S. Joy, Task Manager  
Waste Stream Analysis  
Development



P. B. Hoke, Manager  
ORNL Quality Assurance



C. G. Cowart, Quality Assurance  
Specialist, Waste Research and  
Development Programs

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## POLICY STATEMENT

It is the policy of ORNL that all quality affecting activities relating to OCRWM Systems Integration work will be performed to prescribed quality requirements. The Quality Assurance (QA) program, as described in the Quality Assurance Program Description (QAPD), has been structured to provide for assignment of controls that are appropriate for each activity's importance to safety, importance to waste isolation, or importance to the mission objectives of the sponsor. Implementation of and compliance with the QAPD is mandatory for all Systems Integration personnel.

All personnel (Oak Ridge National Laboratory and supporting organizations) involved in or responsible for the quality of the tasks covered by the QAPD will comply with the requirements of the QAPD. All such personnel are responsible for implementation of those portions of the QA program pertinent to their respective areas of responsibility and involvement.



---

A. P. Malinauskas  
Waste Research and Development Programs  
Director

## INTRODUCTION

The Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) has identified the need for Systems Integration activities which support the OCRWM mission of siting, licensing, constructing and operating a repository for disposal of spent nuclear fuel and high-level radioactive waste. In support of its mission, OCRWM has assigned responsibility for the following, quality-affecting activities to Oak Ridge National Laboratory (ORNL), and specifically to the Systems Integration support organization. Other activities, performed by ORNL, may be added to the scope of this document when determined to be quality-affecting by OCRWM management.

- a) **Waste Characteristics Database**, which will be used by all OCRWM offices requiring a consistent, quality source of data on waste characteristics and properties. This includes the use of data for assisting in establishing waste management facility designs, site characterization activities, and possibly licensing.
- b) **Waste Stream Analysis Development**, which provides a model with the capability to support various types of studies, such as facility designs, cask and waste package designs, and systems analysis.
- c) **ORIGEN2 Upgrade**, which will enhance a family of models relevant for predicting radionuclide characteristics of spent fuel and high-level waste. The ORIGEN2 code capability will be used by all Program participants for design, site characterization, and possibly licensing.

The purpose of ORNL's assignment is to provide, quality assured, integrated data sources and modeling capabilities which will assist OCRWM in the accomplishment of its mission objectives. The purpose of the Quality Assurance Program Description (QAPD), is to describe the Systems Integration QA program established to meet the QA requirements of DOE/RW-0214, OCRWM Quality Assurance Requirements Document (QARD). The QAPD delineates responsibilities for both achieving and assuring quality by Systems Integration (including ORNL, subcontractors, and other supporting organizations performing work for these tasks). The QAPD discusses policies and procedures established, and those to be established, which implement the applicable requirements of the QARD. The nineteen sections of this QAPD are directly correlated to the applicable sections of the QARD.

The policies, requirements, and procedures established in the QAPD are applicable and mandatory for all activities affecting quality associated with Systems Integration tasks. The extent of QA to be applied to each task is dependent upon the scope or complexity of the activity, and its importance to the mission objectives of OCRWM.

The ORNL Office of Civilian Radioactive Waste Programs (OCRWP) Manager is responsible for the QA program; ensures its development, implementation, and verification; and retains ultimate review and approval authority on matters pertaining to the implementation of QA program requirements. The Systems Integration Task Managers are responsible for development, implementation and verification of this QA program as it applies to their respective tasks.

The QA program provides for both the achievement and verification of quality, and is based on the principle that each person is responsible for the quality of the work that person performs. The programmatic organization is responsible for the achievement of quality for all work. The QA organization has the responsibility to provide independent assurance to senior programmatic management of the programmatic organization's achievement and verification of quality.

The QA organization maintains a strong overview presence in the Systems Integration support work. To implement an overview program the QA organization performs sufficient and effective verifications (such as audits, surveillances, reviews and assessments) of activities affecting quality. Overview activities, accomplished by both the QA organization and program management, are scheduled to coincide with the actual performance of activities affecting quality. The scheduling process is flexible to meet changes in work activities and newly identified concerns.

The documents listed below are the requirements documents currently applicable to the Systems Integration support QAPD, and represent the basis for the Program.

1. 10 CFR 60, Subpart G; Quality Assurance
2. 10 CFR 50, Appendix B; Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
3. DOE Order 5700.6B, September 23, 1986; Quality Assurance
4. ASME NQA-1 - 1989 Edition; Quality Assurance Program Requirements for Nuclear Facilities
5. DOE/RW-0214, Rev 4, October 1990; OCRWM Quality Assurance Requirements Document
6. NUREG-0856, June 1983; Final Technical Position on Documentation of Computer Codes for High-Level Waste Management
7. NUREG-1297, February 1988; Peer Review for High-Level Nuclear Waste Repositories
8. NUREG-1298, February 1988; Qualification of Existing Data for High-Level Nuclear Waste Repositories
9. DOE Order 5000.3A, May 30, 1990; Occurrence Reporting and Processing of Operations Information

## ACRONYMS AND ABBREVIATIONS

ASME:	American Society of Mechanical Engineers
CFR:	Code of Federal Regulations
DOE:	Department of Energy
GP:	General Policy (MMES document)
GS:	General Standard (MMES document)
MMES:	Martin Marietta Energy Systems, Inc.
NQA:	Nuclear Quality Assurance
NUREG:	Nuclear Regulatory Commission document series
OCRWM:	Office of Civilian Radioactive Waste Management (DOE/HQ)
OCRWP	Office of Civilian Radioactive Waste Programs (ORNL)
ORIGEN:	Oak Ridge Isotope Generation and Depletion Code
ORNL:	Oak Ridge National Laboratory
ORS:	Occurrence Reporting System
QA:	Quality Assurance
QAPD:	Quality Assurance Program Description
QARD:	Quality Assurance Requirements Document
QAS:	Quality Assurance Specialist (MMES)
QP:	Quality Procedures
SQAP:	Software Quality Assurance Plan
WR&D:	Waste Research & Development

## ACRONYMS AND ABBREVIATIONS

ASME:	American Society of Mechanical Engineers
CFR:	Code of Federal Regulations
DOE:	Department of Energy
GP:	General Policy (MMES document)
GS:	General Standard (MMES document)
MMES:	Martin Marietta Energy Systems, Inc.
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QARD:	Quality Assurance Requirements Document
QAS:	Quality Assurance Specialist (MMES)
QP:	Quality Procedures
SQAP:	Software Quality Assurance Plan
WR&D:	Waste Research & Development

## 1.0 ORGANIZATION

The ORCWP support staff, which has responsibility for the QAPD, is programmatically a part of the Waste Research and Development (WR&D) Programs under the Advanced Energy Systems Directorate within Oak Ridge National Laboratory. The ORCWP staff reports administratively to the Advanced Energy Systems Directorate through the Engineering Coordination and Analysis Section of the Chemical Technology Division. The Program organization - ORNL and its supporting organizations - is depicted in Figure 1-1. Although Department of Energy organizations are not governed by this QAPD, they are included in the organization chart to show reporting relationships.

A Quality Department representative (termed a Quality Assurance Specialist [QAS] at ORNL) is assigned to support the Systems Integration tasks by the ORNL Quality Assurance Manager, with concurrence by the WR&D Programs Director. The QAS reports administratively to the WR&D Programs Director and directly to the ORNL Quality Assurance Manager. This organizational placement and relationship is identified in Figure 1-1. The QAS has no other duties, unrelated to QA, that could prevent full attention to QA program matters.

1.1 The Systems Integration support organization consists of the OCRWP Manager, Task Managers, and personnel from supporting organizations (which includes subcontractors). These personnel are responsible for implementation of the QAPD.

1.1.1 The ORCWP Manager reports to the WR&D Programs Director and is responsible for the following:

- o Implementation of DOE policy and Mission objectives as they apply to the tasks covered by this QAPD;
- o Establishment, implementation and maintenance of a QA program based on DOE Orders, the OCRWM Quality Assurance Requirements Document, regulatory codes and standards, and national consensus standards, to include the determination of appropriate QA controls for each affected task;
- o Review, approval and implementation of the QAPD and supporting Quality Procedures (QP);
- o Establishment, implementation, and maintenance of an indoctrination/training and/or qualification program to assure that personnel assigned to perform activities affecting quality are appropriately trained, indoctrinated, and qualified for the position to which they are assigned, and are indoctrinated into the requirements of this QAPD;
- o Delegation of responsibility for implementation of the QA program to all personnel performing activities affecting the quality objectives defined in the QA program;

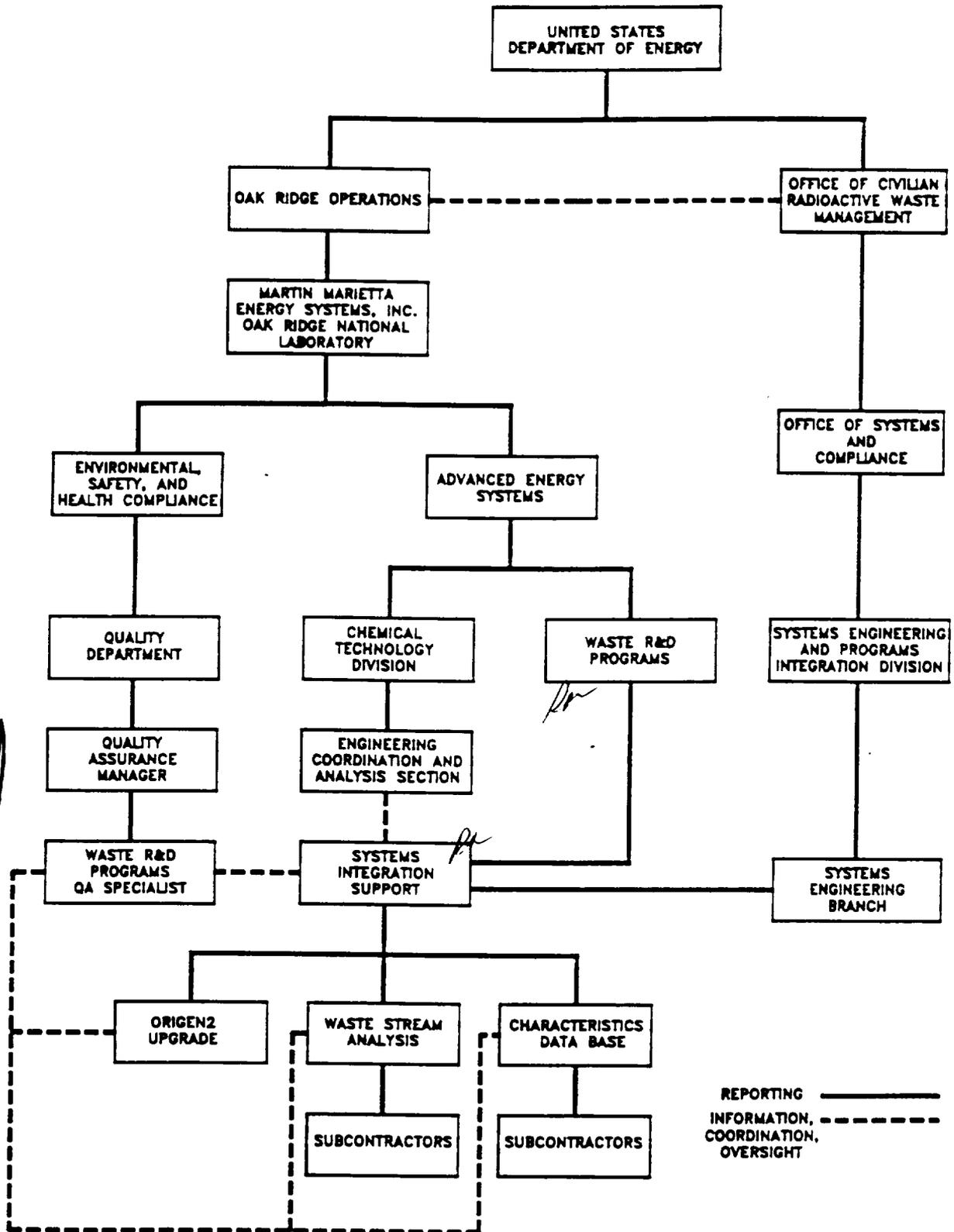


FIG. 1-1

- o Continued involvement in QA activities through periodic meetings with the QAS, review of QA audit reports, surveillance reports, corrective action reports, and sponsoring the performance of an independent assessment of QA program implementation and effectiveness.
  - o Assurance of timely responses/resolutions to corrective action reports and QA audit findings;
  - o Resolution of disputes involving quality of work arising from a difference of opinion between Program personnel. Disputes will be resolved in accordance with Section 1.6 of the QAPD and procedure QA-SI-01-001.
  - o Approving stop work orders, assuring implementation of corrective actions, and lifting stop work orders, when required.
- 1.1.2 The Systems Integration Task Managers report to the OCRWP Manager and are responsible for the following:
- o Implementation of DOE policy and Mission objectives as they apply to their respective tasks;
  - o Implementation of this QAPD and supporting Quality Procedures;
  - o Review and approval of the QAPD;
  - o Delegation of responsibility for implementation of the QA program to all personnel performing activities affecting the quality objectives defined in the QA program;
  - o Continued involvement in QA activities through periodic meetings with the QAS, review of QA audit reports, surveillance reports, and corrective action reports; and
  - o Assurance of timely responses/resolutions to corrective action reports and QA audit findings.
- 1.1.3 The Systems Integration support organization (ORNL and subcontractors) is responsible for the following:
- o Implementation of DOE policy and Mission objectives as they apply to their respective tasks;
  - o Implementation of this QAPD and supporting Quality Procedures;
  - o Assurance of timely responses/resolutions to corrective action reports and QA audit findings.

- 1.2 The QAS reports directly to the ORNL Quality Assurance Manager, and administratively to the WR&D Programs Director.

The QAS has a primary reporting relationship that is not subordinate to the OCRWP Manager and has knowledge and experience in the area of quality assurance. The QAS has no other duties or responsibilities unrelated to quality assurance that could prevent full attention to quality assurance matters and has sufficient freedom from cost and schedule considerations when addressing quality considerations. The QAS has access to senior ORNL management and management at higher Program organizational levels to identify, and obtain resolution to, unresolved quality concerns. The QAS is responsible for:

- o Review and approval of this QAPD and associated Quality Procedures.
- o Independent review of supporting organization's QA programs and revisions thereto, and recommending disposition to the respective Task Managers, when applicable;
- o Verification of QA program implementation and effectiveness through internal audits and/or surveillance of activities affecting quality;
- o Assurance through audit, surveillance or other recognized QA techniques, that supporting organizations approved quality programs and procedures are implemented and maintained, when applicable;
- o Identification of quality problems;
- o Review of the latest regulatory requirements, consensus codes and standards, and recommendation of any appropriate changes to the QAPD;
- o Provision of QA indoctrination/training of task personnel, when delegated by the OCRWP Manager, to assure familiarity with applicable quality systems, methods, and requirements contained in this QAPD;
- o Review and concurrence with task procurement documents to assure inclusion of appropriate quality requirements for quality-affecting equipment, items or services;
- o Assurance that further processing, delivery, installation, or use of an item or service is controlled until proper disposition of any nonconformance, deficiency, or unsatisfactory condition has occurred; and
- o Exercising stop work authority, through established channels, as required.

### 1.3 Internal ORNL Interfaces

ORNL is operated for the DOE by Martin Marietta Energy Systems, Inc. (MMES). Systems Integration may interface with other elements of MMES using task directives for technical performance and direct administrative channels for staff support, as required. Systems Integration will specify the appropriate QA requirements for these tasks and will assure that information and data received from such interfaces, for use in the performance of Systems Integration work, was developed in accordance with applicable QAPD controls. Alternatively, Systems Integration may accept an existing QA program providing it satisfies the requirements of this QAPD.

### 1.4 External ORNL Interfaces

Systems Integration management will establish interfaces with non-ORNL members of the tasks covered by this QAPD (subcontractors and other supporting organizations). Systems Integration management will assure that information and data received from such interfaces, for use in the performance of task activities, was developed under the auspices of this QAPD or that the information is validated by an acceptable method.

### 1.5 Delegation of Work

Systems Integration management retains responsibility for any portion of the work which it delegates to other supporting organizations. Applicable QA requirements will be imposed upon these supporting organizations who are delegated work for any of the tasks covered by this QAPD. Systems Integration management will assure the adequacy of its delegated work through rigorous management controls including overview, as appropriate, of the supporting organization's QA program implementation.

Subcontractors will not be required to develop their own QA programs but will be directed to perform quality-affecting work in accordance with applicable sections of the Systems Integration QAPD. When work is delegated to subcontractors, it will be done in accordance with QAPD Section 4, Procurement Document Control. Adequacy of delegated work will be assured through the controls imposed in QAPD Section 7, Control of Purchased Items and Services.

### 1.6 Dispute Resolution

Differences of opinion involving technical or QA programmatic issues within the tasks covered by this QAPD will be elevated to the next higher management level for resolution. A procedure, QA-SI-01-001, will be developed to describe the dispute resolution mechanism.

### 1.7 Resolution of Allegations

The Systems Integration Program will use the OCRWM Headquarters system which is to be developed and implemented by OCRWM Headquarters.

### 1.8 Stop Work Provisions

All Systems Integration Program personnel have the responsibility to stop work whenever imminent danger to personnel exists. Systems Integration management has

the responsibility to question any work which has the perceived potential to produce results that are not in accordance with established requirements, and to initiate an investigation into the necessity of stopping work until deficiencies are corrected.

The QAS has the authority to: identify quality problems; initiate, recommend, or provide solutions to problems; stop work which is perceived as an imminent threat to health, safety, or the environment; and control further processing, delivery, or use of nonconforming or unsatisfactory work until proper disposition is obtained.

Supporting organization personnel, performing delegated work, have the responsibility to inform the Task Manager of quality problems so that stop work actions may be initiated, if required.

Lifting of a Stop Work Order may be initiated only after verification of implementation of corrective action to prevent recurrence of the condition leading to the issuance of the Stop Work Order.

A Stop Work procedure, QA-SI-001-002, will be developed for the Systems Integration Program which provides for:

- o Criteria and methodology for stopping work and for lifting stop work orders/requests;
- o Exact definition of work being stopped;
- o Authorities and responsibilities of personnel; and
- o Corrective action and follow-up activities.

## 2.0 QUALITY ASSURANCE PROGRAM

The Systems Integration QA program is planned, implemented and maintained in accordance with the OCRWM QARD; and referenced NQA-1 Basic Requirements, Supplements and Appendices, as directed. The Systems Integration QA program is responsive to those QA requirements which have been determined by OCRWM management to be applicable to quality-affecting Systems Integration tasks. The QA program consists of this QAPD, plus supporting QA and line procedures. The controls described in the QAPD and supporting procedures are applied to quality-affecting activities, and are verified by audit, surveillance, review and assessment.

### 2.1 Systems Integration QA Program

2.1.1 The OCRWP Manager is responsible for development and implementation of the QA program, and has management overview involvement in verification of its effectiveness. Execution of the QA program rests with Systems Integration personnel as detailed in the QAPD and supporting QA and line procedures. In addition to program management's responsibilities, the QAS has responsibility for overview and verification of implementation of the QA program.

2.1.2 ORNL does not expect lower-tier supporting organizations to develop separate QAPD's. Appropriate requirements of the Systems Integration

QAPD will; therefore, be imposed on supporting organizations. Specific applicability of the QARD requirements to supporting organizations will be in accordance with QAPD Sections 4 and 7. However, if supporting organizations already have QA programs previously approved as meeting the OCRWM QARD, Systems Integration may accept their QA programs for implementation on the tasks covered by the QAPD, pending review.

2.1.3 After review and acceptance by OCRWM Headquarters, the QAPD will be maintained as a controlled document by Systems Integration. The QAPD will be reviewed at least annually, and it will be modified as necessary to assure that it is responsive to changes in Headquarters QA requirements. In the interim, changes will be reflected by amendments/revisions accepted by OCRWM Headquarters. These changes will be approved by the same positions approving the QAPD.

2.1.4 The Systems Integration Program will maintain QA and line procedures which describe in greater detail the controls established in the QAPD. These procedures are an extension of the QAPD and are controlled by the Systems Integration Program. Some of the procedures will be adapted from existing MMES and ORNL procedures. When this is the case, those procedures will be converted to the Systems Integration Program procedure format and controlled by the Systems Integration Program. Those procedures will be revised or enhanced to meet applicable QARD requirements, and subsequent changes to those procedures will be controlled at the Systems Integration Program level. Other Systems Integration specific QA and line procedures will be developed wholly by Systems Integration personnel and will also be controlled by the Systems Integration Program. All procedures, whether adapted from other sources or developed specifically for use on the Systems Integration Program, will be prepared, reviewed, approved and controlled in accordance with sections 5.0 and 6.0 of the QAPD.

## 2.2 Reporting Independence of Personnel

The Systems Integration QAS, Systems Integration Program personnel and others perform verification activities to assure implementation of QARD requirements, as reflected in this QAPD and associated Program procedures, plans and instructions. The QAS and other personnel with responsibility for verification have sufficient independent authority, access to work areas, and organizational freedom to:

- o Identify quality problems;
- o Initiate, recommend, or provide solutions to quality problems through designated channels;
- o Verify implementation of solutions; and
- o Assure that further processing, delivery installation, or use of an item or service is controlled until proper disposition has occurred to resolve a nonconformance, deficiency, or unsatisfactory condition.

When personnel outside the QA organization perform quality verification activities (e.g., surveillance, audit, review or assessment), their activities will be monitored by the Systems Integration QAS.

### 2.3 Planning

The Systems Integration QAPD has been developed with the intent to coordinate the activities of all Systems Integration personnel under a single QA program rather than requiring each task or supporting organization to prepare an individual QA program which is responsive to the QARD. The types of activities to be performed and the information to be collected, analyzed and used in the various tasks have been considered in QAPD development, and provisions have been made for selective application of QA controls as described in section 2.4, below. The QAPD assigns responsibilities for QA to the Program Manager, Task Managers, supporting organizations and the Quality organization. The QAPD identifies control and verification activities throughout the document and references additional details in supporting procedures. Provisions have also been made in the QAPD for identification, collection and protection of QA records generated by the tasks.

### 2.4 Graded Quality Assurance Program

Each Systems Integration task covered by the QAPD will be evaluated in accordance with procedure QA-SI-02-001 (which is consistent with the OCRWM procedure for establishing QA controls) after approval of the QAPD. Task Managers evaluate each of their quality-affecting tasks to determine which sections of the QAPD apply specifically to that work. That evaluation is documented on a Systems Integration QA Controls Matrix after giving consideration to the following factors:

- Consequence of failure;
- Importance of data;
- Complexity of function;
- Reliability of process;
- Reproducibility of results;
- Uniqueness of product;
- Degree of functional product demonstration;
- Degree of standardization;
- History of quality;
- Impact on schedule or cost to replace in the event of failure;
- Necessity of special controls or processes; and
- Significance to licensing process.

### 2.5 QA Requirements Matrix

A separate QA requirements matrix which correlates the applicable requirements of the QARD, NQA-1 and NUREG-0856 with the Systems Integration QA program described in this QAPD has been developed and will be maintained by Systems Integration management. The matrix identifies where each applicable requirement is met in the QAPD, and provides a rationale for exclusion of each requirement that is determined to be not applicable.

### 2.6 Personnel Selection, Indoctrination, Training, and Qualification

Task Managers, of each Systems Integration organization, evaluate staff job positions to determine if their staff are performing activities affecting quality. For such activities, position descriptions will be established setting forth job duties. Minimum education and/or experience requirements will be established and documented. Internal memoranda will be maintained by each organization identifying the

evaluation by management that staff are qualified with the necessary education, experience and/or training to perform their intended functions in support of the Systems Integration Program. Indoctrination and training will be conducted in accordance with Systems Integration procedure QA-SI-02-002 which will identify the responsibilities for indoctrination and training, the methods to be used, and the records to be maintained. The extent of indoctrination and training will be commensurate with the scope, complexity, and nature of the activity; and the education, experience and proficiency of the person. As a minimum, Systems Integration personnel will be familiarized with the QAPD (including applicable portions of ASME NQA-1 and DOE/RW-0214), supporting QA procedures, and job responsibilities and authority.

Personnel selected to perform or verify activities affecting quality will be provided indoctrination or training, or both prior to performance or verification of quality-affecting activities. Indoctrination and training may be informal (non-classroom) or formal (classroom). Indoctrination and training notifications will take the form of memoranda, training attendance sheets, or required reading lists and will be maintained in the Systems Integration QA records files. Indoctrination and training records will include, as appropriate, the objective, content of the program, attendees, date of attendance, training aids or materials, and due dates for retraining. All such records are designated as QA Records.

Systems Integration Program management will assess the performance of personnel doing work affecting quality at least annually to determine the need for retraining and will assure that retraining is provided based upon changes in task scope or changes in the QA program.

2.6.1 Qualification of QA audit personnel, providing QA verification services to the Systems Integration Program, is described in Systems Integration QA procedure QA-SI-18-002, which meets the requirements for auditors and lead auditors as defined in NQA-1, Supplement 2S-3. The procedure includes the system used by ORNL (administered by MMES) for assuring that auditors and lead auditors meet applicable requirements. Lead auditors will have the skills necessary to communicate effectively; sufficient training to assure knowledge of NQA-1, QA programs, auditing techniques and audit planning; and on-the-job training. Lead auditors will also meet the audit participation requirements and examination requirements of NQA-1, Appendix 2A-3. The procedure addresses the maintenance of auditor qualification and administration of the auditor training and qualification program. Auditor certification records content and maintenance are also described.

## 2.7 Surveillance

In addition to audits conducted in accordance with Section 18, surveillance of Systems Integration tasks will be conducted to assess the quality of activities and compliance with the QA program. Surveillance will be conducted by the QAS, or a designee, and will include (as appropriate) personnel who are knowledgeable in, but not directly responsible for, the activities under surveillance.

Surveillance results will be reported to Systems Integration Program management and documentation will include, as appropriate:

- o Date of surveillance;

- o Description of the activity under surveillance;
- o Persons conducting the surveillance;
- o Persons contacted during the surveillance;
- o The requirements governing the activity;
- o Deficiencies identified during the surveillance;
- o Measuring and test equipment used during the surveillance; and
- o Summary of any immediate corrective actions taken.

Surveillance will be conducted in accordance with procedure QA-SI-18-003, which describes the surveillance process and establishes requirements for documentation of planning and results, deficiency control and corrective action.

## 2.8 Management Assessment

The OCRWP Manager assures that assessments, to determine the effective implementation of the QA program, are conducted at least annually. Those personnel conducting these assessments will be independent of the QA organization. Management assessments will include the criteria required by the QARD as follows:

- o Adequacy of organizational structure and staffing to implement the QA program;
- o Effectiveness of QA program implementation;
- o Adequacy of the indoctrination and training program;
- o Adequacy of planning and procedural controls;
- o Effectiveness of the nonconformance and corrective action system; and
- o Adequacy of the QA management information tracking, evaluation, and reporting system.

The results of management assessments will be documented and corrective actions for those assessments that indicate conditions adverse to quality, will be determined, documented and tracked to completion. Management assessments will be performed in accordance with Procedure QA-SI-02-003.

## 2.9 Quality Assurance Program Management-Information Reporting and Tracking

The ORNL QAS collects and tracks information about, and reports the status of the following types of QA activities:

- o Development of the QA program;
- o Resolution of significant conditions adverse to quality and any QA issues

- o Management overview results.
- o Results of audit, surveillance, review and assessment.

Quality management information is reported monthly to the OCRWP Manager, the Systems Integration Task Managers, the WR&D Programs Director, and the ORNL QA Manager.

### 3.0 DESIGN CONTROL

No design activities are being conducted in the tasks covered by the QAPD. The quality-affecting tasks conducted by Systems Integration are instead concerned with providing integrated data sources and modeling capabilities to OCRWM. Controls appropriate to these tasks are covered in section 19.0 of the QAPD.

#### 3.1 Technical Reviews

Because Systems Integration is producing information and documents, which will be used as input sources into the design of components of the Federal Waste Management system, which are important to safety and waste isolation; technical reviews will be conducted, as appropriate, and will meet the following requirements specified in the QARD:

- o Technical reviews will be performed when the information or document under review is within the state of the art and is based on accepted standards, criteria, principles, and practices.
- o Technical reviews will be used when documents, activities, material, or data require technical evaluation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.
- o Technical reviews will be performed by individuals with sufficient technical knowledge of the area under review.
- o The results of reviews and follow-up action will be documented.

Technical reviews will be conducted in accordance with Systems Integration procedure QA-SI-05-002. The procedure requires that reviews are conducted in a specific manner and are documented on a specific review form which identifies the document under review by title, revision and date; and which specifies review criteria appropriate to the document. The mechanics of how the review and comment cycle is accomplished, including resolution of comments and collection of QA records, is described in the procedure.

#### 3.2 Peer Reviews

When peer review is required to establish the adequacy of quality-affecting work, Systems Integration will accomplish such reviews in accordance with NUREG-1297, "Peer Review for High Level Nuclear Waste Repositories". This type of review, performed by peers who are independent of the work being reviewed, will be conducted in accordance with a peer review plan approved by the OCRWP Manager and accepted by OCRWM management. Such plans will describe the peer review

process and establish the review criteria. The qualifications of the peer reviewers will be established and each reviewer's qualifications will be documented. The peer review process will include written comments which must be resolved and a mechanism for concluding comment resolution. A peer review activity will result in a peer review report which documents the reviewer's judgement as to the adequacy of the work reviewed. Peer review plans, reviewer qualifications, comments and resolution, and peer review reports will become QA records.

#### 4.0 PROCUREMENT DOCUMENT CONTROL

Procurement document control will be accomplished in accordance with Systems Integration procedure QA-SI-04-001. Although Systems Integration typically procures only services from subcontractors to support its tasks, the procedure applies to items, when appropriate. Common commercial grade office supplies, floppy discs, personal computers or other catalog hardware are not considered as quality-affecting for the work covered by the QAPD.

- 4.1 When Systems Integration procures services (or items, if applicable), procurement documents such as procurement/purchase requisitions, purchase orders, task orders, contracts, or other contractual instruments contain the following, as appropriate:
  - 4.1.1 A statement of the scope of the work to be performed by the supplier is always included in the procurement document;
  - 4.1.2 Applicable design bases, applicable regulatory requirements, and other technical and QA program requirements which must be followed by the supplier when performing the work are defined;
  - 4.1.3 Procurement documents specify which portions of the QAPD apply to the work the suppliers are performing for Systems Integration. Should the supplier use a sub-tier support organization (sub-contractor), the supplier is required to pass down those portions of the QAPD which apply to the work.
  - 4.1.4 Systems Integration includes right of access as a contractual condition for suppliers performing quality-affecting work. Systems Integration retains the right to visit the suppliers facilities for the purpose of audit, surveillance or review;
  - 4.1.5 The documentation to be prepared and submitted to Systems Integration is detailed in the procurement documentation, which includes a schedule for accomplishment. Collection and maintenance of QA records, by the supplier, is also defined;
  - 4.1.6 Requirements for nonconformance control will be specified should procurement of items become a part of the Systems Integration Program.
  - 4.1.7 Requirements for spare and replacement parts will only be included in procurement documentation when items requiring such parts are procured for the Systems Integration work.

#### 4.2 Procurement Document Review

Procurement documents, for quality-affecting services (or items, if applicable) will be reviewed by QA and technical personnel who have an adequate understanding of the specific procurement and have access to information pertinent to the procurement. These reviews assure that procurement documents contain appropriate provisions (including those specified in paragraph 4.1 above) which delineate those requirements to which the supplier will perform the work and by which the supplier will be evaluated. Reviews will be documented by each reviewer initialing the procurement document. Disagreements between the originator of the procurement and reviewers will be resolved by the OCRWP Manager. Changes to procurement documents are reviewed by the same or equivalent staff, and are initialed to indicate approval. Reviews of changes give consideration to the requirements specified in paragraph 4.1 above, assess any new or modified criteria, and evaluate changes requested by the supplier for impact on the procurement.

#### 4.3 Applicability of Purchaser's Quality Assurance Program

As described in paragraph 2.1.2 above, ORNL does not expect lower-tier supporting organizations to develop separate QAPD's. Appropriate requirements of the Systems Integration QAPD are instead imposed on supporting organizations. Specific applicability of the QAPD to such delegated work is defined in the supporting organization's procurement documentation. However, if supporting organizations already have QA programs previously approved as meeting the OCRWM QARD, Systems Integration may accept their QA programs for implementation on the tasks covered by the QAPD, pending review by the OCRWP Manager, the affected Task Manager and the QAS.

### 5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

Activities affecting quality are accomplished in accordance with documented plans, manuals, procedures and instructions, as applicable to each task. Since design work is not being conducted in any of the Systems Integration tasks, no drawings are expected. Quality-affecting documents are also subject to document control in accordance with section 6.0 of the QAPD.

Plans, manuals, procedures, and instructions will be uniquely identified, developed, coordinated, controlled, and approved. Changes thereto will be subject to the same controls as applied in the preparation of the original document. Plans and manuals will be prepared in a form appropriate to the subject matter and will be reviewed in accordance with Systems Integration procedure QA-SI-05-002.

Procedures and instructions will be prepared in accordance with Systems Integration procedure QA-SI-05-001. That procedure specifies a format to be followed when developing QA and line procedures, and defines an outline of contents to be included. The procedure also specifies reviews and the collection of records generated as a result of performing procedural activities. Procedures and instructions will reference appropriate quantitative or qualitative acceptance criteria for determining satisfactory performance and quality compliance.

The OCRWP Manager and the respective Task Managers are responsible for including the QAS, in the review of quality-affecting plans, manuals, procedures and instructions.

5.1 Reviews will be performed by independent reviewers, in accordance with Systems Integration procedure QA-SI-05-002, to assure technical adequacy, including the correct translation of technical requirements and inclusion of quality requirements.

## 5.2 Quality Assurance Records

Documents controlled by Systems Integration will delineate those documents generated as a result of implementation of an instruction, procedure or plan which are to be designated as quality records. These records will be handled as QA Records in accordance with section 17.0 of the QAPD.

## 6.0 DOCUMENT CONTROL

Systems Integration will control quality-affecting documents to assure that the preparation, issue and change of those documents is performed in accordance with acceptable practices as described in Systems Integration procedure QA-SI-06-001. That procedure will establish responsibilities for control of quality-affecting documents; and methods for preparation, issue and change of such documents. Only the latest approved documents which prescribe quality requirements and quality-related activities will be available at the location where the activity will be performed. The document control methods used assure that controlled documents, and subsequent changes thereto are reviewed for adequacy and approved for release by authorized personnel.

Quality-affecting documents (such as instructions, procedures, plans, and manuals) will be identified by the OCRWP Manager and the responsible Task Managers. Each document identified for control will be added to a controlled document list which is prepared and maintained in accordance with procedure QA-SI-06-002. The controlled document list for the Systems Integration Program is the responsibility of the OCRWP Manager (or a designee), and it includes the title, document number, revision number, date, responsible author, and distribution for each controlled document. The list is updated each time a change in status of a controlled document occurs. The Program Manager and the Task Managers assign individuals with responsibility for each controlled document, which includes its revision, review and reissue.

Changes to documents will be reviewed for adequacy, and approved by the OCRWP Manager and responsible Task Manager prior to release. Reviewers will have access to all pertinent information necessary to assure themselves of the acceptability of each document reviewed. Major changes to documents will be processed in the same manner as the original documents, which includes the review cycle in accordance with procedure QA-SI-05-002. Minor changes, such as typographical errors, do not require the formal review and approval process; however, minor changes are checked and approved by the responsible Task Manager (or a designee). All changes to controlled documents, both major and minor, require document revision and reissuance in accordance with procedure QA-SI-06-001. That procedure details the responsibility for change control and the designated authority for approval of changes.

### 6.1 Control System

The Systems Integration document control system assures that:

- o Documents to be controlled are identified and their specific distribution is established and maintained;

- o Responsibility for preparing, reviewing, approving, and issuing controlled documents is assigned to individuals in accordance with procedure QA-SI-06-001;
- o Review of documents for adequacy, completeness and correctness prior to approval and issuance will be conducted in accordance with procedure QA-SI-05-002;
- o Review comments will be documented in accordance with procedure QA-SI-05-002. Review comment record forms, including comment resolutions, will be maintained as QA records in accordance with procedure QA-SI-17-001;
- o All review comments will be resolved in accordance with procedure QA-SI-05-002 prior to approval and issuance of a controlled document;
- o A Systems Integration Program controlled documents list will be developed and maintained in accordance with procedure QA-SI-06-002;
- o A receipt acknowledgement system, as described in procedure QA-SI-06-001, will assure that each person receiving a controlled document must return a form which indicates receipt of the document and acceptance of the requirement to maintain it;
- o Procedure QA-SI-06-001 includes a method for handling superseded documents and requires that they be either marked as superseded by the document holder, destroyed or returned to Systems Integration for disposition.

## 6.2 Controlled Documents

When controlled documents, which require verification or approval, are released prior to verification or approval; they will be so identified, controlled, and authorized through signature approval by the OCRWP Manager, with the basis for release described and the unverified portions identified. When this occurs, it will be done in accordance with procedure QA-SI-06-001.

## 6.3 Quality Assurance Organization Review

The Systems Integration QAS, or a designee, will be included in the review process for controlled documents in accordance with procedure QA-SI-05-002 to assure that quality-affecting, controlled documents contain appropriate QA requirements.

## 7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

Control of purchased items and services will be accomplished in accordance with Systems Integration procedure QA-SI-07-001 to assure that services procured to accomplish quality-affecting activities for Systems Integration tasks conform to the requirements specified in the procurement documentation for those activities. Procurement of services for quality-affecting activities for each Systems Integration task will be planned to assure that procurement documentation clearly states what is to be accomplished, who is to accomplish the work stated, how the task is to be performed, and when the activities defined in the statement of work are to be completed. Since the activities covered by the QAPD have been ongoing for several years, the Systems Integration Task Managers will assure that each supplier's

procurement documentation conforms with the requirements stated above and that renewals of contracts are accomplished in accordance with procedure QA-SI-07-001. For any new task initiated, the responsible Task Manager will assure that procurement planning is accomplished as early as practicable, in accordance with procedure QA-SI-07-001, and no later than the start of the activity to be controlled. Early initiation of procurement planning will help assure compatibility of interfaces and a uniform procurement approach.

**7.1** The planning process established in procedure QA-SI-07-001 requires that the following functions are integrated as appropriate during the planning process:

- procurement document preparation, review and change control
- selection of procurement sources
- bid evaluation and award
- purchaser control of supplier performance
- verification (surveillance, inspection or audit) by purchaser, including notification for hold and witness points
- control of nonconformances
- corrective action
- acceptance of an item or service
- quality assurance records

**7.2** The Systems Integration Task Managers are responsible for selection of suppliers for new Systems Integration tasks based on evaluation of the prospective supplier's capability to perform a quality-affecting activity in accordance with the requirements of the procurement document. The Systems Integration QAS is responsible for assessing the evaluation and selection process to assure that the process was conducted and documented in accordance with procedure QA-SI-07-001. One or more of the following measures will be used by Task Managers when evaluating and selecting suppliers:

- evaluation of the supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability.
- supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated.
- supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.

**7.3** When Systems Integration accepts bids for new tasks, those bids will be evaluated to determine the bidder's conformance to procurement documents. Bid evaluations will be conducted by the Systems Integration Task Manager responsible for the activity, any additional technical experts deemed necessary by the Task Manager, and the Systems Integration QAS. Personnel charged with bid evaluation will assess the following characteristics of the potential supplier's proposals: technical considerations, quality assurance requirements, supplier's personnel, supplier's production capability, supplier's past performance, alternates and exceptions. All unacceptable conditions discovered during evaluation will be resolved prior to award of contract.

**7.4** Systems Integration Task Managers establish interfaces with their suppliers to assure that the supplier's performance can be verified, and the Task Managers develop an understanding with their suppliers as to what is expected in accordance with the

organizations. Specific applicability of the QAPD to supporting organizations is defined in the supporting organization's procurement documentation.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Systems Integration does not plan to procure materials, parts, or components for the tasks covered by the QAPD. Systems Integration is procuring the services of subcontractors who are responsible for assisting in the development of computer data bases and computer models, plus associated documentation. Identification and control of these data bases and models will be accomplished in accordance with the requirements of section 19.0 of the QAPD.

9.0 CONTROL OF PROCESSES

This section of the QARD is not applicable to the tasks covered by this QAPD.

10.0 INSPECTION

Systems Integration does not plan to procure hardware items requiring inspections for any of the tasks covered by this QAPD. Systems Integration is; however, procuring the services of subcontractors who are responsible for assisting in the development of computer data bases and computer models, plus associated documentation. Acceptance of these services will be accomplished through appropriate reviews of documentation (procedure QA-SI-05-002), and verification and/or validation of computer data bases and models in accordance with the requirements of section 19.0 of the QAPD.

11.0 TEST CONTROL

This section of the QARD is not applicable to the tasks covered by this QAPD.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

This section of the QARD is not applicable to the tasks covered by this QAPD.

13.0 HANDLING, STORAGE, AND SHIPPING

This section of the QARD is not applicable to the tasks covered by this QAPD.

14.0 INSPECTION, TEST, AND OPERATING STATUS

This section of the QARD is not applicable to the tasks covered by this QAPD.

15.0 CONTROL OF NONCONFORMING ITEMS

Systems Integration does not plan to procure hardware items affecting quality for any of the

procurement documents. Task Managers will assure that the following measures are taken, as appropriate to the type of activity performed by the supplier:

- requiring the supplier to identify planning techniques and processes to be utilized in the activity
- reviewing supplier's documents which are generated or processed during the activity
- identifying and processing change information
- establishing document information exchange methods
- establishing the extent of surveillance activities

7.4.1 Verification by Systems Integration personnel does not relieve the supplier of responsibility for verification of quality. This requirement is included in procurement documents.

7.4.2 The extent of verification activities - such as audit, surveillance, review or other assessment method - by Systems Integration personnel will be appropriate to the importance, complexity or quantity of the activity.

7.4.3 Verification activities, performed by Systems Integration personnel, will be recorded in the appropriate format depending on the type of verification conducted. For example, audit and surveillance reports will be prepared in accordance with Section 18.0 of the QAPD and procedures QA-SI-18-001 and QA-SI-18-003, respectively. All verification documents will be processed as QA records in accordance with procedure QA-SI-17-001.

7.5 Systems Integration Task Managers will assure that supplier generated documents, which are quality-affecting, are given an acceptance review appropriate to the document type. Acceptance reviews will include evaluation of supplier submittals in accordance with the requirements specified in the procurement document applicable to the submittal. Documents such as plans, reports and procedures will be reviewed in accordance with procedure QA-SI-05-002. Supplier generated documents which are complete will be processed as QA records in accordance with procedure QA-SI-17-001.

7.6 Changes in procurement documents, whether initiated by Systems Integration or a supplier, will be reviewed and approved by the same or equivalently qualified personnel as were responsible for review and approval of the original procurement documents.

7.7 Systems Integration is not procuring any hardware items beyond common commercial grade office supplies, floppy discs, personal computers or other catalog hardware which are not considered as quality-affecting for the work covered by the QAPD. Systems Integration is procuring the services of subcontractors who are responsible for assisting in the development of computer data bases and computer models, plus associated documentation. Acceptance of these services will be accomplished through appropriate reviews of documentation (procedure QA-SI-05-002), and verification and/or validation of computer data bases and models in accordance with the requirements of section 19.0 of the QAPD.

7.8 As stated in paragraph 2.1.2 of the QAPD, Systems Integration does not expect lower-tier supporting organizations to develop separate QAPD's. Appropriate requirements of the Systems Integration QAPD are instead imposed on supporting

tasks covered by the QAPD. Therefore, the nonconformance control system used by ORNL is not applicable to Systems Integration task products. However, the Task Managers are procuring the services of subcontractors who are responsible for assisting in the development of computer software, such as data bases, models and codes; plus associated documentation. Deficiencies in task software products or documentation will be handled in accordance with section 19.0 of the QAPD. When corrective actions are required, they will be documented, completed and verified in accordance with Section 16.0 of the QAPD.

## 16.0 CORRECTIVE ACTION

The Systems Integration Program, as an organization under ORNL and MMES, is required to report occurrences (which includes conditions adverse to quality) to DOE in accordance with DOE Order 5000.3A, Occurrence Reporting and Processing of Operations Information. The requirement to implement this DOE Order is stated in ORNL Procedure X-GP-13, Occurrence Reporting System which in turn invokes MMES Procedures GP-13, Occurrence Reporting System (ORS), GS-13.1, Occurrence Reporting Method, and GS-13.2, Analysis and Corrective Actions for Reported Occurrences which provide the detailed instructions for ORS and related corrective actions. Systems Integration procedure QA-SI-16-001 encapsulates ORNL procedure X-GP-13 which in turn references the MMES procedures. Corrective actions are documented on a standard form contained in procedure QA-SI-16-002. That procedure provides instructions for completing the form. This includes identification of the problem found, a proposed corrective action, responsible signatures, schedule for completion, and verification of implementation. The ORS procedures also require identification of the root cause of the condition.

### 16.1 Corrective Action For Significant Conditions Adverse To Quality

Significant conditions adverse to quality may include but are not necessarily limited to:

- o Failure to implement elements of the Systems Integration QA program;
- o Discrepancies encountered in computer software products during review or during comparison of alternate calculations with original results;
- o Deficiencies in the use of instructions or procedures;
- o Failure to implement corrective action in response to surveillance, audit or other verification process used by Systems Integration staff.

Significant conditions adverse to quality will be documented and corrected in accordance with procedure QA-SI-16-002.

### 16.2 Deficiencies

Deficiencies and related corrective actions will be tracked by the Systems Integration QAS (or a designee) using the WR&D Programs, Quality Information System which is maintained by the QAS. This is a personal computer based system controlled by the QAS. It is structured to collect and track information about corrective actions as well as other QA functions such as planning, training, audit, surveillance and records.

The system is also used for issuing status reports on any of the functions listed above.

### 16.3 Remedial Action

Remedial action will be documented in accordance with procedure QA-SI-16-002 and initiated after a deficiency is identified. The affected Systems Integration Task Manager will determine remedial action appropriate to the deficiency. The QAS will concur with the remedial action to assure that QA requirements are satisfied. Follow-up action will be taken by the QAS, and where necessary appropriate technically qualified personnel assigned by the OCRWP Manager, to verify implementation of remedial action and to close out the action in a timely manner.

## 17.0 QUALITY ASSURANCE RECORDS

Quality Assurance records produced by each Systems Integration task are those completed documents or items that furnish evidence of the quality of those activities affecting quality. Systems Integration Task Managers will specify, prepare and maintain such records for each of their quality-affecting tasks. QA records categories will be established for each of the tasks covered by the QAPD and may include those categories of documentation listed in paragraph 17.2, as appropriate to each task. Quality-affecting documents prepared for Systems Integration tasks will specify the QA records to be generated as a result of implementing such documents.

Originals of QA Records will be stored and maintained in a manner to minimize the risk of damage or destruction by natural disasters, abnormal environmental conditions, or infestation of insects. To satisfy the storage requirements of NQA-1, Supplement 17S-1, the dual records storage alternative will be used for Systems Integration records. The original of each QA record will be maintained by the responsible Task Manager while the QAS will maintain the duplicate records collection for each task. Both original and duplicate records will be legible, accurate and complete before inclusion in the records system.

QA records will be controlled and handled in accordance with procedure QA-SI-17-001 which describes how records are to be processed by the Task Managers. The procedure addresses records administration (generation, validation, indexing, identification, classification, retention and correction), receipt, storage, preservation, safekeeping, facility, retrieval and distribution. Each of these aspects of QA records control is described in the procedure.

Systems Integration QA records will be maintained for the duration of each quality-affecting task at ORNL. Upon completion of a task, a records package will be turned over to OCRWM Headquarters Program Manager for disposition in accordance with Headquarters procedures.

### 17.1 QA Records

Documents that are authenticated and that will receive no more entries are QA records and are subject to the requirements for QA records storage. Each Systems Integration Task Manager will be the record authenticator for their respective tasks. Authentication also applies to corrections made to QA records by the responsible Task Managers. Prior to authentication, each Task Manager will provide interim protection to those records identified as quality-affecting in the manager's area of responsibility.

17.2 Systems Integration QA records will include such categories of documentation as:

- Procedures
- Plans
- Manuals
- Reports
- Technical and peer reviews
- Personnel qualifications
- Procurement documents
- Computer software documents
- Audit and surveillance plans and reports
- Correction action plans and reports
- Occurrence reports
- Systems Integration QAPD and procedures
- Guidance letters
- Systems Integration QA requirements matrix
- Assessment reports
- Evaluations of supplier's programs
- Auditor certifications

## 18.0 AUDITS

The OCRWP Manager will assure that a QA audit program is implemented to provide independent verification of the status, adequacy, compliance and effectiveness of the Systems Integration QA program, including its implementing procedures. Systems Integration will use audit and surveillance as two of its most important management tools to measure the effectiveness of and compliance with the QA program. These oversight activities will be conducted in accordance with Systems Integration QA procedures identified in this section.

Audits will be planned and scheduled in a manner which provides coverage and coordination with ongoing QA activities. The frequency of Systems Integration audits will be consistent with the status and importance of the on-going task activities. The audit schedule will be reviewed at least annually and updated more frequently if additional audits are required. Audits will be planned, conducted and documented in accordance with Systems Integration procedure QA-SI-18-001.

### 18.1 Audit Planning and Performance

18.1.1 The Systems Integration audit program will include both technical and programmatic verifications. Audit teams will be selected from the ORNL quality assurance and technical staff, independent of the area audited, and based upon the expertise needed for the audit. Each audit team will be headed by a lead auditor who is responsible for organizing, directing and concluding the audit. Training and indoctrination will be provided to quality assurance and technical staff in auditing techniques. Auditor and lead auditor training and qualification programs are administered by MMES as described in section 2.6 of the QAPD and specifically in procedure QA-SI-18-002. Audit teams may include consultants in the event that the necessary technical expertise is not available within ORNL. Audit team members collectively will have the necessary programmatic and technical expertise in the work being audited.

18.1.2 The Systems Integration QAS, working in conjunction with appropriate technical staff, will be responsible for planning and execution of audits. The OCRWP Manager and the respective Task Managers will support the audit program by assisting in assignment of technical specialists to audit teams; and will assure that time, personnel, and documents are available for QA audits of their functional areas.

18.1.3 Audits will be planned and conducted in accordance with procedure QA-SI-18-001 which requires written audit plans and/or checklists. Audited activities will be evaluated against specified QA program requirements, and objective evidence will be examined by the auditors to the extent necessary to determine if implementation satisfies requirements. Audit team members will document the results of their investigations and will regularly communicate the status of activities as well as problems and potential problems to the audit team leader and the audited organization's representatives. Problems requiring prompt attention will be immediately reported to the management of the audited organization. Regular discussions with the audited organization's representatives will be held during audits to discuss the status of audit activities, including potential deficiencies, and to promote effective communications between the auditors and the audited organization.

## 18.2 Reporting and Response

18.2.1 Observed deficiencies will be analyzed by the audit team and formalized into audit findings and observations by the audit team leader. Results of audits will be presented to the audited organization's representatives by the audit team leader (and team members) in a post-audit conference to complete the audit phase.

18.2.2 Results of Systems Integration audits will be documented in an audit report containing the scope of the audit, a summary of results, a participants list, audit findings, observations, comments, and an evaluation of the effectiveness of the audited activity. Audit reports will be signed by the lead auditor and approved by the QAS prior to distribution. Reports will be distributed to the audit team members, the OCRWP Manager, the Task Manager of the audited activity, the QAS, and the ORNL Quality Department.

18.2.3 The Task Manager, or designee, of the audited organization must respond in writing to the audit findings and observations identified in the audit report by the date requested in the report. The audit response will include a determination of root cause, and a schedule for completion of corrective action including measures to prevent recurrence. Audit responses will be reviewed by the Lead Auditor, the QAS and the OCRWP Manager. Corrective actions will be documented in accordance with section 16.0 of the QAPD.

18.2.4 Follow-up actions will be conducted by the audit team leader, Systems Integration QAS or other designated, qualified personnel to verify that satisfactory action was taken to implement corrective and preventive actions which satisfy audit findings and observations. Verification of corrective and preventive action implementation will be documented to support close-out of each finding and observation. Close-out will be in accordance with procedure QA-SI-16-001 which details the process for documenting verification of

closure.

18.2.5 Records generated as a result of audits will include: audit plans and checklists, documentary evidence gathered, audit reports, and documentation of corrective actions.

### 18.3 Internal Audits

Internal audits (those conducted at ORNL, by ORNL personnel or designees) will be conducted at least annually on the quality-affecting elements of the Systems Integration tasks performed at ORNL, or at least once during the life of the activity, whichever is shorter. An annual audit schedule will be prepared by the Systems Integration QAS and updated as changes occur. The audit schedule and the scope of audits will be based on an evaluation of the activities to be audited. The evaluation will consider results of previous surveillances and audits, and the impact of significant changes in personnel, organization, or QA program; as well as the content of the activity and its schedule of key events.

### 18.4 External Audits

External audits (those conducted by ORNL personnel or designees at subcontractor/supplier facilities) will be conducted at a frequency based on an evaluation (same as that defined in paragraph 18.3 above) of the activities performed by the supplier. Part of the evaluation will include a determination of the need for external audits of a supplier based on the type of service or product being provided.

18.4.1 When it is determined that audits of suppliers are necessary, these audits will be conducted at least triennially. When a triennial schedule is adopted for a supplier, the Systems Integration Task Manager and the QAS will conduct and document an annual evaluation of the supplier, which considers the following:

- Review of documents and records
- Results of previous verifications, surveillances, audits, and assessments
- Quality of similar services or products furnished by the supplier
- Results of audits of the supplier from other sources

18.4.2 Systems Integration management may determine that external audit of a supplier is not necessary if:

- the service or product is relatively simple and standard
- procedures for acceptance of the service or product are standard

The rationale for not performing an external audit will be maintained as a QA record for each supplier determined to not require an audit.

18.4.3 The Systems Integration audit schedule, identified in paragraph 18.3 above, will also include external audits of suppliers, as appropriate.

### 18.5 Surveillance

The Systems Integration QAS is responsible for implementing the surveillance program and will schedule surveillance activities in coordination with the Task

**Managers.** Surveillance will be used to assess on-going activities through observation and/or examination of work practices. Surveillance teams may include non-QA personnel or may be solely comprised of such personnel as long as they do not report to the manager of the activity under surveillance. Surveillance will be conducted in accordance with procedure QA-SI-18-003 which provides the method for planning, conducting and documenting these oversight activities.

Surveillance activities are similar to audits in that they are planned and documented; and in that deficiencies found are documented, including preparation of corrective actions. Surveillances are scheduled at times appropriate to the status of the Systems Integration task activities, and are reported to the OCRWP Manager, the Task Manager of the activity, the QAS, and the ORNL Quality Department.

## 19.0 COMPUTER SOFTWARE

The Systems Integration Program will establish a computer software, development and control program which applies to computer software determined to be quality-affecting. Systems Integration tasks covered by the QAPD will implement software control in accordance with the minimum requirements of applicable paragraphs of QARD Section 19. Quality-affecting computer software, whether developed or adopted for use, will be documented in accordance with the applicable elements of the documentation guidance specified in NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.

Software controls will be applied to each computer software product in a graded manner. Systems Integration Task Managers will implement grading by evaluating each software product in consideration of factors such as: function to be performed, complexity and nature of the product, importance to the OCRWM Program, sensitivity to regulatory and licensing requirements, and intended end use. The Systems Integration Software QA Plan will describe how selective application of controls by grading will be accomplished and documented.

### 19.1 Systems Integration Computer Software

There are two basic types of computer software which may be used in support of Systems Integration tasks: existing and new development. Existing is that software which was developed prior to implementation of the QAPD and includes: a) products developed within the Systems Integration Program, b) products developed by an organization outside the Systems Integration Program, or c) commercially developed products. New development software includes products to be developed for Systems Integration in accordance with the QAPD. New development may be performed within the Systems Integration organization or by an outside organization contracted to perform the work.

19.1.1 When computer software is to be developed to support activities affecting quality, the developers will adhere to an accepted computer software life cycle model. The life cycle to be used by Systems Integration will include phases for requirements definition, design description, implementation of the design into software, test of implementation, installation and checkout, and operation and maintenance. The complexity of phases in the software life cycle, for a specific computer software product, will be dependent on the results of the evaluation performed to grade the software controls. Documentation of applicable phases of the software life cycle, for each software product, will be

reviewed and approved according to the Software QA Plan developed for that software.

19.1.2 When existing software is to be used for activities affecting quality, the responsible Task Manager will make a determination as to which controls (as described in section 19 of the QAPD) are applicable for acceptance and use of that software (code, model or data base). The applicable requirements and corresponding controls will be documented in a Software QA Plan (SQAP) which covers either single or multiple software products. The SQAP will address the life cycle phases appropriate for that software.

19.1.3 Plans and procedures for each of the following QAPD sections, applicable to Systems Integration software, will be prepared, reviewed and approved as appropriate to the software to be used.

## 19.2 Computer Software Quality Assurance Plan

The computer software life cycle will be applied to Systems Integration software in accordance with the SQAP(s) developed for use with software supporting the tasks covered by the QAPD. The SQAP(s) will be submitted to OCRWM for review and approval since the Systems Integration tasks are managed by OCRWM Headquarters staff. The SQAP(s) will identify the software to which it applies, the organizations involved and their responsibilities, documentation required, and reviews to be conducted. Any standards, conventions, techniques or methodologies referenced will be identified in the SQAP(s).

19.2.1 The SQAP(s) will address the following:

- Criteria for application of controls
- Methods for implementing the life cycle
- Types of documentation
- Interface control
- Baseline management
- Verification and validation
- Discrepancy reporting, evaluation and corrective action

19.2.2 The life cycle controls used by Systems Integration will be described in the SQAP(s) and will be implemented as applicable to the software products covered. The following life cycle phases will be addressed, as appropriate:

19.2.2.1 Requirements definition: those software requirements pertaining to functionality, performance, design constraints, attributes, and external interfaces will be specified, documented and reviewed. Requirements will assure that format and language are understandable, detail is sufficient to allow verification, definition is adequate for the software to respond to input, and enough information is given to design the software without being prescriptive.

19.2.2.2 Design description: a software design based on established requirements will be specified, documented and reviewed. The design documentation will define the overall software structure and the detailed algorithms, equations, logic, and

data structures which accomplish the intended functions. Verification in this phase will encompass development of test cases, review and analysis of design, and verification of design.

- 19.2.2.3 Implementation: the design will be translated into a product using a programming language(s). Verification activities will include modification of test cases, examination of source code, and debugging.
- 19.2.2.4 Testing: the software product will be evaluated by exercising the test cases. Verification activities will include evaluation of the product in accordance with the requirements and reporting verification results.
- 19.2.2.5 Installation and checkout: installing and integrating the software product with hardware and other computer software will be accomplished in this phase. Test cases will be exercised to assure that installation and integration was successful.
- 19.2.2.6 Operation and maintenance: after approval of the product for use in quality-affecting work, maintenance will be conducted to correct and prevent discrepancies, and to make enhancements to assure compatibility with the operating environment. Modifications will be subjected to appropriate tests to assure that design integrity has been maintained.

### 19.3 Computer Software Verification and Validation

Verification of computer software and validation of computer models will be performed prior to the use of such quality-affecting software for technical calculations. When verification and/or validation of a software product has not been completed, that condition will be documented and reported to OCRWM management, and a schedule for completion will be developed to assure that the software is verified and/or validated before use in quality-affecting work.

Systems Integration Task Managers will be responsible for developing verification and/or validation plans to determine that computer software products function correctly. The extent of verification and/or validation activities will be dependent on the complexity, nature and importance of the software product. Final version computer software to be used for a licensing activity will be verified and/or validated by an independent individual who did not work on the original software.

Verification and validation activities will be accomplished in accordance with Systems Integration procedure QA-SI-19-001. That procedure establishes responsibilities for conducting verification and validation activities, and describes the methodology to be used on quality-affecting Systems Integration tasks to plan, perform, report and review the verification and validation process for a software product.

### 19.4 Verification

Verification activities for Systems Integration computer software will be integrated into applicable phases of each computer product's life cycle, as appropriate, and will

be performed to an extent commensurate with the critical importance of the computer software. Verification will assure that software requirements are implemented in the design and that the design is implemented in the code, model or data base. Verifications will be accomplished in accordance with Systems Integration procedure QA-SI-19-001.

#### 19.5 Validation

Validation of computer models will be documented and will demonstrate that a model is a correct representation of the process or system for which it is intended. This will entail comparing computer software results against actual data. If actual data does not exist, alternative approaches will be used and documented to validate models. Alternative approaches may include peer review or comparison with other verified computer software. Validations will be accomplished in accordance with Systems Integration procedure QA-SI-19-001.

#### 19.6 Computer Software Configuration Management

A computer software configuration management system for Systems Integration tasks will be established by the OCRWP Manager and Task Managers in a Configuration Management Plan (or Plans). The Plan(s) will address identification and control of computer software baselines and changes thereto. The configuration controls applicable to each task covered by the QAPD will be included, either separately or as a unit, in the Configuration Management Plan(s).

##### 19.6.1 Configuration Identification

Each approved software product used in a quality-affecting task will have a baseline established in accordance with the applicable Configuration Management Plan. As changes to the software product are approved, they will be incorporated into the next iteration of the software as part of the new baseline. The Systems Integration Configuration Management Plan(s) will also specify a labeling convention appropriate to each software product covered.

##### 19.6.2 Configuration Change Control

The Systems Integration Configuration Management Plan(s) will define a change control method which requires specific documentation that describes and justifies a proposed change, and which adequately identifies the affected part or parts of the baseline. The method used will require designation of a change control authority who will require evaluation of proposed changes by qualified personnel to assure that the impact of such changes is assessed and that changes are in line with the software product requirements before approval.

##### 19.6.3 Configuration Status Accounting

The Systems Integration Configuration Management Plan(s) will define a method for recording and reporting baseline and change information for each quality-affecting software product. The accounting method will assure that the baseline is identified, change status is maintained, change history is maintained, and information to support the configuration control system is

available.

#### 19.7 Qualification of Existing Software

Existing computer software will be qualified for use prior to application in a Systems Integration task. Qualification will be based on the ability of the software to provide results acceptable for the intended use. Verification and/or validation of each software product, not developed under a QA program meeting the requirements of the QARD and approved by OCRWM, will be required to qualify such software in accordance with the applicable process detailed in paragraphs 19.3, 19.4 and 19.5 of the QAPD. Where commercial auxiliary software is used for Systems Integration tasks, all available documentation will be obtained from the supplier and such software will be controlled by Systems Integration in accordance with the SQAP(s) applicable to the task.

#### 19.8 Documentation

Documentation applicable to each computer software product, used on the tasks covered by the QAPD, will be identified in the SQAP covering each product. As appropriate to each software product, documentation will be prepared which provides a record of the applicable life cycle phases described in paragraphs 19.2.2.1 through 19.2.2.6 of the QAPD. The documentation specified in NUREG-0856 will be completed as appropriate to the software products and as defined in the SQAP(s) developed by the Systems Integration Task Managers.

#### 19.9 Reviews

Reviews of Systems Integration software products (code, model or data base) will be conducted in accordance with the SQAP covering each computer software product. Reviews of supporting documentation will be conducted in accordance with Systems Integration procedure QA-SI-05-002 which provides a standard process for conducting a review to include documenting and resolving comments, and assuring that review records are maintained as QA records. Software products, and supporting documentation, will be reviewed to assure the completeness and integrity of each applicable life cycle phase described in paragraphs 19.2.2.1 through 19.2.2.6 of the QAPD to include the considerations pertinent to the quality of each phase. Review documentation will contain a record of review comments, a plan and timetable for resolution of comments, and identification of those persons responsible for resolution.

#### 19.10 Discrepancy Reporting and Corrective Action

A formal computer software discrepancy reporting and corrective action system will be established in Configuration Management Plan (or Plans) prepared in accordance with paragraph 19.6 of the QAPD. The discrepancy reporting and corrective action system will assure that:

- Defects are documented and corrected
- Defects are assessed for criticality and impacts on previous applications
- Corrections are reviewed and approved before baseline changes are made
- Notification of corrective actions is made to affected organizations

If a deficiency is identified which affects previous work and requires the work to be done again, the deficiency will be documented and dispositioned in accordance with section 16.0 of the QAPD.

#### 19.11 Media Control and Physical Security

The Systems Integration SQAP(s) will describe the method used to assure that the physical media containing the images of computer software will be protected to prevent inadvertent or deliberate damage or degradation. The system utilized for each computer software product will assure that the product and associated data can be restored.

#### 19.12 Acquired Computer Software

19.12.1 The Systems Integration Task Managers will control the transfer of quality-affecting computer software, both coming into and going out of each of their tasks covered by the QAPD. A Systems Integration procedure, QA-SI-19-002, describing the process to be used for control of incoming and outgoing software will be developed in accordance with Systems Integration procedure QA-SI-05-001. The Task Managers will be responsible for requesting as much documentation from the software supplier as is necessary to meet the appropriate requirements of Section 19.0 of the QAPD. The procedure will require completion of any deficiencies in the software product's life cycle, or when it is not possible to complete the life cycle, a justification will be prepared to document the condition. The procedure will also require notification of affected users of that condition.

19.12.2 Acquired computer software will be placed under control of the Configuration Management Plan(s) applicable to the affected task. The Task Manager will assure that any software conversion required is documented and appropriate tests are performed and documented. Acquired computer software will be baselined and maintained in accordance with the applicable Configuration Management Plan(s).

#### 19.13 Computer Software Application

19.13.1 Systems Integration Task Managers will assure that applications of quality-affecting computer software are performed in accordance with procedures appropriate to that software such that technical calculations resulting from the application can be independently repeated. In cases where technical calculations fall outside the existing test cases used to verify or validate the software used, those applications will be tested to the extent established for the software in Section 19.3 of the QAPD. In the event that a Systems Integration task should be directed to generate primary data for OCRWM, the affected Task Manager will establish any additional procedures needed to control such applications.

19.13.2 The SQAP(s) governing each computer software product used on quality-affecting tasks will include measures for documenting and reviewing the results of applications of that software. These measures

will include identification of records of results, and identification of supporting documentation for the computer software and input sources.

19.13.3 Computer software used for technical calculations will be developed or accepted for use, and documented in accordance with life cycle established by the Task Manager in the SQAP for that software. Any auxiliary software used in technical calculations will be reviewed and controlled in accordance with the complexity, function, nature and importance of the software.

19.13.4 When computer software is to be used in a quality-affecting application, the Task Manager will assure that it is independently reviewed and approved to assure that the software selected is appropriate for the problem and that input and assumptions are valid and accurate.

19.14 Exceptions to ASME NQA-1

Supplement 11S-2, Section 2.2, In-Use Tests; Section 3, Test Procedures, item (e); Section 5, Test Records, Part A, items (3), (4), (5), and (6) and Part B in its entirety are excluded as requirements for the tasks covered by the QAPD, as directed by the QARD.

PEER REVIEW PLAN  
for Revision 1 of DOE/RW-0184  
"Characteristics of Potential Repository Wastes"

February 15, 1991

Prepared for the  
U.S. Department of Energy  
Office of Civilian Radioactive Waste Management  
(Activity No. DB 04 02 11)

Prepared by the  
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Martin Marietta Energy Systems, Inc.  
for the  
U.S. Department of Energy  
under contract DE-AC04-84OR21400

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This Peer Review Plan approved by:

ORNL Task Manager and Senior Author of the Draft Report  
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ORNL QA Specialist and Secretary of the Peer Review Group  
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ORNL Group Leader and Chairman of the Peer Review Group  
(W. C. McClain) William C. McClain Date 2-1-91

OCRWM Branch Chief  
(W. Lemeshewsky) William Lemeshewsky Date 2/15/91

OCRWM Division Director  
(H. J. Hale) H. J. Hale Date 2/15/91

OCRWM Associate Director  
(D. Shelor) D. Shelor Date 2/15/91

Designees:

The Chairman of the Peer Review Group is hereby designated to be responsible for Sections 4.1.2, 4.2.2, 4.2.3, 4.4.1, and 4.4.4 of QAAP 3.3:

OCRWM Division Director  
(H. J. Hale) H. J. Hale Date 2/15/91

OCRWM Associate Director  
(D. Shelor) D. Shelor Date 2-20-91

## PEER REVIEW PLAN for DOE/RW-0184 Rev. 1, "Characteristics of Potential Repository Wastes"

### 1. INTRODUCTION

This document provides the plan for peer review of DOE/RW-0184, Rev. 1.<sup>1</sup> This document has been determined by OCRWM to be "quality-affecting" and will undergo a peer review because the data were not collected in conformance with an OCRWM-approved QA program. Revision 1 will be issued in draft form for peer review in six volumes. After the peer review has been completed, including incorporation of recommended changes, the six volumes will be issued for distribution. The purpose of this peer review is to qualify Revision 1 under current OCRWM QA standards. These standards include QAAPs 2.1, 2.2, 3.1, 3.3, as appropriate, and NUREG-1297 and-1298.<sup>2,3,4,5,6,7</sup>

The original version of DOE RW-0184, which was titled "Characteristics of Spent Fuel, High-Level Waste, and Other Radioactive Wastes which may Require Long-Term Isolation," was issued in eight volumes, six in December 1987 and the remaining two in June 1988.<sup>8</sup> These eight volumes were supported by five menu-driven PC data bases. Much of the data in the printed report was taken directly from these PC data bases. Revision 1 also includes these five PC data bases (which have also been revised) plus an additional one, for a total of six. The general structure and contents of the 6 volumes and the 6 PC data bases of Revision 1 are outlined in Tables 1 and 2. Collectively, these are referred to as the Waste Characteristics Data Base or simply the Characteristics Data Base (CDB).

Revision 1 includes updating, revision, and expansion of the original data base.<sup>8</sup> The more significant changes are:

- An improved LWR assembly classification scheme;
- More data on LWR assemblies, especially GE BWR assemblies;
- Revised LWR radiological data, including specific inclusion of enrichment, newly recalculated effective cross sections, utility data on cycle- and down-times, built-in interpolation functions for burnup, enrichment, and decay times, and an improved method for calculating integral heats;
- Another PC data base, for LWR assembly serial numbers;
- New activation factors for reactor hardware, based on recent experimental determinations;
- The addition of fuel pin data to the assembly data base;
- Improved neutron source strength data in the HLW data base; and
- Improved user interface with all of the PC data bases.

The format of the printed volumes has been revised somewhat by the incorporation of two volumes of appendices into other volumes. The scope of coverage remains as it was: LWR Spent Fuel, High-Level Waste, Non-LWR Spent Fuel, and Miscellaneous Wastes.

The objectives in having prepared the characteristics Data Base were (a) to provide OCRWM with a single, unified source of detailed technical data on potential repository wastes and (b) to make this information available to all parts of OCRWM and OCRWM contractors involved in planning and

implementing the Federal Waste Management System. This includes systems integration/engineering, storage, transportation, and disposal. The kinds of technical data tabulated in the CDB are outlined in Table 3.

Certain of the OCRWM users of the CDB may be directly involved in facility design. For this reason the CDB is now classified as quality affecting. All users will receive the CDB via OCRWM QA-controlled distribution.

The CDB relies on the EIA (Energy Information Administration) for basic LWR spent fuel data and utilizes the ORIGEN2 code to calculate radiological properties. This peer review will qualify our specific usage of EIA data and ORIGEN2 in Revision 1. It is not intended to provide generic qualification for EIA data and ORIGEN2. Those programs are implementing their own QA plans which will, at some future date, provide generic QA qualification for EIA data and the ORIGEN2 code.

## 2. BACKGROUND

The original reports and data bases were prepared under QA standards existing at that time. An ORNL QA plan was prepared and followed. That plan stressed adequate documentation of data sources, archiving of key data source documents, and thorough documentation of the PC data bases via both user's guides and programmer's guides. It also required keeping a record of all persons who received the PC data bases. The hard-copy reports were given wide distribution by OSTI via "category" distribution (404 copies) plus a specific (by name) distribution of 230 copies. Subsequently, about 300 copies were distributed to various requestors.

Since the original report was issued, work has continued to upgrade, expand, and update the CDB, in preparation for the revision which is the subject of this peer review. This upgrading work is documented and has been (or will be) published as ORNL technical reports. The pertinent reports are listed in the References section and cover (a) a classification scheme for LWR assemblies,<sup>9</sup> (b) descriptive data on GE BWR assemblies,<sup>10</sup> (c) aspects of non-LWR spent fuels,<sup>11</sup> and (d) sensitivity tests on ORIGEN2, the code used to calculate radiological properties.<sup>12</sup>

The above upgrading work, plus a 3-year update on inventories and various other improvements, have been (or will be) incorporated in Revision 1. Table 1 gives the overall contents of Revision 1 by volumes, chapters, and appendices. Volumes 1-4 were issued in draft form last July and are ready for peer review. Volumes 5-6 are in preparation and will be issued in draft form later this year. The numbering scheme for volumes, chapters, and appendices is described in Section 4.

In order to comply with current QA requirements, Revision 1 will undergo a formal peer review to qualify it for use by OCRWM and OCRWM contractors for the purposes stated earlier. After peer review has been completed and the draft report modified accordingly, the new volumes and their supporting PC data bases will be issued. It is planned to have open publication but to use controlled distribution to directly-involved OCRWM staff and OCRWM-contractor personnel.

### 3. PEER REVIEW PROCESS

The peer review process is an acceptable procedure to qualify data which were not collected in conformance with an established (OCRWM-level) QA program.<sup>7</sup> The purpose of this peer review is to establish the adequacy of the data reported in Rev. 1 of DOE/RW-0184.<sup>1</sup> The first step in the peer review process is the preparation of a plan, which is fulfilled by this document. The plan must address these topics:

- Organization of the peer review group, including a chairman, secretary, and technically-qualified peer review panels;
- Identification of specialized technical areas and structure of the peer review panels;
- Duties and qualifications of the peer review group chairman, secretary, and panel members;
- Review criteria and methodology;
- Submittal of comments and response;
- Comment resolution meeting;
- Preparation of the Peer Review final report; and
- Schedule to be followed.

The peer review group will consist of a chairman, secretary, and peer reviewers, whose qualifications and duties are described in Section 5. Because of its technical scope, peer review of DOE/RW-0184, Rev. 1 will require several review panels, each consisting of three or more members. The rationale for this is given in Section 4.

The OCRWM Systems Integration Program manager, Oak Ridge National Laboratory, has been designated by OCRWM as peer review chairman. The peer review chairman has also been delegated responsibility, under section 4.0 of QAAP 3.3, to appoint members to the peer review panels, determine the scope of the peer review, establish peer reviewer qualifications, and assure that the peer review plan is prepared and carried out.

### 4. TECHNICAL AREAS AND STRUCTURE OF REVIEW PANELS

The draft Revision 1 report consists of six volumes that include five chapters and 17 appendices, as follows (note that the appendices are numbered to indicate the chapter they support):

Volume 1: Chapter 1, Summary  
Chapter 2, LWR Spent Fuel  
Chapter 3, Immobilized HLW  
Appendix 1A, ORIGEN2 Overview  
Appendix 1B, ORIGEN2 Library Data  
Appendix 1C, ORIGEN2 Interpolation Functions

Volume 2 Appendix 2A: Physical Descriptions of LWR Fuel Assemblies

Volume 3 Appendices 2B, C, D, E:

LWR Assemblies Data User's Guide  
LWR Radiological Data User's Guide  
LWR Quantities Data User's Guide  
LWR Serial Numbers Data User's Guide

Volume 4 Appendices 3A, B, C:

ORIGEN2 Decay Tables for HLW  
Interim HLW Forms  
User's Guide to the HLW PC Data Base

Volume 5 Appendices 2F and 2G:

Physical Descriptions of LWR Nonfuel Assembly Hardware  
User's Guide to the LWR Nonfuel Assembly Data Base

Volume 6: Chapter 4. Non-LWR Spent Fuels

Chapter 5. Miscellaneous Wastes

Appendices 4A, B, C, D.

Nuclear Reactors at Educational Institutions In The United States  
Supplemental Data for Fort St. Vrain Spent Fuel  
Supplemental Data for Peach Bottom 1 Spent Fuel  
Supplemental Data for FFTF Spent Fuel

There are seven broad technical areas represented in the above volumes (but not necessarily on a volume-by-volume basis). These are:

1. Summary (and Overall Content): Chapter 1
2. LWR Spent Fuel: Chapter 2 and Appendices 2A, B, C, D, & E
3. High-Level Waste: Chapter 3 and Appendices 3A, B, & C
4. ORIGEN2: Appendices 1A, B, & C
5. LWR Non-Fuel Assembly Hardware: Appendices 2F & G
6. Non-LWR Spent Fuel: Chapter 4 and Appendices 4A, B, C, & D
7. Miscellaneous Wastes: Chapter 5

Thus, seven review panels will be required in order to adequately cover these seven specialized technical areas. The suggested organizational representation on these panels is given in Table 4. A check list showing which chapters and/or appendices each panel is responsible for is given in Table 5. In order to achieve the goal of determining technical competence and organizational comprehensiveness, the panel members shall be selected to represent a spectrum of DOE, contractor, and utility interests. Substitutions or additions of panel members may be made at the discretion of the peer review group chairman, with confirmation by the OCRWM Task manager.

## 5. DUTIES AND QUALIFICATIONS

Duties and qualifications are summarized in Table 6 for all of the Peer Review Group: the chairman, the secretary, and the panel members. Forms to be filled out by panel members verifying their independence and their technical qualifications are given as Tables 7 and 8. In those cases where total independence cannot be met, a documented rationale as to why someone of equivalent technical qualifications and greater independence was not selected shall be included in the peer review report. Each panel member will attach a resume to the qualifications form (Table 8). These forms are to be completed and returned prior to commencement of the Peer Review.

The chairman and secretary are not required to be independent of the work being reviewed. In fact, the requirement that they be familiar with the work requires some direct prior involvement on their part. On the other hand, panel members must be independent, as defined in Table 6. However, this does not preclude involvement in related work, or DOE funding via other activities. Because of the highly-specialized nature of some of the subject matter of this report, only people who work for (or have worked for) DOE or DOE prime contractors may have the necessary expertise to perform an adequate review of some sections.

The Peer Review checklist (Table 9) will be maintained by the Peer Review Chairman. As each action is completed, the Chairman will sign and date the form in the space to the left of each action. Upon completion of the Checklist, the Chairman will transmit it to the cognizant OCRWM Associate Director for approval.

## 6. REVIEW CRITERIA AND METHODOLOGY

The report is to be reviewed for its adequacy, in terms of accuracy, assumptions, calculations, extrapolations, interpretations, methodology, and references. In this instance, since the report is simply a data base, there are no conclusions as such to be critiqued. Because of the nature of this report, documentation of data sources is an especially important aspect of the peer review. Reviewers are to pay particular attention to the following:

- Adequacy: Is enough information provided? Is it provided in a suitable format? Where explanations are needed, are they given?
- Accuracy: Are the data and other information correct? Are they presented correctly?
- References: Are the proper references provided? Are enough references provided? Have the references been cited correctly?

In addition, the following factors should also be considered:

- Validity of basic assumptions and acceptance requirements employed.
- Uncertainty of results, and consequences if incorrect.
- Appropriateness and limitations of methodology and procedures;
- Alternative interpretations; and
- Verification of computer software.

The procedures to be used are as follows: Each reviewer will review those portions of the subject matter as delineated in Table 5 and as specifically instructed in each reviewer's copy of the Peer Review transmittal letter. The reviewers will use the comment form shown in Table 10 to document each comment. This comment form provides a uniform format which identifies the location in the text, gives the comment, and provides space for the author's response. Where it would be helpful, the reviewer may mark up the item in question on the draft report and submit a copy of that page. Wherever it is not unreasonable to do so, comments should be submitted one per page; this will facilitate all steps of the review process. Generic comments, which apply to more than one specific location, can be made using the standard form, citing the multiple locations to which the same comment applies. Minor editorial comments (spelling, obvious typos, etc.) are not an objective of this review but will, of course, be welcomed; these can simply be listed on a single piece (or pieces) of paper, or marked directly on the reviewer's copy and returned to the chairman. Reviewers may also use corroborating data or results of confirmatory testing (if acquired under a 10 CFR 60, subpart G QA program) for the purpose of establishing the qualification of the material subject to this Peer Review, should those techniques be appropriate.

The Chairman will arrange for copies of references or other documents, requested by individual reviewers, to be transmitted to those reviewers on an as-needed basis. The Chairman will assure that the materials transmitted are the correct revisions, editions, etc.

## 7. COMMENTS AND RESPONSE

The form for submittal of comments was described in the previous section. This form also has space for response by the authors. The comment forms will be sent to the chairman by the panel members. The chairman will review these, then give them to the authors for their response. Prior to the comment resolution meeting, the chairman will review the authors' response.

## 8. COMMENT RESOLUTION MEETING AND PEER REVIEW REPORT

The purpose of the comment resolution meeting is to allow discussion between authors and reviewers and among the reviewers themselves. Such discussion stimulates additional comments and also allows authors and reviewers to achieve understanding on more complex questions. The peer review report will be issued by the chairman. This will be a consensus-type report, signed by all panel members. However, if there are any dissenting opinions these will be duly noted and explanations given with the minority views included in the report.

## 9. SCHEDULE

The desired schedule is given in Table 11. Changes can be made by the chairman, should this be necessary. The Appendix gives suggestions for panel members.

## 10. REFERENCES

1. Oak Ridge National Laboratory, "Characteristics of Potential Repository Wastes", DOE/RW-0184, R1 (DRAFT), Volumes 1-4, July 1990; Volumes 5-6, to be issued.
2. OCRWM, Indoctrination and Training, QAAP 2.1, Rev. 1.
3. OCRWM, Verification of Personnel Qualifications, QAAP 2.2, Rev. 0.
4. OCRWM, Technical Document Review, Procedure No. QAAP 3.1., Rev. 0
5. OCRWM, Peer Review, QAAP 3.3, Rev. 0.
6. U.S. Nuclear Regulatory Commission, Peer Review for High-level Nuclear Waste Repositories, NUREG-1297, February 1988.
7. U. S. Nuclear Regulatory Commission, Qualification of Existing Data for High-level Nuclear Waste Repositories, NUREG-1298, February 1988.
8. U.S. Department of Energy, Characteristics of Spent Fuel, High-Level Waste, and Other Radioactive Wastes Which May Require Long-term Isolation, DOE/RW-0184, Vols. 1-6, December 1987; Vols. 7-8, June 1988.
9. R.S. Moore, D.A. Williamson, and K.J. Notz, A Classification Scheme for LWR Fuel Assemblies, ORNL/TM-10901, Oak Ridge National Laboratory, November 1988.
10. R.S. Moore, and K.J. Notz, Physical Characteristics of GE BWR Fuel Assemblies, ORNL TM-10902, Oak Ridge National Laboratory, June 1989.
11. R. Salmon, and K.J. Notz, Non-LWR and special LWR Spent Fuels: Characteristics and Criticality Aspects of Packaging and Disposal, ORNL/TM-11016, Oak Ridge National Laboratory, January 1990.
12. T.D. Welch, K.J. Notz, and R.J. Andermann, ORIGEN2 Sensitivity to Enrichment and Other Factors, ORNL/TM-11333, (In preparation).

TABLE 1. ORGANIZATIONAL STRUCTURE OF DOE/RW-0184, REVISION 1

VOLUME 1

FOREWORD

PREFACE

ORDER FORM FOR PC DATA BASES

ACKNOWLEDGEMENTS

LIST OF ACRONYMS

1. SUMMARY
    - 1.1 INTRODUCTION
    - 1.2 LWR SPENT FUEL
    - 1.3 HIGH-LEVEL WASTE
    - 1.4 NON-LWR SPENT FUELS
    - 1.5 MISCELLANEOUS WASTES
  
  2. LWR SPENT FUEL
    - 2.1 INTRODUCTION
    - 2.2 ASSEMBLY DESCRIPTIONS
    - 2.3 QUANTITIES OF INTACT SPENT FUEL
    - 2.4 RADIOLOGICAL PROPERTIES OF INTACT SPENT FUEL
    - 2.5 DEFECTIVE FUEL
    - 2.6 SPECIAL LWR FUEL FORMS
    - 2.7 SPENT FUEL DISASSEMBLY HARDWARE
    - 2.8 NONFUEL ASSEMBLY HARDWARE
  
  3. IMMOBILIZED HIGH-LEVEL WASTE
    - 3.1 SUMMARY
    - 3.2 WEST VALLEY DEMONSTRATION PROJECT FOR COMMERCIAL HLW
    - 3.3 SAVANNAH RIVER SITE (SRS) DEFENSE HLW
    - 3.4 HANFORD SITE (HANF) DEFENSE HLW
    - 3.5 IDAHO NATIONAL ENGINEERING LABORATORY (INEL) DEFENSE HLW
- APPENDIX 1A ORIGEN2 OVERVIEW  
1B ORIGEN2 LIBRARY DATA  
1C ORIGEN2 INTERPOLATION FUNCTIONS

DISTRIBUTION LIST

**TABLE 2. Menu-driven PC Data Bases Supporting  
Characteristics Data Base (DOE/RW-0184, Rev. 1)**

**LWR Radiological Data Base** - Contains radionuclide compositions, heat generation rates, curies, photon spectra, and other information as a function of spent fuel type (i.e. BWR or PWR), burnup, enrichment, and decay time.

**LWR Assemblies Data Base** - Contains detailed physical descriptions of fuel assemblies and radiological properties of spent fuel disassembly (SFD) hardware.

**High-Level Waste Data Base** - Contains physical, chemical, and radiological descriptions of high-level waste, both as the interim form and the immobilized form in canisters.

**LWR NFA Hardware Data Base** - Contains physical and radiological descriptions of nonfuel assembly hardware; i.e. nonfuel-bearing hardware other than SFD hardware.

**LWR Quantities Data Base** - Contains data on discharged fuel, as historical inventories and as projected quantities, based on EIA data supplied to them by the utilities.

**LWR Serial Numbers Data Base** - Contains the serial numbers of individual fuel assemblies; easily cross-referenced to the Quantities, Assemblies, and Radiological data bases.

TABLE 1. Continued

VOLUME 2

APPENDIX 2A

PHYSICAL DESCRIPTIONS OF LWR FUEL ASSEMBLIES

VOLUME 3

APPENDICES 2B, 2C, 2D, and 2E

USER'S GUIDE TO THE LWR ASSEMBLIES DATA BASE

USER'S GUIDE TO THE LWR RADIOLOGICAL DATA BASE

USER'S GUIDE TO THE LWR QUANTITIES DATA BASE

USER'S GUIDE TO THE SERIAL NUMBER DATA BASE

VOLUME 4

APPENDICES 3A, 3B, and 3C

ORIGEN2 DECAY TABLES FOR IMMOBILIZED HIGH-LEVEL WASTE

INTERIM HIGH-LEVEL WASTE FORMS

USER'S GUIDE TO THE HIGH-LEVEL WASTE PC DATA BASE

VOLUME 5

APPENDICES 2F AND 2G

PHYSICAL DESCRIPTIONS OF LWR NON-FUEL ASSEMBLY HARDWARE

USER'S GUIDE TO THE LWR NON-FUEL ASSEMBLY DATA BASE

VOLUME 6

4. NON-LWR SPENT FUEL

5. MISCELLANEOUS WASTES

APPENDICES 4A, 4B, 4C, AND 4D

NUCLEAR REACTORS AT EDUCATIONAL INSTITUTIONS  
SUPPLEMENTAL DATA FOR FORT ST. VRAIN SPENT FUEL  
SUPPLEMENTAL DATA FOR PEACH BOTTOM 1 SPENT FUEL  
SUPPLEMENTAL DATA FOR FFTF SPENT FUEL

TABLE 3. Kinds of Data in the CDB

Physical Descriptions

Dimensions

Mass

Fabrication Data

Drawings

Chemical Compositions

Fuel or Waste Form per se

Structural Materials (alloys) of

Assemblies, Elements, or Canisters

Radiological Properties

Thermal Source Strength

Gamma Radiation

Neutron Source Strength

Individual Nuclides

Integral Heats

Inventories

Mass

Unit Count (Assemblies, elements, canisters)

LWR Assembly Serial Numbers

Projected Quantities

Mass

Unit Count

**TABLE 4. Technical Review Panels  
(Suggested organizational representation)**

	<u>Number of Members</u>
1. <u>Summary and Overall Panel</u> DOE/RW: System Engineering Transportation & Logistics MRS/storage Geologic Disposal	4
2. <u>LWR Spent Fuel Panel</u> EPRI (utility point-of-view) EIA (RW-859 data) PNL/MCC (ATMs) LLNL (Waste Package) PNL (Assemblies and SFD Hardware)	5
3. <u>HLW Panel</u> West Valley Savannah River Hanford Idaho Falls IDB (all HLW)	5
4. <u>ORIGEN2 Panel</u> DOE/RW Edison Electric Institute Johnson Associates, Inc.	3
5. <u>Non-Fuel Assembly Hardware Panel</u> PNL General Electric Westinghouse	3
6. <u>Non-LWR Spent Fuel Panel</u> Idaho Chemical Processing Plant Savannah River General Atomics	3
7. <u>Miscellaneous Wastes Panel</u> EG&G/IDAHO PNL DOE/NE	3
<b>TOTAL</b>	<hr/> 26

**TABLE 5. Responsibilities of each Panel**  
 (For Peer Review of DOE/RW-0184, Rev. 1 Draft)

	Peer Review Panels						
	Summary	LWR S. Fuel	HLW	ORIGEN2	NFA Hardware	Non-LWR S. Fuel	MISC/ GTCC
<b>Volume 1:</b>							
Chapter 1 - Summary	x	x	x				
Chapter 2 - LWR Spent Fuel	x	x					
Chapter 3 - Immobilized HLW	x		x				
Appendices 1A, B, C - ORIGEN2				x			
Appendix 2A - LWR Assemblies		x					
Appendices 2B, C, D, E - User's Guides		x					
Appendices 3A, B, C - HLW			x				
Appendices 2F, G - NFA Hardware					x		
<b>Volume 2</b>							
Chapter 4 - Non-LWR Spent Fuel						x	
Chapter 5 - Miscellaneous Wastes							x
Appendices 4A, B, C, D, - Non-LWR Spent Fuel						x	

TABLE 6. Duties and Qualifications of Peer Review Group

Chairman:

Duties

1. Generally oversee that materials are provided, work is getting done, and schedule is followed;
2. Provide any procedures that may be required;
3. Provide any additional back-up data or reports that may be requested;
4. Act as the chairman of the close-out meeting, and resolve any differences;
5. Complete all actions required by the peer review checklist (see Table 9);
6. Establish Indoctrination and Training requirements.

Qualifications

1. Overall familiarity with the draft report and its intended utilization;
2. Substantial related technical background;
3. Appropriate formal education (B.S. or higher) pertinent to the technical areas;
4. Chairmanship abilities;
5. Prior experience as a peer review committee member is desirable, but not essential;
6. Certification per QAAP 2.2;
7. Indoctrination and Training per QAAP 2.1.

Secretary:

Duties

1. Keep records of panel members' qualifications and independence certifications;
2. Keep records of reviewers' comments, the authors' responses, and final resolutions;
3. Provide any forms or QA documents that may be required;
4. Prepare the draft and final versions of the peer review report;
5. Do the above in keeping with QA requirements.

Qualifications

1. Familiarity with QA procedures and requirements;
2. Appropriate training and experience with QA work (at least two years);
3. General familiarity with the technical task;
4. Access to clerical assistance;
5. Prior experience with peer review functions is desirable, but not essential.
6. Certification per QAAP 2.2;
7. Indoctrination and Training per QAAP 2.1.

## Panel Members

### Duties

1. Review the draft report against the criteria described in Section 6 of this plan;
2. Submit written comments of the above review, in particular for their area of specialization, but with the option of also commenting on other areas;
3. Attend and participate in the close-out meeting, to be held in Oak Ridge;
4. Review the draft review summary and either concur or provide a written minority position;
5. Sign the final version of the peer review report.

### Qualifications

1. Independence from the work being reviewed. This means that the panel member was not directly involved in the work as a participant, supervisor, or consultant and that his or her primary funding is not dependent on this review;
2. Time available during the scheduled period to perform the review;
3. Availability to attend their 1-day review close-out session in Oak Ridge; panel members are free to sit-in on the other review sessions if they desire;
4. Certification per QAAP 2.2;
5. Indoctrination and Training per QAAP 2.1;
6. Detailed technical knowledge and experience in their area of specialization, including the related technical literature. This should be an appropriate combination of educational background, prior and current work experience, and evidence of direct personal activity in the area of specialization e.g., by authorship of technical reports and/or journal articles, presentation of papers at technical symposia, or participation in pertinent technical meetings, such that the panel member would be technically capable of having written the section under review assuming, of course, that suitable resources were made available.

**TABLE 7 Certification of Independence**

(Required of all Panel Members)

Name:

Affiliation:

Panel:

This is to certify that I am independent of the preparation of DOE/RW-0184, Rev. 1. I was not involved in its preparation as either a participant, supervisor, or consultant. My funding is not connected to this report nor dependent on this review. I have also read the Peer Review Plan and concur with it.

\_\_\_\_\_  
Signed Date

NOTE: Because of the highly specialized technical nature of this report, a panel member may have been involved in providing certain data to CDB staff. If so this uniquely qualifies that person as a reviewer of those data. Where this is not the case, certify to that fact:

\_\_\_\_\_  
Signed Date

Where this is the case, identify the data involved and so certify:

Nature of data provided:

\_\_\_\_\_  
Signed Date

**TABLE 8. Certification of Technical Qualification  
and Indoctrination and Training**

(Required of Chairman, Secretary, and all Panel Members)

Name:  
Affiliation:  
Address:  
Phone No.:

**TECHNICAL QUALIFICATIONS**

Education (degrees obtained, when and where obtained; areas of specialization; special training courses):

Work Experience (brief summary, citing facts pertinent to this peer review):

Resume (please attach to this form).

**INDOCTRINATION AND TRAINING**

I have read and understand the following materials:

- a) Peer Review Plan for DOE/RW-0184, Rev. 1
- b) QAAP 3.3 "Peer Review"

\_\_\_\_\_  
Signed

\_\_\_\_\_  
Date

**VERIFICATION**

I hereby verify that the individual named above has the stated qualifications, and has completed the required Indoctrination and Training exercise.

\_\_\_\_\_  
Signed

\_\_\_\_\_  
Date

\_\_\_\_\_  
Position

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

SHEET \_\_\_\_\_ OF \_\_\_\_\_  
WBS NO \_\_\_\_\_

PEER REVIEW NUMBER \_\_\_\_\_

PEER REVIEWER SHALL SIGN AND DATE THE FOLLOWING WHEN COMPLETED

- |           |       |  |
|-----------|-------|--|
| _____     | _____ | The scope of the review identified.  |
| Signature | Date  |  |
| _____     | _____ | Review personnel identified, qualifications documented and indoctrination provided, as appropriate.                          |
| Signature | Date  |  |
| _____     | _____ | All reference material and data are available for review.  |
| Signature | Date  |  |
| _____     | _____ | All written reviewer comments have been received and reviewed.   |
| Signature | Date  |  |
| _____     | _____ | Revised documents peer reviewed, as appropriate.   |
| Signature | Date  |  |
| _____     | _____ | Peer review report prepared and submitted to the cognizant Associate Director, OCRWM.  |
| Signature | Date  |  |
| _____     | _____ | Peer review report and other applicable documents transmitted to originator with Director, OCRWM, acceptance or concurrence. |
| Signature | Date  |  |
| _____     | _____ | Peer review documents entered into records system.   |
| Signature | Date  |  |

The above peer review steps have been carried out in compliance with QAAP 3.3.

\_\_\_\_\_ Date  
PEER REVIEWER CHAIRMAN

\_\_\_\_\_ Date  
COGNIZANT ASSOCIATE DIRECTOR

**TABLE 10. Comment Form**

**(To be submitted by Review Panel members; one comment per page.)**

**Commentor (initials):**

**Location (page, paragraph, line):**

**Comment:**

**Response by authors:**

**Final resolution:**

**TABLE 11. Suggested Schedule for Peer Review**

For All Six Volumes

- |    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Prepare Peer Review Plan              | Feb. 1, 1991 |
| 2. | Obtain acceptance of Plan from DOE/HQ | Feb. 15      |
| 3. | Issue final report of peer review     | Aug. 30      |

For Volumes 1, 2, 3, and 4

- |    |   |              |
|----|---|--------------|
| 1. | Confirm reviewers                         | Feb. 28      |
| 2. | Mail draft report to reviewers            | March 1      |
| 3. | Receive written comments                  | April 1,     |
| 4. | Respond to comments                       | April 26     |
| 5. | Comment resolution meeting (in Oak Ridge) | May 8, 9, 10 |
| 6. | Send out draft of review summary          | May 31       |
| 7. | Receive final responses                   | June 17      |

For Volumes 5 and 6

- |    |   |               |
|----|---|---------------|
| 1. | Confirm reviewers                         | April 1, 1991 |
| 2. | Mail draft report to reviewers            | April 15      |
| 3. | Receive written comments                  | June 3        |
| 4. | Respond to comments                       | June 28       |
| 5. | Comment resolution meeting (in Oak Ridge) | July 11, 12   |
| 6. | Send out draft of review summary          | July 26       |
| 7. | Receive final responses                   | Aug 16        |

## Appendix: Technical Review Panels

(Suggested Individual Members)

### Volumes 1, 2, 3, 4

1. Summary and Overall Panel  
System Engineering  
Transportation & Logistics  
MRS/storage  
Geologic Disposal
  
2. LWR Spent Fuel Panel  
EPRI (utility point-of-view)  
EIA (RW-859 data)  
PNL/MCC (ATMs)  
LLNL (Waste Package)  
PNL (SFD Hardware)
  
3. HLW Panel  
West Valley  
Savannah River  
Hanford  
Idaho Falls  
IDB (all HLW)
  
4. ORIGEN2 Panel  
DOE/RW  
Edison Electric Institute  
Johnson Associates, Inc.

### Volumes 5 and 6

5. Non-Fuel Assembly Hardware Panel  
General Electric  
Westinghouse  
PNL

OAK RIDGE NATIONAL LABORATORY  
QUALITY ASSURANCE PROGRAM

PROCEDURE: QA-SI-02-001

SYSTEMS INTEGRATION PROGRAM  
QUALITY ASSURANCE PROCEDURE

DATE: August 20, 1991

PAGE 1 OF 5

SUPERSEDES: New

TITLE: ESTABLISHING QUALITY ASSURANCE CONTROLS

1.0 PURPOSE:

To describe the method used to evaluate quality-affecting tasks in the Systems Integration Program and to determine the application of specific quality controls appropriate to each task.

2.0 SCOPE:

This procedure applies to all Systems Integration Program tasks determined to be quality-affecting by the Office of Civilian Radioactive Waste Management (OCRWM) Headquarters.

3.0 REFERENCES:

3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214.

3.2 "Quality Assurance Program Description for Systems Integration", QAP-X-91-WMRD-045.

4.0 REQUIREMENTS:

In accordance with OCRWM QAAP 4.2 "Establishing Procurement Quality Assurance Controls", paragraph 6.5.3, the OCRWM Programmatic Funding and Guidance memorandum for the Oak Ridge Operations Office to support the Office of Systems and Compliance requires that: "ORNL shall submit a procedure defining the process by which QA controls for work performed by ORNL will be established."

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By:



Office of Civilian Radioactive  
Waste Programs Manager

Approved By:



QA Specialist

## TLE: ESTABLISHING QUALITY ASSURANCE CONTROLS

5.0 RESPONSIBILITIES:5.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:

5.1.1 Assuring that this procedure is implemented by the Task Managers of quality-affecting tasks.

5.1.2 Reviewing and approving the QA Controls Matrix selected for each task.

5.1.3 Forwarding approved QA Controls Matrices to the cognizant OCRWM Program Manager.

5.2 Systems Integration Task Managers:

5.2.1 Implementing this procedure for their respective, quality-affecting tasks.

5.2.2 Assuring that all changes in the work are evaluated against the QAPD to determine if changes are needed in the QA controls applicable to the work.

5.3 Quality Assurance Specialist (QAS):

5.3.1 Assisting the Task Managers in implementing this procedure.

5.3.2 Reviewing the QA controls selected for each task and approving the QA Controls Matrix.

5.3.3 Maintaining a duplicate record of the approved QA Controls Matrix for each task.

6.0 DEFINITIONS:

6.1 Quality Assurance Program Description (QAPD) - The quality assurance document prepared by ORNL and approved by OCRWM which describes the ORNL QA program for meeting OCRWM QA requirements.

6.2 Quality Assurance Controls - The specific QA procedures and line procedures implemented to assure that the work is conducted in accordance with sponsor requirements.

6.3 Quality Controls Matrix - A checklist of the QAPD sections which is used by the Task Managers to specify those sections which apply to their tasks. (Attachment A)

7.0 GENERAL:

7.1 This procedure is not concerned with a process to determine if a task is quality-affecting. That determination is made by OCRWM Headquarters, and is directed to the Systems Integration group at ORNL via a formal guidance letter.

7.2 This procedure is concerned with the next lower level of detail, i.e., assignment of specific quality controls to each quality-affecting task.

**TITLE: ESTABLISHING QUALITY ASSURANCE CONTROLS****8.0 PROCEDURE:**

- 8.1 The Task Manager evaluates the work in the task against each section of the QAPD for applicability of QA controls. Consideration is also given to the OCRWM QA Controls Specification included in the OCRWM guidance memorandum. The Task Manager completes a Systems Integration QA Controls Matrix (Attachment A) for the task by checking those boxes in the Matrix determined to be applicable. (Full size copies of Attachment A are available from the QAS).
- 8.2 The Task Manager also documents any (all) discrepancies between the Systems Integration QA Controls Matrix and the OCRWM QA Controls Specification on the last page of Attachment A.
- 8.3 When the Systems Integration QA Controls Matrix has been completely filled out, the Task Manager signs it in the appropriate block on page 1 of 2 and sends it to the QAS for review.
- 8.4 The QAS reviews and signs the Systems Integration QA Controls Matrix in the appropriate block on page 1 of 2 and sends it to the OCRWP Manager for review and approval.
- 8.5 The OCRWP Manager reviews and signs the Systems Integration QA Controls Matrix in the appropriate block on page 1 of 2.
- 8.6 The Task Manager implements those controls determined to be applicable to each task.
- 8.7 Each approved Systems Integration QA Controls Matrix is maintained by the responsible Task Manager as a QA record, and a duplicate record is maintained by the QAS.
- 8.8 Each approved Systems Integration QA Controls Matrix is forwarded to the cognizant OCRWM Program Manager by the OCRWP Manager, for information.

**9.0 RECORDS**

Approved Systems Integration QA Controls Matrices.

**10.0 ATTACHMENTS**

Attachment A - Systems Integration QA Controls Matrix Form

## TLE: ESTABLISHING QUALITY ASSURANCE CONTROLS

## ATTACHMENT A

SYSTEMS INTEGRATION  
QA CONTROLS MATRIX

Page 1 of 2

This QA Controls Matrix has been prepared in accordance with the Systems Integration Program Description "QAP-X-91-WMRD-045" for:

Task Title: \_\_\_\_\_

Revision: \_\_\_\_\_ Date: \_\_\_\_\_

- |                          |                          |   |                          |                          |   |
|--------------------------|--------------------------|---|--------------------------|--------------------------|---|
| <input type="checkbox"/> | 1.0                      | Organization  | <input type="checkbox"/> | 8.0                      | Identification and Control of Materials, Parts and Components         |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.1 Systems Integration Organization  | <input type="checkbox"/> | <input type="checkbox"/> | 9.0 Control of Processes  |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.2 Quality Assurance Organization  | <input type="checkbox"/> | <input type="checkbox"/> | 10.0 Inspection   |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.3 Internal ORNL Interfaces  | <input type="checkbox"/> | <input type="checkbox"/> | 11.0 Test Control   |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.4 External ORNL Interfaces  | <input type="checkbox"/> | <input type="checkbox"/> | 12.0 Control of Measuring and Test Equipment                          |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.5 Delegation of Work  | <input type="checkbox"/> | <input type="checkbox"/> | 13.0 Handling, Storage and Shipping                                   |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.6 Dispute Resolution  | <input type="checkbox"/> | <input type="checkbox"/> | 14.0 Inspection, Test, and Operating Status                           |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.7 Resolution of Allegations   | <input type="checkbox"/> | <input type="checkbox"/> | 15.0 Control of Nonconforming Items                                   |
| <input type="checkbox"/> | <input type="checkbox"/> | 1.8 Stop Work Provisions  | <input type="checkbox"/> | <input type="checkbox"/> | 16.0 Corrective Action  |
| <input type="checkbox"/> | 2.0                      | Quality Assurance Program   | <input type="checkbox"/> | <input type="checkbox"/> | 16.1 Corrective Actions for Significant Conditions Adverse to Quality |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.1 Systems Integration QA Program  | <input type="checkbox"/> | <input type="checkbox"/> | 16.2 Deficiencies   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.2 Reporting Independence of Personnel                                       | <input type="checkbox"/> | <input type="checkbox"/> | 16.3 Remedial Action  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.3 Planning  | <input type="checkbox"/> | <input type="checkbox"/> | 17.0 Quality Assurance Records  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.4 Graded Quality Assurance Program  | <input type="checkbox"/> | <input type="checkbox"/> | 17.1 QA Records   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.5 QA Requirements Matrix  | <input type="checkbox"/> | <input type="checkbox"/> | 17.2 Systems Integration QA Records                                   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.6 Personnel Selection, Indoctrination, Training and Qualification           | <input type="checkbox"/> | <input type="checkbox"/> | 18.0 Audits   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.7 Surveillance  | <input type="checkbox"/> | <input type="checkbox"/> | 18.1 Audit Planning and Performance                                   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.8 Management Assessment   | <input type="checkbox"/> | <input type="checkbox"/> | 18.2 Reporting and Response   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.9 Quality Assurance Program Management - Information Reporting and Tracking | <input type="checkbox"/> | <input type="checkbox"/> | 18.3 Internal Audits  |
| <input type="checkbox"/> | <input type="checkbox"/> |   | <input type="checkbox"/> | <input type="checkbox"/> | 18.4 External Audits  |
| <input type="checkbox"/> | <input type="checkbox"/> |   | <input type="checkbox"/> | <input type="checkbox"/> | 18.5 Surveillance   |
| <input type="checkbox"/> | 3.0                      | Design Control  | <input type="checkbox"/> | <input type="checkbox"/> | 19.0 Computer Software  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.1 Technical Reviews   | <input type="checkbox"/> | <input type="checkbox"/> | 19.1 Systems Integration Computer Software                            |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.2 Peer Reviews  | <input type="checkbox"/> | <input type="checkbox"/> | 19.2 Computer Software Quality Assurance Plan                         |
| <input type="checkbox"/> | 4.0                      | Procurement Document Control  | <input type="checkbox"/> | <input type="checkbox"/> | 19.3 Computer Software Verification and Validation                    |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.1 Systems Integration Procurement   | <input type="checkbox"/> | <input type="checkbox"/> | 19.4 Verification   |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.2 Procurement Document Review   | <input type="checkbox"/> | <input type="checkbox"/> | 19.5 Validation   |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.3 Applicability of Purchaser's Quality Assurance Program                    | <input type="checkbox"/> | <input type="checkbox"/> | 19.6 Computer Software Configuration Management                       |
| <input type="checkbox"/> | 5.0                      | Instructions, Procedures, Plans and Drawings                                  | <input type="checkbox"/> | <input type="checkbox"/> | 19.7 Qualification of Existing Software                               |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.1 Reviews   | <input type="checkbox"/> | <input type="checkbox"/> | 19.8 Documentation  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.2 Quality Assurance Records   | <input type="checkbox"/> | <input type="checkbox"/> | 19.9 Reviews  |
| <input type="checkbox"/> | 6.0                      | Document Control  | <input type="checkbox"/> | <input type="checkbox"/> | 19.10 Discrepancy Reporting and Corrective Action                     |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.1 Control System  | <input type="checkbox"/> | <input type="checkbox"/> | 19.11 Media Control and Physical Security                             |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.2 Controlled Documents  | <input type="checkbox"/> | <input type="checkbox"/> | 19.12 Acquired Computer Software                                      |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.3 Quality Assurance Organization Review                                     | <input type="checkbox"/> | <input type="checkbox"/> | 19.13 Computer Software Application                                   |
| <input type="checkbox"/> | 7.0                      | Control of Purchased Items and Services                                       | <input type="checkbox"/> | <input type="checkbox"/> | 19.14 Exceptions to ASME NQA-1  |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.1 Planning Process  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.2 Selection of Suppliers  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.3 Bid Evaluation  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.4 Supplier Interface  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.5 Supplier Generated Documents  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.6 Procurement Document Changes  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.7 Systems Integration Procurements  |                          |                          |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.8 Supporting Organization's QA Programs                                     |                          |                          |   |

Office of Civilian Radioactive Waste Programs Manager

Task Manager

QA Specialist



TITLE: INDOCTRINATION AND TRAINING

**UNCONTROLLED COPY**

1.0 PURPOSE:

To establish the methods used in the Systems Integration program to assign, conduct and document indoctrination and training activities.

2.0 SCOPE:

This procedure applies to all Systems Integration tasks determined to be quality-affecting.

3.0 REFERENCES:

- 3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214
- 3.2 "Systems Integration Support, Quality Assurance Program Description", QAP-X-91-WMRD-045
- 3.3 "QA Records", QA-SI-17-001

4.0 REQUIREMENTS:

Quality Assurance Requirements for the Civilian Radioactive Waste Management Program, DOE/RW-0214, Section 2.8. "A systematic approach to the determination of applicable indoctrination and training for personnel performing activities affecting quality shall be established."

5.0 DEFINITIONS:

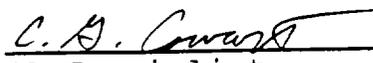
- 5.1 Classroom Training - A method of training characterized by formal instruction presented in a classroom environment by a qualified instructor using a lesson plan.
- 5.2 Indoctrination - An orientation designed to familiarize personnel with documents, requirements, regulations, and policies applicable to assigned work.
- 5.3 Indoctrination and Training Matrix (I&T Matrix) - A form (Attachment II) used to identify the requirements for and status of indoctrination and training.

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By: 

Office of Civilian Radioactive  
Waste Programs Manager

Approved By: 

QA Specialist

## TITLE: INDOCTRINATION AND TRAINING

- 5.4 Instructor - An individual selected to train staff in a classroom environment, who is qualified by education, experience or training to prepare lesson plans and/or conduct classes on specific topics.
- 5.5 Learning Objective - A statement that specifies measurable behavior that a trainee should exhibit after instruction, including the conditions and standards for performance, when necessary.
- 5.6 Quality-Affecting - A term indicating status, applied to Systems Integration work (as determined by OCRWM management), which requires application of the QA program requirements specified in the OCRWM Quality Assurance Requirements Document.
- 5.7 Quality Assurance Program Description (QAPD) - The ORNL prepared, OCRWM approved quality assurance document which describes the Systems Integration QA program for meeting OCRWM QA requirements.
- 5.8 Self-Study - A method of training, used by an individual or a group, in which the pace of training is controlled by the Task Manager and guided by training materials. This type of training includes mandatory reading assignments.
- 5.9 Training - A systematic process designed to assure that personnel possess the knowledge and skills necessary to perform assigned work.

6.0 RESPONSIBILITIES:

(Accomplishment of responsibilities assigned in sections 6.0 and 7.0 may be delegated to others but the responsibility remains with the assigned position.)

6.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:

- 6.1.1 Assuring that QA-SI-02-002 is implemented by Task Managers and staff.

6.2 Systems Integration Task Managers:

- 6.2.1 Implementing QA-SI-02-002 for their respective, quality-affecting tasks.
- 6.2.2 Determining, documenting and approving initial and continuing indoctrination and training requirements for staff.
- 6.2.3 Providing approval of completed indoctrination and training.
- 6.2.4 Ensuring that staff complete indoctrination and training requirements in a timely manner.
- 6.2.5 Maintaining an I&T Matrix for task specific technical training.
- 6.2.6 Selecting qualified instructors for classroom training on task specific technical topics.
- 6.2.7 Reviewing and updating indoctrination and training requirements when position or work duties of staff change.

FILE: **INDOCTRINATION AND TRAINING**6.3 Systems Integration Staff:

6.3.1 Assuring that indoctrination and training requirements are completed as assigned.

6.3.2 Documenting completion of assigned training.

6.4 Instructors:

6.4.1 Developing indoctrination and training materials.

6.4.2 Conducting and documenting classroom training.

6.4.3 Forwarding training records to the Task Manager or QAS, as appropriate.

6.5 Quality Assurance Specialist (QAS):

6.5.1 Assisting the Task Managers in implementing QA-SI-02-002.

6.5.2 Maintaining the Indoctrination and Training Matrix for QA topics.

6.5.3 Providing oversight of compliance with QA-SI-02-002 through surveillance and audit.

6.5.4 Selecting qualified instructors for classroom training on QA topics.

7.0 PROCEDURE: (See Flowsheet, Attachment I)7.1 General

7.1.1 Indoctrination and training may be conducted as classroom training or self-study. The selection of the method used is made by the Task Manager (with assistance from the QAS on QA topics) based on:

- Complexity of the activity,
- Need for consistency of interpretation, and
- Education, experience and initial proficiency of the staff member.

7.1.2 When classroom training is selected, a lesson plan is used which is based on learning objectives. The lesson plan provides a consistent structure to the training.

7.1.3 Indoctrination and training requirements for each staff member are identified on the indoctrination and training matrix. Staff members are required to complete training requirements assigned by the Task Manager or QAS.

7.1.4 As a minimum, staff receive indoctrination in the following areas:

- General criteria (codes, standards, regulations) applicable to their scope of work
- QA Program Description and supporting procedures
- Program responsibilities and authority

**FILE: INDOCTRINATION AND TRAINING**

7.1.5 Staff receive training necessary to achieve and maintain proficiency, and to accommodate changes in program, procedures, methods, responsibilities or technology.

7.1.6 The type and frequency of training are appropriate to the scope, complexity and importance of the work.

**7.2 Indoctrination and Training Matrix (I&T Matrix)**

7.2.1 I&T Matrix forms (Attachment II) are prepared by the QAS, to identify the QA topics requiring training, and are distributed to the Task Managers.

7.2.2 Each Task Manager fills in the names of staff who require training along with their corresponding identification number (badge or social security number).

7.2.3 Additional task specific technical topics requiring indoctrination or training are identified by each Task Manager on their respective task I&T Matrix by topic and document number (if applicable).

7.2.4 The Task Manager selects the topics applicable to each staff member and indicates the training method (classroom or self study) for each staff member.

7.2.5 The Task Managers update their I&T Matrix whenever there is a change requiring new or revised training.

**7.3 Classroom Training**

7.3.1 The Task Manager or QAS, as appropriate, selects a qualified instructor for each topic on the I&T Matrix requiring classroom training.

7.3.2 When an approved lesson plan does not exist for the topic, the instructor develops one in accordance with the following guidelines:

7.3.2.1 The lesson plan is identified by title and revision number, and indicates the author.

7.3.2.2 The lesson plan is signed by an authorized reviewer and approved by the Task Manager or QAS, as appropriate.

7.3.2.3 The lesson plan contains the following information:

- course objectives
- course summary
- terms to be defined
- documentation to be discussed
- prerequisites
- instructional method (lecture, seminar, workshop, etc.)
- course length
- testing
- method of evaluation
- target audience

**TITLE: INDOCTRINATION AND TRAINING**

- 7.3.3 When an approved lesson plan does exist, the instructor reviews the plan to assure that the material is consistent with current requirements.
- 7.3.3.1 If the material is not current, the instructor updates the lesson plan and any accompanying materials, changes the revision number, and obtains review and approval as indicated in 7.3.2.2 above.
- 7.3.3.2 If the material is current, the instructor proceeds with arrangements.
- 7.3.4 The instructor arranges for appropriate training facilities, equipment and materials; and notifies staff to be trained.
- 7.3.5 The instructor conducts the training class and documents the results in accordance with the lesson plan.
- 7.3.6 The instructor initials and dates the I&T Matrix for each staff member successfully completing the course.
- 7.3.7 The instructor forwards the lesson plan, I&T Matrix, results of tests, and certifications (if applicable) to the Task Manager or QAS, as appropriate.
- 7.3.8 The Task Manager or QAS reviews the completed records and forwards to the Records Custodian for inclusion in the QA records file.
- 7.4 Self Study
- 7.4.1 The Task Manager distributes self study materials to those staff members determined to require training on the topic. Study materials on QA topics are obtained from the QAS.
- 7.4.2 Staff members complete self study assignments, initial the I&T Matrix in the appropriate columns, and return the I&T Matrix to the Task Manager.
- 7.4.3 The Task Manager initials and dates the I&T Matrix in the appropriate columns for each staff member and topic, and forwards a copy of the I&T Matrix to the Records Custodian for inclusion in the QA records file.

TLE: **INDOCTRINATION AND TRAINING**

8.0 RECORDS

8.1 Completed Indoctrination and Training Matrix forms

8.2 Lesson Plans

8.3 Classroom Test Results

8.4 Certifications

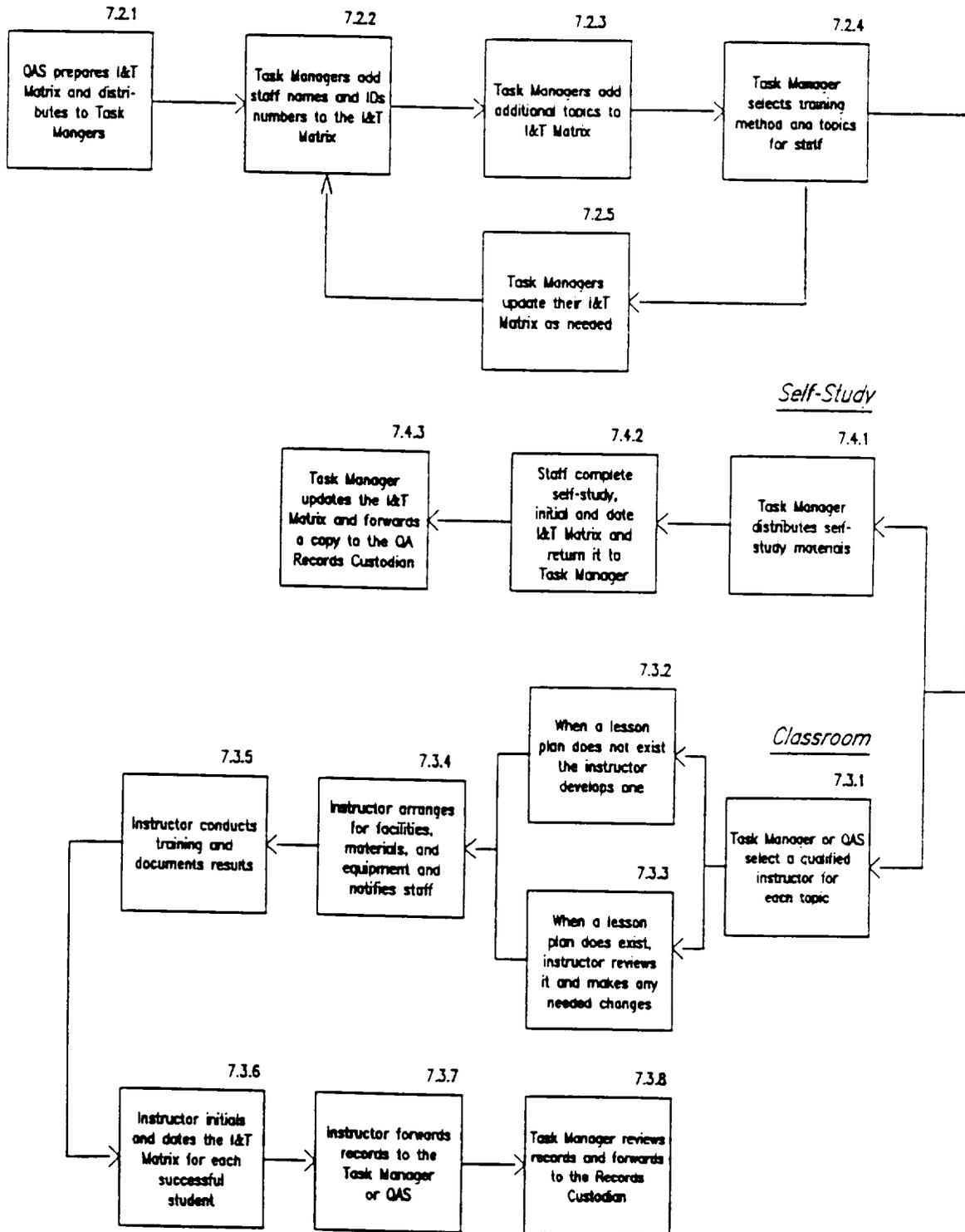
9.0 ATTACHMENTS

9.1 Attachment I - Indoctrination and Training Flowsheet

9.2 Attachment II - Indoctrination and Training Requirements and Status Matrix

FILE: INDOCTRINATION AND TRAINING

Attachment I  
INDOCTRINATION AND TRAINING FLOWSHEET





TITLE: COMPUTER CODE VERIFICATION AND VALIDATION

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1.0 PURPOSE:

To describe the methods used, for Systems Integration tasks, to conduct and document, computer code verification and validation (V&V) activities.

2.0 SCOPE:

This procedure applies to computer codes, used in Systems Integration tasks, which require verification and, if appropriate, validation, in order to be qualified for use in quality affecting work. For commercial software products, the source code is not subject to V&V but applications by the user may require V&V.

3.0 REFERENCES:

- 3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214, R4.
- 3.2 "Quality Assurance Program Description for Systems Integration", QAP-X-91-WMRD-045, R1.
- 3.3 "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management", NUREG-0856.

4.0 REQUIREMENTS:

DOE/RW-0214, Section 19 "Computer Software".

5.0 RESPONSIBILITIES:

5.1 Systems Integration Program Manager:

- 5.1.1 Approving this procedure, and revisions thereto.
- 5.1.2 Assuring that this procedure is implemented, when required.

**TLE: COMPUTER CODE VERIFICATION AND VALIDATION**

5.1.3 Approving V&V plans and reports, and revisions thereto.

5.2 Systems Integration Task Managers:

5.2.1 Implementing this procedure for computer codes in their respective, quality-affecting tasks which require verification and, if appropriate validation.

5.2.2 Assuring that a V&V plan is prepared, reviewed and approved.

5.2.3 Assuring that V&V is conducted according to the plan.

5.2.4 Assuring that a V&V report is prepared, reviewed and approved.

5.3 Quality Assurance Specialist (QAS):

5.3.1 Approving this procedure, and revisions thereto.

5.3.2 Reviewing V&V plans and reports.

6.0 DEFINITIONS:

6.1 Verification - Assurance that a computer code correctly performs the operations specified in a numerical model.

6.2 Validation - Assurance that a model, as embodied in a computer code, is a correct representation of the process or system for which it is intended.

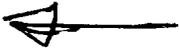
6.3 V&V - Verification and Validation.

7.0 PROCEDURE:

7.1 The Task Manager, with concurrence by the Systems Integration Program Manager, determines the scope of the V&V process, i.e., is the activity limited to verification or does it also require validation. The scope and justification for the decision is documented in the V&V plan.

7.2 The Task Manager assumes responsibility for leading the verification/validation process, or designates another qualified individual or organization to do so.

**FILE: COMPUTER CODE VERIFICATION AND VALIDATION**

- 7.3 A plan is developed by the V&V lead (as established in paragraph 7.2 above) which describes the V&V activities. Suggested section titles and their order are listed below.
- Purpose and scope
  - References
  - Definitions
  - Organization (Identifies the organizational entities, positions and key personnel dedicated to perform the V&V activities. Includes an appendix to the plan for key personnel resumes)
  - Responsibilities (Defines the responsibilities of those entities and positions identified in Organization for accomplishment of the V&V effort)
  - V&V Procedures (Includes topics such as Testing Requirements, Testing Methods and Evaluation Criteria, and Test Case Descriptions)
  - QA Records (List of plans, reports and supporting documentation to be retained as QA records of the V&V effort)
- 7.4 The plan is reviewed and approved by the Task Manager, the Systems Integration Program Manager and the QAS.
- 7.5 Once the plan is approved, the V&V lead conducts the verification/validation process.
- 7.6 When the V&V process is complete, the V&V lead prepares a V&V report. Suggested section titles and their order are listed below.
- Brief description of the code
  - Summary of the V&V activities performed
  - Results and findings
  - Conclusions and recommendations
  - References
- 7.7 The Task Manager selects two or more reviewers for the draft V&V report. One of the reviewers is the QAS, and one or more reviewers who are qualified to review the report for technical content.
- 7.8 The report review, including resolution of comments, is documented and retained as a quality assurance record.
- 7.9 The report is approved by the Task Manager and the Systems Integration Program Manager.
- 7.10 The computer code is placed under configuration control. 

TITLE: **COMPUTER CODE VERIFICATION AND VALIDATION**

8.0 RECORDS -

8.1 V&V plans

8.2 V&V reports

8.3 V&V report review records.

9.0 ATTACHMENTS

None

TITLE: COMPUTER SOFTWARE TRANSFER

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1.0 PURPOSE:

To establish the methods used in the Systems Integration program to transfer computer software and associated documentation both out of and into Systems Integration tasks.

2.0 SCOPE:

This procedure applies to all Systems Integration tasks determined to be quality-affecting.

3.0 REFERENCES:

- 3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214
- 3.2 "Systems Integration Support, Quality Assurance Program Description ", QAP-X-91-WMRD-045
- 3.3 "QA Records", QA-SI-17-001

4.0 REQUIREMENTS:

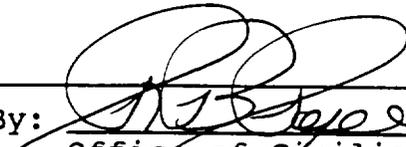
Quality Assurance Requirements for the Civilian Radioactive Waste Management Program, DOE/RW-0214, Section 19.11. "Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization."

5.0 DEFINITIONS:

- 5.1 Computer Software - A set of computer instructions for performing the operations specified in a numerical model.
- 5.2 Controlled Transfer Record - a file maintained by a Software Custodian which contains records of the distribution of the software to all requestors, or contains records received from a source which support incoming software.

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By: 

Office of Civilian Radioactive  
Waste Programs Manager

Approved By: 

QA Specialist

FILE: **COMPUTER SOFTWARE TRANSFER**

- 5.3 Qualified Software - Software which has been developed in accordance with an OCRWM accepted Quality Assurance program which meets the requirements of the OCRWM Quality Assurance Requirements Document (Ref. 3.1), or existing software which has been qualified for use in accordance with Section 19.6 of the OCRWM Quality Assurance Requirements Document.
- 5.4 Quality-Affecting - A term indicating status, applied to Systems Integration work (as determined by OCRWM management), which requires application of the QA program requirements specified in the OCRWM Quality Assurance Requirements Document.
- 5.5 Quality Assurance Program Description (QAPD) - The ORNL-prepared, OCRWM-approved quality assurance document which describes the Systems Integration QA program for meeting OCRWM QA requirements.
- 5.6 Software Custodian - An individual, assigned responsibility for control of a specific software package, who is also knowledgeable about the software package and has the ability to answer questions, explain software functions and help solve problems.
- 5.7 Software Transfer Package - a combination of software and supporting documentation containing all items necessary to load, test and operate the software.

6.0 RESPONSIBILITIES:

(Accomplishment of responsibilities assigned in sections 6.0 and 7.0 may be delegated to others but the responsibility remains with the assigned position.)

6.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:

- 6.1.1 Assuring that QA-SI-19-002 is implemented by Task Managers and staff.

6.2 Systems Integration Task Managers:

- 6.2.1 Implementing QA-SI-19-002 for their respective, quality-affecting tasks.
- 6.2.2 Assuring that computer software designated for transfer into or out of Systems Integration has a Software Custodian designated to control the software.

6.3 Software Custodian:

- 6.3.1 Assuring that computer software assigned to the Custodian is controlled in accordance with QA-SI-19-002.

6.4 Systems Integration Staff

- 6.4.1 Assuring that they are in compliance with the requirement to use only qualified software on quality-affecting tasks, and that software they intend to use has been qualified in accordance with Section 19.0 "Computer Software" of the Systems Integration QAPD (Ref. 3.2)

TITLE: **COMPUTER SOFTWARE TRANSFER**

6.4.2 Assuring that software under their control is transferred in accordance with QA-SI-19-002.

6.5 Quality Assurance Specialist (QAS):

6.5.1 Assisting the Task Managers in implementing QA-SI-19-002.

6.5.2 Providing oversight of compliance with QA-SI-19-002 through surveillance and audit.

7.0 PROCEDURE: (See Flowsheet, Attachment I)

7.1 General

7.1.1 Systems Integration Task Managers assign Software Custodians (may be a Task Manager or designee) who have responsibility for control of specific software packages.

7.1.2 Software Custodians are the only authorized distributors or receivers of quality-affecting software within Systems Integration.

7.2 Software Transfers Out Of Systems Integration

7.2.1 When a request is received for a specific software package, the Software Custodian assures that the request is documented to include the name, address and organization of the requestor. Requests are acceptable in writing or verbally but, if verbal, must be documented by the Custodian.

7.2.2 Upon receipt of a valid request, the Custodian prepares an appropriate software transfer package which includes:

7.2.2.1 Source and/or object program on appropriate media

7.2.2.2 User's Manual, Guide or other instructions appropriate to the software

7.2.2.3 Sample problem input and output, when appropriate

7.2.2.4 Other appropriate or requested information (e.g. V&V Report or other system description documentation)

7.2.2.5 A transfer package listing (which describes what is in the package) containing a place for acknowledgement of receipt by the requestor when transferring controlled, qualified software

7.2.3 When a source program is included in the transfer package, an appropriate disclaimer covering requestor-made modifications is also included in the transfer package listing.

7.2.4 When a software package, produced by Systems Integration but not yet qualified for use on OCRWM quality-affecting work, is transferred to an outside organization, the transfer package listing clearly states the software status with a caution to the requestor regarding its use.

7.2.5 The Software Custodian ships the transfer package to the requestor by an appropriate means to protect the magnetic media.

**FILE: COMPUTER SOFTWARE TRANSFER**

- 7.2.6 As a condition of transferring controlled, qualified software, the requestor is required to acknowledge receipt of the transfer package in complete and usable condition by signing and returning the transfer package listing.
- 7.2.7 The returned acknowledgement is included, by the Software Custodian, in the controlled transfer record file for the software package. This file is maintained to assure that all recipients of a controlled software package can be identified and that they receive approved modifications to the package.
- 7.2.7.1 If discrepancies in the contents of the package are identified by the requestor, they are corrected by the Software Custodian.
- 7.2.7.2 Perceived deficiencies in the software or documentation, or proposed improvements which are subsequently identified by a requestor will be accepted in writing by the Software Custodian and will be addressed in accordance with the software configuration management plan applicable to the software package.
- 7.2.8 If acknowledgement forms are not returned, the Software Custodian works with the requestor (if necessary the Task Manager) to complete the acknowledgement documentation.

**7.3 Software Transfers Into Systems Integration**

- 7.3.1 When a Task Manager (or staff member) identifies externally controlled software (controlled outside of Systems Integration) as needed for use on a quality-affecting task, a Software Custodian is designated by the Task Manager to receive and control the requested software transfer package.
- 7.3.2 The Software Custodian determines the request format required by the software owner and submits a request for the software package to the owner. Where no specified format exists, the Software Custodian makes the request by letter. The letter identifies the software and supporting documentation desired.
- 7.3.2.1 The Software Custodian also requests documentation which assures that the software was developed under an OCRWM approved QA program, or has been qualified for use in quality-affecting work subsequent to its development.
- 7.3.3 When the software transfer package is received, it is put under control by the Software Custodian.
- 7.3.3.1 For software packages which have been accepted by OCRWM for use in quality-affecting work, the Software Custodian processes the evidence of that acceptability into the Systems Integration QA Records system in accordance with procedure QA-SI-17-001 (Ref. 3.3).

**LE: COMPUTER SOFTWARE TRANSFER**

7.3.3.1.1 The Software Custodian also prepares a configuration management plan for the software in accordance with Section 19.6 "Computer Software Configuration Management" of the Systems Integration QAPD (Ref. 3.2).

7.3.3.2 For software packages which have not been accepted by OCRWM for use in quality-affecting work, the Task Manger initiates qualification of the software in accordance with Section 19.7 "Qualification of Existing Software" of the Systems Integration QAPD (Ref. 3.2).

7.3.3.2.1 The Software Custodian maintains control of the software package to assure that it is not used in quality affecting work until properly qualified for use.

7.3.3.2.2 If the Task Manager determines that an unqualified software package is to be made available for use, the Software Custodian is instructed to issue the package under cover of a memorandum to the user which clearly states that the software is not qualified for use on OCRWM quality-affecting work and that any reporting of results from use of the software must reflect that condition.

**8.0 RECORDS**

8.1 Software Transfer Package Listing Acknowledgements

8.2 Documentation received with software transferred into Systems Integration

8.3 Notification to users of the status of non-qualified software

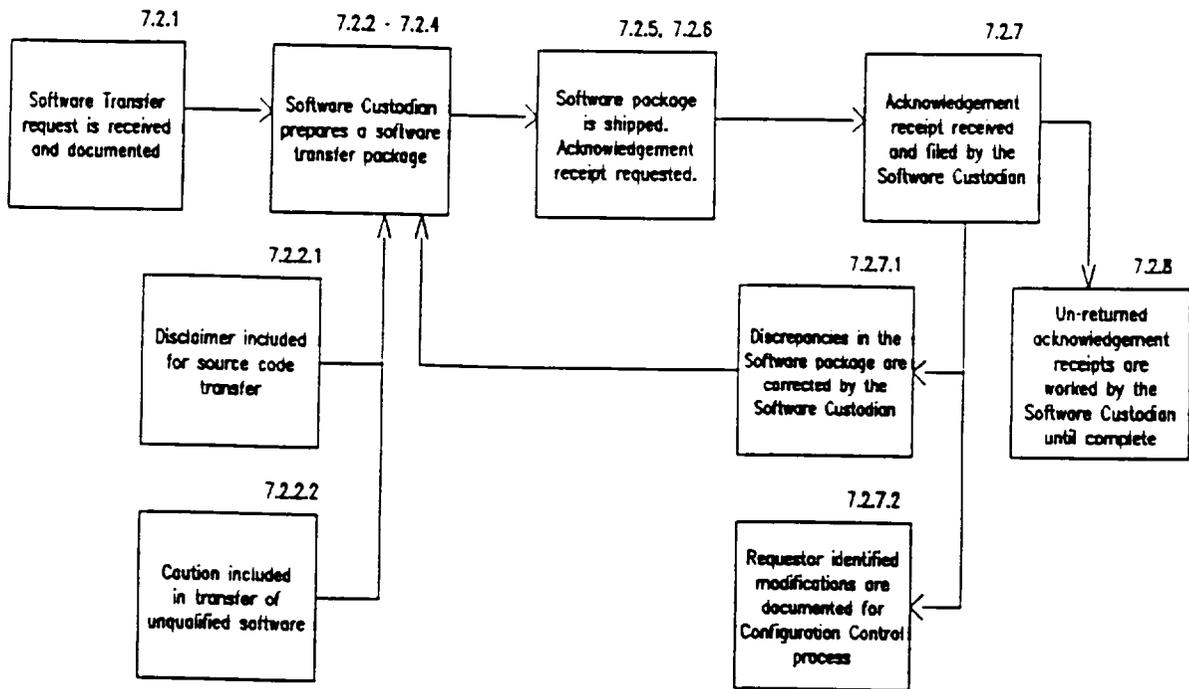
**9.0 ATTACHMENTS**

9.1 Attachment I - Computer Software Transfer Flowsheet

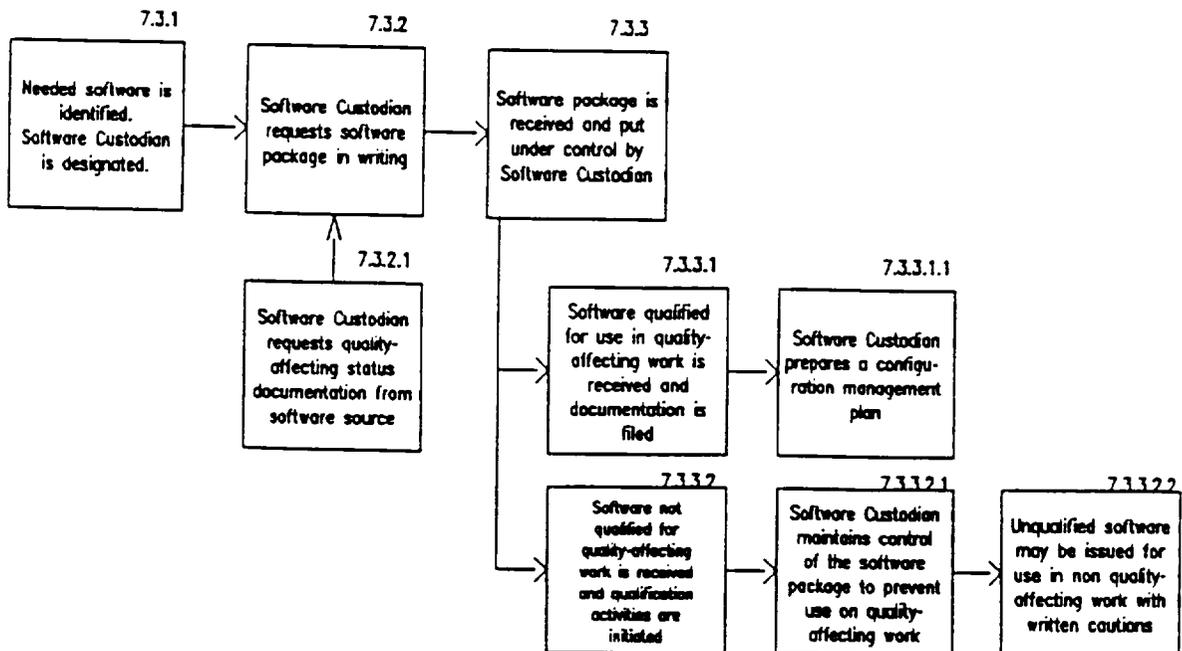
TLE: COMPUTER SOFTWARE TRANSFER

Attachment I  
COMPUTER SOFTWARE TRANSFER FLOWSHEET

*Software Transfers Out Of Systems Integration*



*Software Transfers Into Systems Integration*



OAK RIDGE NATIONAL LABORATORY  
QUALITY ASSURANCE PROGRAM

PROCEDURE: QA-SI-05-002. Rev. 0

SYSTEMS INTEGRATION PROGRAM  
QUALITY ASSURANCE PROCEDURE

DATE: January 6, 1992

PAGE 1 OF 8

SUPERSEDES: New

TITLE: DOCUMENT REVIEWS

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1.0 PURPOSE:

To establish the methods used in the Systems Integration Program to conduct reviews of project documents.

2.0 SCOPE:

2.1 This procedure applies to all Systems Integration quality-affecting documents.

3.0 REFERENCES:

3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214.

3.2 ASME NQA-1-1989 "Quality Assurance Program Requirements for Nuclear Facilities"

3.3 "Systems Integration Support, Quality Assurance Program Description ", QAP-X-91-WMRD-045

3.4 "Establishing Quality Assurance Controls", QA-SI-02-001.

3.5 "Procedure Preparation", QA-SI-05-001.

3.6 "Document Control", QA-SI-06-001.

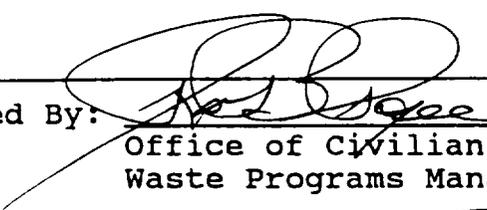
3.7 "QA Records", QA-SI-17-001.

4.0 REQUIREMENTS:

NQA-1, Basic Requirements 5 and 6: "activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures or drawings. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel."

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
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Approved By: 

Office of Civilian Radioactive  
Waste Programs Manager

Approved By: 

QA Specialist

FILE: **DOCUMENT REVIEWS****5.0 DEFINITIONS:**

- 5.1 Author - The individual assigned direct responsibility for preparation of a new document or update of an existing document.
- 5.2 Document - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.
- 5.3 Quality-Affecting - A term indicating status, applied to Systems Integration work (as determined by OCRWM management), which requires application of the QA program requirements specified in the OCRWM Quality Assurance Requirements Document.
- 5.4 Technical Review - A documented, traceable, in-depth, critical review, of documents, materials, or data that fall within the state of the art, conducted to evaluate both its applicability, correctness, adequacy, and completeness. Technical reviews are performed by qualified personnel with technical expertise at least equivalent to those who conducted the original work, and who are independent of those who conducted the work being reviewed.
- 5.5 Preliminary Review - An informal review conducted in a manner selected by the Task Manager and which is not a QA record.
- 5.6 Record Review - A formal review of a document conducted in accordance with paragraph 7.2.2 and which is a QA record.

**6.0 RESPONSIBILITIES:**

(Accomplishment of responsibilities assigned in sections 6.0 and 7.0 may be delegated to others but the responsibility remains with the assigned position.)

**6.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:**

- 6.1.1 Assuring that this procedure is implemented by Task Managers and staff.
- 6.1.2 Resolving comments to documents when disagreements cannot be resolved between the author and reviewer.

**6.2 Task Managers:**

- 6.2.1 Implementing this procedure for their respective tasks.
- 6.2.2 Identifying documents, within their areas of responsibility, that require review; and assuring that those documents are reviewed in accordance with this procedure.
- 6.2.3 Assuring that review comments are resolved and that final documents reflect comment resolutions.

TLE: **DOCUMENT REVIEWS**

6.2.4 Assisting the staff in resolving comments to documents within their areas of responsibility, when necessary.

6.2.5 Performing document reviews in accordance with this procedure when assigned by the OCRWP Manager.

6.3 Systems Integration Staff:

6.3.1 Notifying the Task Manager that a document they authored is ready for a record review in accordance with this procedure.

6.3.2 Performing document reviews in accordance with this procedure when assigned by their respective Task Managers.

6.3.3 Assuring that review comments are resolved and that final documents reflect comment resolutions, when assigned by the responsible Task Manager.

6.4 Quality Assurance Specialist (QAS):

6.4.1 Assisting the Task Managers in implementing this procedure.

6.4.2 Performing document reviews in accordance with this procedure, when assigned by the OCRWP Manager.

6.4.3 Providing oversight of compliance with this procedure through surveillance and audit.

7.0 **PROCEDURE** (See: Document Review Process Flowsheet, Attachment I)

7.1 GENERAL

7.1.1 Responsibility for preparation of new or revision of existing documents is assigned by the OCRWP Manager to the Task Managers and staff.

7.1.2 The author prepares the draft document in accordance with the appropriate format as specified by the OCRWP Manager. Procedures are prepared in accordance with QA-SI-05-001 (Ref. 3.5)

7.1.3 Systems Integration documents fall into two general categories: a) quality-affecting and b) non quality-affecting. Within those categories are such documents as procedures, plans, technical reports, white papers, technical memoranda, letter reports, and external publications. The QA Controls Matrix prepared for each task in accordance with procedure QA-SI-02-001 (Ref. 3.4) contains the documented decision as to the quality-affecting status of each task. In the event a Task Manager assigns fewer QA requirements to a specific lower level task, the reason for the exception is documented in the QA Controls Matrix.

**TITLE: DOCUMENT REVIEWS****7.2 QUALITY-AFFECTING DOCUMENTS****7.2.1 PRELIMINARY REVIEWS**

- 7.2.1.1 Preliminary reviews of documents may be performed in a manner selected by the Task Manager. For example, the method may be to red-line copies of the draft document.
- 7.2.1.2 Preliminary review comments may be maintained as project records at the discretion of the Task Manager, but preliminary reviews are not QA records and as such need not be retained.
- 7.2.1.3 Preliminary review comments are resolved as determined by the Task Manager.

**7.2.2 RECORD REVIEWS**

- 7.2.2.1 The author submits the draft document to the Task Manager for initiation of the review process. The document is distributed to an appropriate distribution of independent reviewers under the cover of a Document Review Record (Attachment II). A copy of the Document Review Continuation Form (Attachment III) is also included for duplication and use by the reviewers, as necessary. Full size document review forms are available from the OCRWP Manager's office.
- 7.2.2.2 Before distribution, the Document Title, Revision Number, Revision Date, Document Number, Review Criteria, Return Comments To, and Due Date sections of the Document Review Record are completed (including the Continuation Form) by the Task Manager.
- 7.2.2.3 The cover sheet of each draft document (new or revised) distributed for review is stamped with the word "DRAFT" in bold black letters.
- 7.2.2.4 The reviewers perform their reviews in accordance with the review criteria specified in the Document Review Record, document their comments on the Document Review Record (and Continuation Form if necessary), and return the comment sheets as instructed.
- 7.2.2.5 The Task Manager then resolves all comments with the reviewers.
- 7.2.2.6 In cases where comments cannot be resolved, the OCRWP Manager is the resolving authority.

**TITLE: DOCUMENT REVIEWS**

7.2.2.7 After the review and comment process is complete, the author updates the document, assembles it in final form, obtains signatures and returns the finished document to the Task Manager for distribution and control in accordance with procedure QA-SI-06-001 (Ref. 3.6). Upon completion of the document review process, the Document Review Record forms are retained as QA records in accordance with procedure QA-SI-17-001 (Ref. 3.7).

**7.3 REVISIONS**

7.3.1 Editorial, typographical, grammatical, punctuation, spelling, numbering or other minor corrections, which do not affect the basic content of the document, may be approved by the Task Manager without reissue for review.

7.3.2 Major revisions which do impact the quality-affecting aspects of the document are reissued for review and comment in accordance with section 7.2.2.

**8.0 RECORDS:**

Records generated as a result of performing reviews in accordance with this procedure, which must be maintained as quality assurance records, are:

8.1 Document Review Record Forms

8.2 Documents Reviewed

**9.0 ATTACHMENTS:**

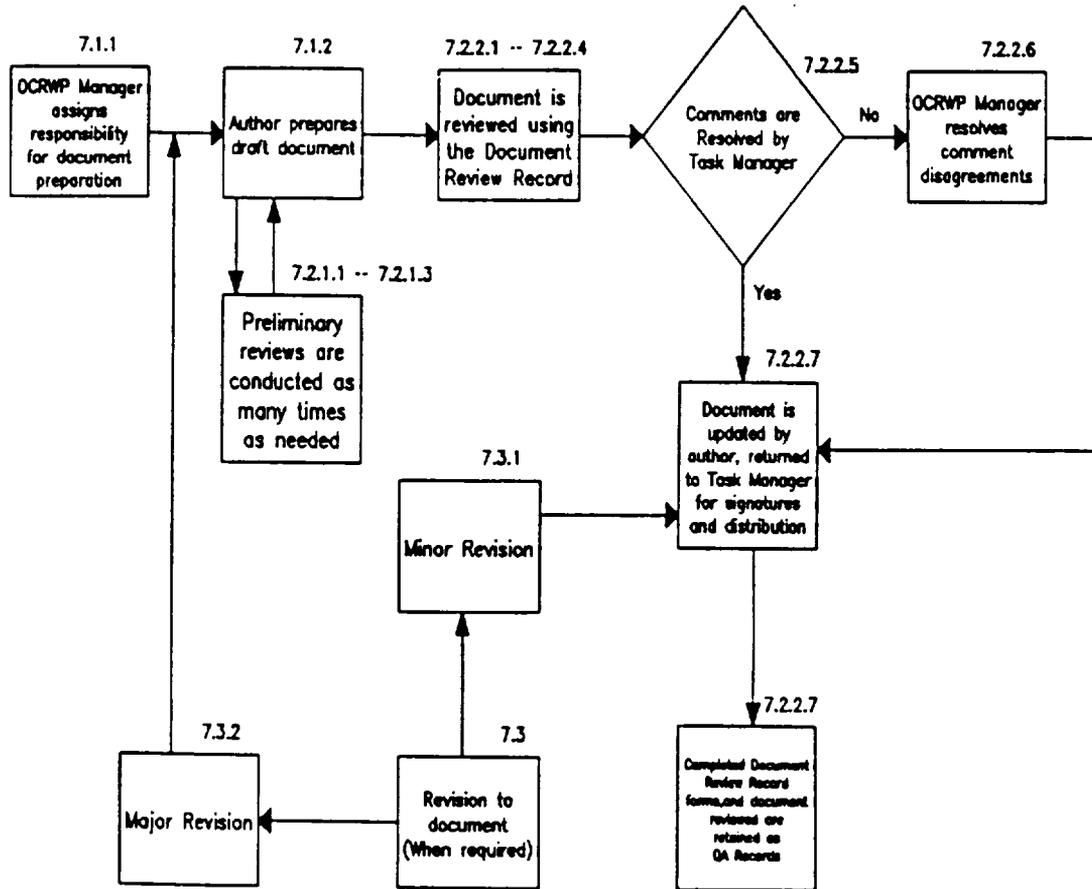
9.1 Attachment I - Document Review Process Flowsheet

9.2 Attachment II - Document Review Form

9.3 Attachment III - Document Review Continuation Form

TITLE: DOCUMENT REVIEWS

Attachment I  
DOCUMENT REVIEW PROCESS FLOWSHEET



TITLE: **DOCUMENT REVIEWS**

**Attachment II  
DOCUMENT REVIEW FORM**

**Systems Integration Program**

**DOCUMENT REVIEW RECORD**

Document Title \_\_\_\_\_  
 Revision Number: \_\_\_\_\_ Revision Date: \_\_\_\_\_ Page \_\_\_\_ of \_\_\_\_  
 Document Number: \_\_\_\_\_

Review Criteria:

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Return Comments To: \_\_\_\_\_  
 Due Date: \_\_\_\_\_

Sect/ Para	Comment	Response	Accept
Reviewed By: _____ Signature _____ Date _____		Comments Resolved By: _____ Signature _____ Date _____	

TITLE: DOCUMENT REVIEWS

**Attachment III**  
**DOCUMENT REVIEW CONTINUATION FORM**

**Systems Integration Program**

**DOCUMENT REVIEW RECORD - Continuation**

Document Title \_\_\_\_\_  
Revision Number: \_\_\_\_\_ Revision Date: \_\_\_\_\_ Page \_\_\_\_ of \_\_\_\_  
Document Number: \_\_\_\_\_

Sect/ Para	Comment	Response	Accept

OAK RIDGE NATIONAL LABORATORY  
QUALITY ASSURANCE PROGRAM

PROCEDURE: QA-SI-17-001

SYSTEMS INTEGRATION PROGRAM  
QUALITY ASSURANCE PROCEDURE

DATE: January 7, 1992

PAGE 1 OF 7

SUPERSEDES: New

TITLE: QA RECORDS

UNCONTROLLED  
COPY

1.0 PURPOSE:

To establish the method used in the Systems Integration program to generate, validate, index, identify, classify, retain, correct and transfer QA records.

2.0 SCOPE:

This procedure applies to all Systems Integration tasks determined to be quality-affecting.

3.0 REFERENCES:

3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214

3.2 "Systems Integration Support, Quality Assurance Program Description ", QAP-X-91-WMRD-045

4.0 REQUIREMENTS:

NQA-1, Basic Requirement 17: Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

5.0 DEFINITIONS:

5.1 Duplicate Records Storage Facility - The location within Oak Ridge National Laboratory (ORNL) designated for storage and protection of backup copies of Systems Integration QA records.

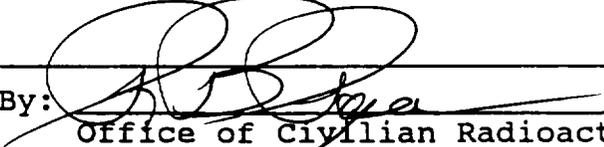
5.2 Machine Readable Record - A record stored on magnetic media and written in ASCII or EBCDIC format.

5.1 Quality Assurance Program Description (QAPD) - The ORNL-prepared, OCRWM-approved quality assurance document which describes the Systems Integration QA program for meeting OCRWM QA requirements.

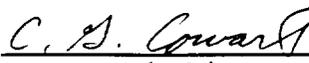
OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By:

  
Office of Civilian Radioactive  
Waste Programs Manager

Approved By:

  
QA Specialist

TLE: **QA RECORDS**

- 5.2 Quality Assurance Record - A completed document that furnishes evidence of the quality of items and/or activities affecting quality. A document that is authenticated and will receive no more entries.
- 5.3 Quality-Affecting - A term indicating status, applied to Systems Integration work (as determined by OCRWM management), which requires application of the QA program requirements specified in the OCRWM Quality Assurance Requirements Document.
- 5.5 Records Validation - The act of reviewing a record or records package to assure it is complete, authenticated, reproducible and microfilmable.

6.0 RESPONSIBILITIES:

(Accomplishment of responsibilities assigned in sections 6.0 and 7.0 may be delegated to others but the responsibility remains with the assigned position.)

6.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:

- 6.1.1 Assuring that QA-SI-17-001 is implemented by Task Managers and staff.
- 6.1.2 Assuring that records packages are validated prior to turnover to OCRWM.

6.2 Systems Integration Task Managers:

- 6.2.1 Implementing QA-SI-17-001 for their respective, quality-affecting tasks.
- 6.2.2 Identifying documents that require retention and protection as QA records.
- 6.2.3 Designating a Records Custodian for their areas of responsibility.
- 6.2.4 Assuring that QA records are transmitted to the Records Custodian.

6.3 Systems Integration Staff:

- 6.3.1 Assuring that records are identified and handled in accordance with QA-SI-17-001.

6.4 Records Custodian:

- 6.4.1 Assuring that QA records received from the Task Managers are identified, indexed, filed and protected.
- 6.4.2 Transmitting copies of QA records to the Duplicate Records Storage Facility custodian.
- 6.4.3 Preparing and transmitting records packages to OCRWM as directed by the OCRWP Manager.

TITLE: **QA RECORDS**

6.5 Quality Assurance Specialist (QAS):

6.5.1 Assisting the Task Managers in implementing QA-SI-17-001.

6.5.2 Assuring that a records index is maintained.

6.5.3 Maintaining the Duplicate Records Storage Facility.

6.5.4 Providing oversight of compliance with QA-SI-17-001 through surveillance and audit.

7.0 PROCEDURE: (See Flowsheet, Attachment I)

7.1 General

7.1.1 Categories of QA records expected to be applicable to Systems Integration are identified in the QA Program Description and include but are not limited to the following: procedures, plans, manuals, reports, technical and peer reviews, personnel qualifications, procurement documents, computer software documents, audit and surveillance plans and reports, corrective action plans and reports, occurrence reports, Systems Integration QAPD and procedures, guidance letters, Systems Integration QA requirements matrix, assessment reports, evaluations of supplier's programs, and auditor certifications.

7.1.2 QA records (paper documents) must be legible, reproducible, microfilmable, and produced and signed in black ink. Application of correction fluid or correction tape to a QA record is unacceptable.

7.1.3 QA records must not contain stamps or other marks that obliterate or obscure the text.

7.1.4 Photocopies submitted as QA records must be as close in appearance to the originals as possible and still meet the criteria of 7.1.2 and 7.1.3 above.

7.1.5 Originals or acceptable photocopies of QA records are stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from (a) natural disasters such as winds, floods, or fires, (b) environmental conditions such as high and low temperatures and humidity, and (c) infestation of insects, mold or rodents.

7.1.6 QA records are maintained by Systems Integration for the duration of each quality-affecting task. Upon termination of a task, all associated QA records will be packaged and turned over to OCRWM for inclusion in their records system.

7.1.7 Duplicate copies of machine readable records are also required since the ORNL Tape Library does not meet the single facility or alternate single facility requirements of ASME NQA-1, Supplement 17S-1.

FILE: QA RECORDS

## 7.2 Preparation of QA Records

- 7.2.1 Each Task Manager develops a list of QA Records to be generated for the tasks within the Manager's area of responsibility.
- 7.2.2 The Task Manager forwards a copy of the list to the Records Custodian designated for the task.
- 7.2.3 As each record is completed, the Task Manager reviews it for completeness, initials and dates it on the first page at top right, and forwards it to the Records Custodian with instructions to include it in the QA Records system.
- 7.2.4 When a record is in machine readable form, the Task Manager stores the record as follows:
  - 7.2.4.1 The Task Manager contacts the Oak Ridge National Laboratory (ORNL) Tape Library custodian to arrange for permanent storage of the computer code on tape.
  - 7.2.4.2 Following the instructions given by the Tape Library custodian, the Task Manager arranges for a permanent retention tape to be created and stored in the Tape Library at ORNL. A second copy is retained at a location selected by the Task Manager.
  - 7.2.4.3 The tape number and locations are documented by the Task Manager in a memo to the Systems Integration QA Records file.

## 7.3 Maintenance of the QA Records Master File

- 7.3.1 The Records Custodian receives QA records from the Task Managers.
- 7.3.2 The Records Custodian makes a copy of each QA record received and forwards those copies to the Duplicate Records Storage Facility custodian for filing and protection as the backup record copy.
- 7.3.3 The Records Custodian then files each record in the Systems Integration project file as a master QA record.
- 7.3.4 The Records Custodian controls access to the records file and no originals are removed without signout by the borrower.

## 7.4 Duplicate Records Storage Facility (DRSF)

- 7.4.1 The DRSF custodian receives copies of Systems Integration QA records from the Records Custodian and adds each record to the QA records index. Each record is assigned a unique record number and is also indexed by date, title and document number (if applicable).
- 7.4.2 The DRSF custodian produces an updated index, forwards a copy to the Records Custodian and maintains a copy with the Systems Integration duplicate QA records.

**TITLE: QA RECORDS**

7.4.3 The DRSF custodian files each duplicate record in the DRSF file by unique record number within a Systems Integration file group.

7.4.4 The DRSF files are kept locked except to add records and update the index.

## 7.5 Records Turnover

7.5.1 Upon termination of a Systems Integration task, the Task Manager determines where to send the task QA records and instructs the Records Custodian to prepare a records turnover package for transmittal to the sponsor's designated records repository.

7.5.1.1 For machine readable records, the Task Manager arranges for a copy of the tape in the ORNL Tape Library to be made and transmitted to the Records Custodian.

7.5.2 The Records Custodian extracts those records associated with the task from the master file and makes a copy of each.

7.5.3 The Records Custodian prepares an index of the records to be transmitted and a transmittal letter. The letter contains a request for written acknowledgement of receipt upon delivery. One copy of the index goes with the master file and one copy is kept with the group of copies to be maintained by Systems Integration.

7.5.4 The Records Custodian delivers the records (including machine readable tapes), index and transmittal letter to the OCRWP Manager.

7.5.5 The OCRWP Manager reviews the records package. After resolving any questions with the Task Manager, the OCRWP Manager signs the letter (indicating validation of the records package) and returns the records, index and letter to the Records Custodian.

7.5.6 The Records Custodian then packages the master file and index (machine readable tapes may have to be sent separately if special packaging is required), and transmits the package to the sponsor's designated records repository under cover of the transmittal letter. If machine readable tapes are sent separately, a copy of the letter accompanies that package also.

7.5.7 The Records Custodian maintains the copies of the records, index and transmittal letter, as a safeguard against loss (the master copy of machine readable tapes remains in the ORNL Tape Library), until obtaining written acknowledgement of receipt from the records repository.

7.5.8 Should written acknowledgement not be returned within 30 calendar days, the Records Custodian first attempts to resolve the problem with the records repository. Should these efforts be unsuccessful for an additional 30 calendar days, the Records Custodian informs the Task Manager who attempts to resolve the problem with the sponsor.

7.5.9 Should all attempts fail to resolve the problem, the Task Manager may use the OCRWM Quality Concerns Program to alert the sponsor's QA organization of possible records system failure.

TLE: **QA RECORDS**

8.0 RECORDS

8.1 Task QA records

8.2 Records transmittal letter

8.3 Records index

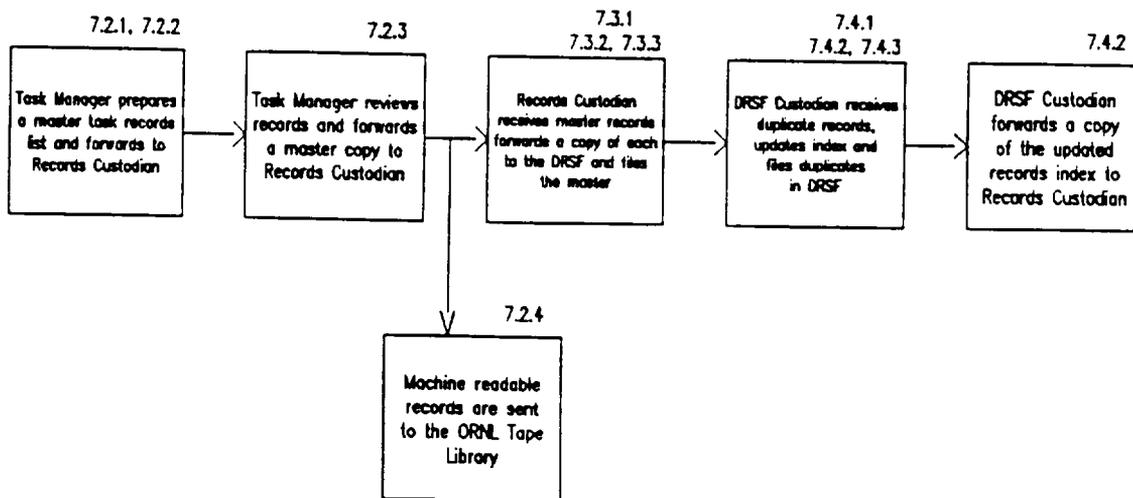
9.0 ATTACHMENTS

9.1 Attachment I - QA Records Flowsheet

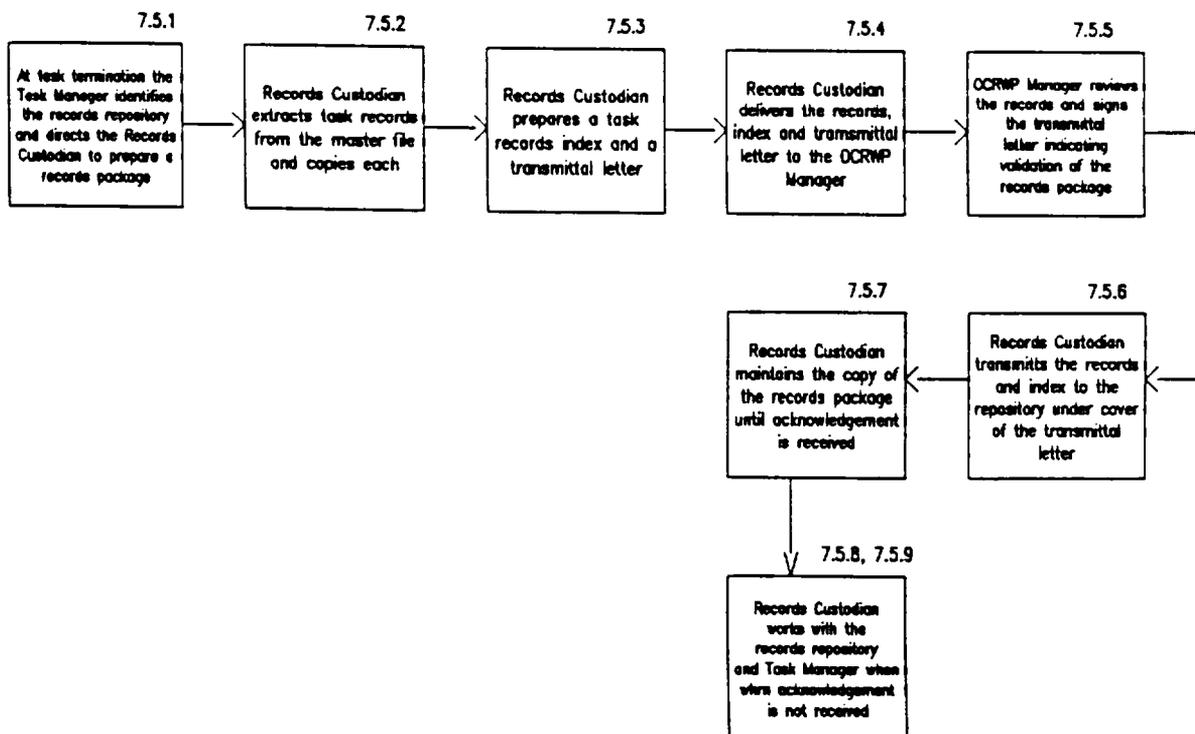
FILE: QA RECORDS

**Attachment I  
QA RECORDS FLOWSHEET**

QA Records Operations



QA Records Turnover



OAK RIDGE NATIONAL LABORATORY  
QUALITY ASSURANCE PROGRAM

PROCEDURE: QA-SI-05-001

SYSTEMS INTEGRATION PROGRAM  
QUALITY ASSURANCE PROCEDURE

DATE: January 6, 1992

PAGE 1 OF 10

SUPERSEDES: New

TITLE: PROCEDURE PREPARATION

**UNCONTROLLED  
COPY**

1.0 PURPOSE:

To establish the method used in the Systems Integration program to prepare, review, approve and distribute program procedures.

2.0 SCOPE:

This procedure applies to all Systems Integration tasks determined to be quality-affecting, and includes technical, administrative and quality assurance activities.

3.0 REFERENCES:

- 3.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214
- 3.2 "Systems Integration Support, Quality Assurance Program Description ", QAP-X-91-WMRD-045
- 3.3 Procedure QA-SI-06-001, "Document Control"
- 3.4 Procedure QA-SI-05-002, "Document Reviews"
- 3.5 Procedure QA-SI-02-002, "Indoctrination and Training"

4.0 REQUIREMENTS:

NQA-1, Basic Requirement 5: Activities affecting quality shall be prescribed by and performed in accordance with documented procedures.

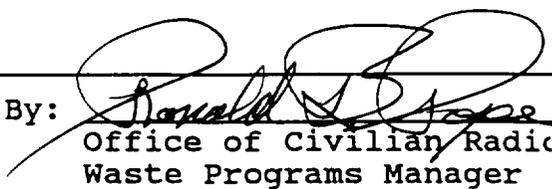
5.0 DEFINITIONS:

- 5.1 Author - The individual assigned direct responsibility for preparation of a new document or update of an existing document.

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By:

  
Office of Civilian Radioactive  
Waste Programs Manager

Approved By:

  
QA Specialist

**TITLE: PROCEDURE PREPARATION**

- 5.2 Line Procedure - A document which specifies the instructions for performing a quality-affecting activity. Both technical and administrative procedures are included.
- 5.3 Quality-Affecting - A term indicating status, applied to Systems Integration work (as determined by OCRWM management), which requires application of the QA program requirements specified in the OCRWM Quality Assurance Requirements Document.
- 5.4 Quality Assurance Procedure - A document which specifies the instructions for performing a quality assurance activity which satisfies a QARD requirement.
- 5.5 Quality Assurance Program Description (QAPD) - The ORNL-prepared, OCRWM-approved quality assurance document which describes the Systems Integration QA program for meeting OCRWM QA requirements.

**6.0 RESPONSIBILITIES:**

(Accomplishment of responsibilities assigned in sections 6.0 and 7.0 may be delegated to others but the responsibility remains with the assigned position.)

**6.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:**

- 6.1.1 Assuring that QA-SI-05-001 is implemented by Task Managers and staff.
- 6.1.2 Approving all procedures and revisions thereto.

**6.2 Systems Integration Task Managers:**

- 6.2.1 Implementing QA-SI-05-001 for their respective, quality-affecting tasks.
- 6.2.2 Identifying activities that require procedural definition and assuring that these activities are documented in accordance with QA-SI-05-001.
- 6.2.3 Approving all procedures and revisions thereto, in their respective areas of responsibility.
- 6.2.4 Assuring that appropriate indoctrination and/or training is conducted for new and revised procedures.
- 6.2.5 Assuring that activities affecting quality are conducted in accordance with established procedures.

**6.3 Systems Integration Staff:**

- 6.3.1 Preparing procedures in accordance with QA-SI-05-001 as directed by their respective Task Managers.
- 6.3.2 Providing procedure reviews as directed by their respective Task Managers.

FILE: **PROCEDURE PREPARATION**

6.3.3 Conducting activities affecting quality in accordance with established Systems Integration procedures.

6.3.4 Completing assigned indoctrination and/or training for new and revised procedures.

6.4 Quality Assurance Specialist (QAS):

6.4.1 Assisting the Task Managers in implementing QA-SI-05-001.

6.4.2 Reviewing all quality-affecting line procedures and revisions thereto.

6.4.3 Reviewing and approving all Quality Assurance procedures and revisions thereto.

6.4.4 Providing oversight of compliance with established procedures through surveillance and audit.

7.0 PROCEDURE: (See Flowsheet, Attachment I)

7.1 PREPARATION

7.1.1 Responsibility for preparation or revision of procedures is assigned by the OCRWP Program Manager, or a designee, to an author.

7.1.2 The author prepares a draft procedure in accordance with the format outlined in Section 7.2 below.

7.1.3 The author prepares a review package and initiates the review process in accordance with procedure QA-SI-05-002 (Ref. 3.4).

7.1.4 After the review and comment process is complete, the author assembles the procedure in final form, obtains signatures (as described in Section 7.4 below) and delivers the finished document to the OCRWP Program Manager, or a designee, for distribution in accordance with procedure QA-SI-06-001 (Ref. 3.3). SP

7.2 FORMAT

7.2.1 Attachments II, III and IV show the forms used for procedure development. Attachment II is the title page for QA procedures, Attachment III is the title page for line procedures, and Attachment IV is the continuation page for both QA and line procedures.

7.2.2 All procedures subject to QA-SI-05-001 are organized into the following sections, as a minimum:

- 1.0 Purpose (statement of what the procedure is intended to do)
- 2.0 Scope (statement of which activities the procedure is used for)

**TITLE: PROCEDURE PREPARATION**

- 3.0 References (documents that require an interface with the procedure or must be used in performing the activity described)
- 4.0 Requirements (referencing the document that specifies the requirements that a procedure will satisfy)
- 5.0 Definitions (meanings of terms or acronyms necessary for understanding the procedure)
- 6.0 Responsibilities (responsibilities of the persons implementing the procedure)
- 7.0 Procedure (detailed steps needed to accomplish the purpose of the procedure)
- 8.0 Records (quality assurance record documents generated as a result of implementing the procedure)
- 9.0 Attachments (any additional text or forms needed to implement the procedure)

7.2.3 Other sections may be added as needed for specific activities. Examples of additional sections include:

- Equipment, tools, instruments
- Environmental conditions
- Calibration
- Protective clothing or barriers
- Interfaces with other equipment, systems or personnel.
- Special restrictions or conditions

7.2.4 The title page (Attachment II or III) includes:

- Title
- Procedure Number (assigned by the OCRWP Program Manager)
- Revision Number (new procedures are revision 0; subsequent revisions are 1, 2, etc.)
- Effective Date
- Approval and/or concurrence blocks
- Page Number (in "x of x" format)

7.2.5 The continuation pages (Attachment IV) include:

- Title
- Procedure Number
- Revision Number
- Page Number

### 7.3 REVIEW

7.3.1 Procedures are reviewed in accordance with procedure QA-SI-05-002 (Ref. 3.4).

### 7.4 APPROVALS

7.4.1 For QA procedures, the QAS assures that the procedure is correctly updated in accordance with the final review comments and indicates approval by signing the procedure title page in the appropriate block.

**TLE:      PROCEDURE PREPARATION**

7.4.2 For line procedures, the Task Manager assures that the procedure is correctly updated in accordance with the final review comments and indicates approval by signing the procedure title page in the appropriate block.

7.4.3 The OCRWP Program Manager assures that each QA and line procedure is correctly updated in accordance with the final review comments and indicates approval by signing the procedure title page in the appropriate block.

**7.5      REVISIONS**

7.5.1 Minor revisions to a procedure to make editorial, typographical, grammatical, punctuation, spelling, numbering or other insignificant corrections, which do not affect the basic content of the document, may be approved by the appropriate signatories without a reissue for review.

7.5.2 Major revisions which do affect the basic content of the document are reissued for review and comment in accordance with section 7.3 above. Approvals are then obtained in accordance with Section 7.4 above.

**7.6      DISTRIBUTION AND CONTROL**

The procedure is put under formal control per procedure QA-SI-06-001 (Ref. 3.3) and distribution is made to those Systems Integration staff determined to require the procedure.

**7.7      TRAINING**

Training requirements are defined, accomplished and documented per procedure QA-SI-02-002 (Ref. 3.5).

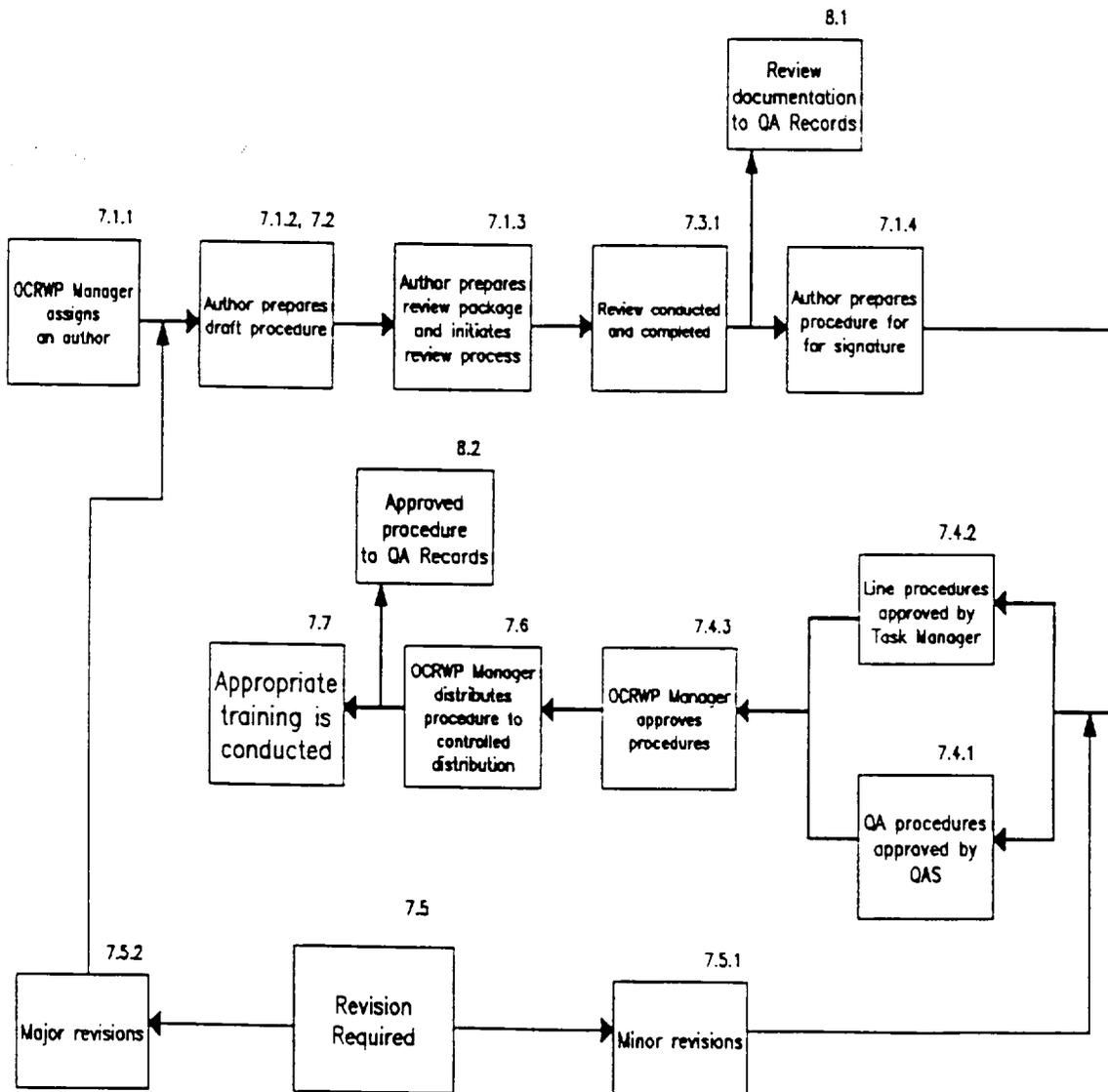
**TITLE: PROCEDURE PREPARATION****8.0 RECORDS**

- 8.1 Completed Document Review Record forms.
- 8.2 Approved procedures.

**9.0 ATTACHMENTS**

- 9.1 Attachment I - Procedure Preparation Flowsheet
- 9.2 Attachment II - QA Procedure Title Page
- 9.3 Attachment III - Line Procedure Title Page
- 9.4 Attachment IV - Procedure Continuation Page (QA and line)

Attachment I  
PROCEDURE PREPARATION FLOWSHEET



SYSTEMS INTEGRATION PROGRAM

PROCEDURE: QA-SI-05-001

PROCEDURE

PAGE 8 OF 10

FILE: PROCEDURE PREPARATION

Attachment II  
QUALITY ASSURANCE PROCEDURE TITLE PAGE

OAK RIDGE NATIONAL LABORATORY  
QUALITY ASSURANCE PROGRAM

SYSTEMS INTEGRATION PROGRAM  
QUALITY ASSURANCE PROCEDURE

TITLE:

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By: \_\_\_\_\_

Office of Civilian Radioactive  
Waste Programs Manager

Approved By: \_\_\_\_\_

QA Specialist

TITLE: PROCEDURE PREPARATION

**Attachment III**  
**LINE PROCEDURE TITLE PAGE**

OAK RIDGE NATIONAL LABORATORY

SYSTEMS INTEGRATION PROGRAM

LINE PROCEDURE

TITLE:

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By: \_\_\_\_\_

Office of Civilian Radioactive  
Waste Programs Manager

Approved By: \_\_\_\_\_

Task Manager

SYSTEMS INTEGRATION PROGRAM

PROCEDURE: QA-SI-05-001

PROCEDURE

PAGE 10 OF 10

TITLE: PROCEDURE PREPARATION

Attachment IV  
PROCEDURE CONTINUATION PAGE

SYSTEMS INTEGRATION PROGRAM

PROCEDURE

TITLE:

OAK RIDGE NATIONAL LABORATORY  
QUALITY ASSURANCE PROGRAM

PROCEDURE: QA-SI-06-001, Rev. 0

SYSTEMS INTEGRATION PROGRAM  
QUALITY ASSURANCE PROCEDURE

DATE: January 6, 1992

PAGE 1 OF 8

SUPERSEDES: New

TITLE: DOCUMENT CONTROL

**UNCONTROLLED  
COPY**

1.0 PURPOSE

To establish the responsibilities and methods used in the Systems Integration Program for identification, distribution and change of Controlled Documents.

2.0 SCOPE

This procedure applies to Systems Integration Controlled Documents used for performing quality-affecting work. This procedure excludes software, which is controlled under a computer software configuration management system.

3.0 REFERENCES

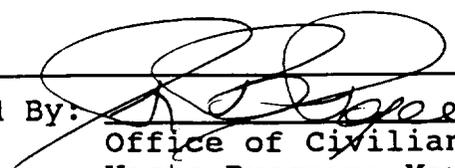
- 3.1 "Quality Assurance Requirements for Nuclear Facilities," ASME NQA-1.
- 3.2 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", DOE/RW-0214.
- 3.3 "Systems Integration Support, Quality Assurance Program Description ", QAP-X-91-WMRD-045
- 3.4 "Procedure Preparation," QA-SI-05-001.
- 3.5 "Document Reviews," QA-SI-05-002.
- 3.6 "QA Records," QA-SI-17-001.

4.0 REQUIREMENTS

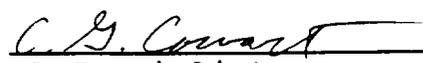
ASME NQA-1, Section 6 and Supplement 6S-1. "The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel."

OAK RIDGE NATIONAL LABORATORY

OPERATED BY  
MARTIN MARIETTA  
ENERGY SYSTEMS, INC.

Approved By: 

Office of Civilian Radioactive  
Waste Programs Manager

Approved By: 

QA Specialist

TLE: DOCUMENT CONTROL

## 5.0 DEFINITIONS

- 5.1 Controlled Copy Number - The sequential number assigned by the Controlled Document Custodian that uniquely identifies the recipient of each controlled copy.
- 5.2 Controlled Document - A document which is prepared, reviewed, and approved according to established procedures; has controlled distribution; and is subject to revision and decontrol.
- 5.3 Controlled Document List - A list of all Controlled Documents maintained by a Controlled Document Custodian. The Controlled Document List specifies document title, document number, revision number, and issue date for each Controlled Document.
- 5.4 Controlled Document Transmittal (CDT) - The form (See Attachments II and III) used when transmitting a Controlled Document. It includes a distribution list, applicable instructions (revision and comments section), and provisions for acknowledging receipt.
- 5.6 Manual - A collection of related documents issued as a unit. Each manual must contain a Table of Contents that identifies each document in the manual by title, document number, revision, and effective date. A new table of contents is issued each time a document is added or revised. The manual is issued as the Controlled Document, not the individual documents contained in the manual.
- 5.3 Quality-Affecting - A term indicating status, applied to Systems Integration work (as determined by OCRWM management), which requires application of the QA program requirements specified in the OCRWM Quality Assurance Requirements Document.

## 6.0 RESPONSIBILITIES

(Accomplishment of responsibilities assigned in sections 6.0 and 7.0 may be delegated to others but the responsibility remains with the assigned position.)

### 6.1 Office of Civilian Radioactive Waste Programs (OCRWP) Manager:

- 6.1.1 Assures that Systems Integration Controlled Documents meet the document control requirements and are administered in accordance with this procedure,
- 6.1.2 Assures the incorporation of program requirements changes into affected documents,
- 6.1.3 Identifies documents or manuals requiring control which are outside the scope of individual Task Managers tasks and assures that such document are prepared, reviewed, and approved in accordance with System Integration procedures,
- 6.1.4 Establishes a distribution list for documents designated in Section 7.2, and
- 6.1.5 Assigns a Controlled Document Custodian for each Controlled Document not under the responsibility of a specific Task Manager.

FILE: **DOCUMENT CONTROL**

6.2 Task Manager

- 6.2.1 Assigns a Controlled Document Custodian for each Controlled Document within the Manager's scope of work.
- 6.2.2 Assures that Controlled Documents (or manuals) and changes thereto, in their area of responsibility are identified, prepared, reviewed, approved, and distributed and
- 6.2.3 Establishes a distribution list for the documents designated in Section 7.2.

6.3 Controlled Document Custodian

- 6.3.1 Processes Controlled Documents in accordance with this procedure,
- 6.3.2 Maintains current Controlled Documents in the Custodian's area of responsibility,
- 6.3.3 Maintains a Controlled Document List for all Controlled Documents within the Custodian's scope of work,
- 6.3.4 Processes QA records generated as a result of this procedure in accordance with QA-SI-17-001 (Ref. 3.6).

6.4 Recipient of Controlled Document

- 6.4.1 Follows instructions on the CDT,
- 6.4.2 Signs, dates, and returns CDT acknowledgment to the designated Custodian within the specified time, and
- 6.4.3 Makes Controlled Documents available to personnel performing quality-affecting work, as applicable.

6.5 Quality Assurance Specialist (QAS):

- 6.5.1 Assists the OCRWP Manager and Task Managers in implementing this procedure,
- 6.5.2 Functions as the Controlled Document Custodian for QA procedures when assigned by the OCRWP Manager,
- 6.5.3 Provides oversight of compliance with this procedure through surveillance and audit, and
- 6.5.4 Prepares and maintains this procedure.

**LE: DOCUMENT CONTROL****7.0 PROCEDURE** (See: Document Control Flowsheet, Attachment I)**7.1 General**

Staff performing quality-affecting work only use information available in the current version of the applicable Controlled Document. (Uncontrolled copies may be used for information purposes only; not when performing quality-affecting work).

7.2 The OCRWP Manager, Task Managers, or designees identify documents for controlled issue within their area of responsibility. Controlled Documents are used when performing quality-affecting work and include documents such as program plans, procedures, manuals, system requirements and descriptions, and reports.

7.3 The OCRWP Manager, Task Managers, or designees prepare documents in accordance with "Procedure Preparation," QA-SI-05-001 (Reference 3.4), and "Document Reviews," QA-SI-05-002 (Reference 3.5). When the Controlled Document is a manual, it includes a Table of Contents prepared by the responsible Task Manager and updated by the Task Manager when revisions or additions are prepared for issue.

→ 7.4 The Controlled Document Transmittal (CDT), Attachment II, is prepared by the responsible Task Manager and concurred with by the OCRWP Manager prior to release.

7.5 The OCRWP Manager forwards the CDT and accompanying documents to the Custodian requesting distribution.

7.6 For individually issued documents, the Custodian stamps "CONTROLLED COPY" in red ink on the first page of each copy, affixes a controlled copy number to each document, enters the numbers on the CDT, and updates the Controlled Document List.

7.7 For controlled manuals, the Custodian stamps "CONTROLLED COPY" in red ink on the Table of Contents of each manual, affixes a controlled copy number to each manual, enters the numbers on the CDT, and updates the Controlled Document List.

7.8 The Custodian prepares the CDT on blue paper and distributes the applicable CDT with the Controlled Document to all recipients named on the CDT.

→ 7.9 The recipient of a Controlled Document follows the instructions on the CDT and signs, dates, and returns the CDT acknowledgement to the Custodian.

7.10 Copies issued for information only are marked "UNCONTROLLED COPY" in black ink by the Custodian.

**FILE: DOCUMENT CONTROL****7.11 The Controlled Document Custodian:**

7.11.1 Tracks, expedites, and processes CDT acknowledgements as QA Records in accordance with QA-SI-17-001 (Reference 3.3).

7.11.2 Decontrols document copies with unacknowledged CDTs according to the following:

7.11.2.1 When a CDT acknowledgement is not received by the return date, the Custodian issues a first reminder to the recipient and specifies a new "return by" date (one calendar month from the previous return date).

7.11.2.2 The Custodian issues a second reminder when a CDT acknowledgement is not received by the extended return date. This reminder also notifies the recipient that this copy will be decontrolled if the CDT acknowledgement is not returned within an additional calendar month.

7.11.2.3 If the CDT is not received after the second reminder, the Custodian decontrols that copy by removing the recipient's name from the applicable distribution list. The Custodian provides written notification to the recipient, responsible Task Manager, and OCRWP Manager of this action.

**8.0 QUALITY ASSURANCE RECORDS**

8.1 Controlled Document Transmittals (CDTs) including attached Controlled Documents.

**9.0 ATTACHMENTS**

9.1 Attachment I - Document Control Flowsheet

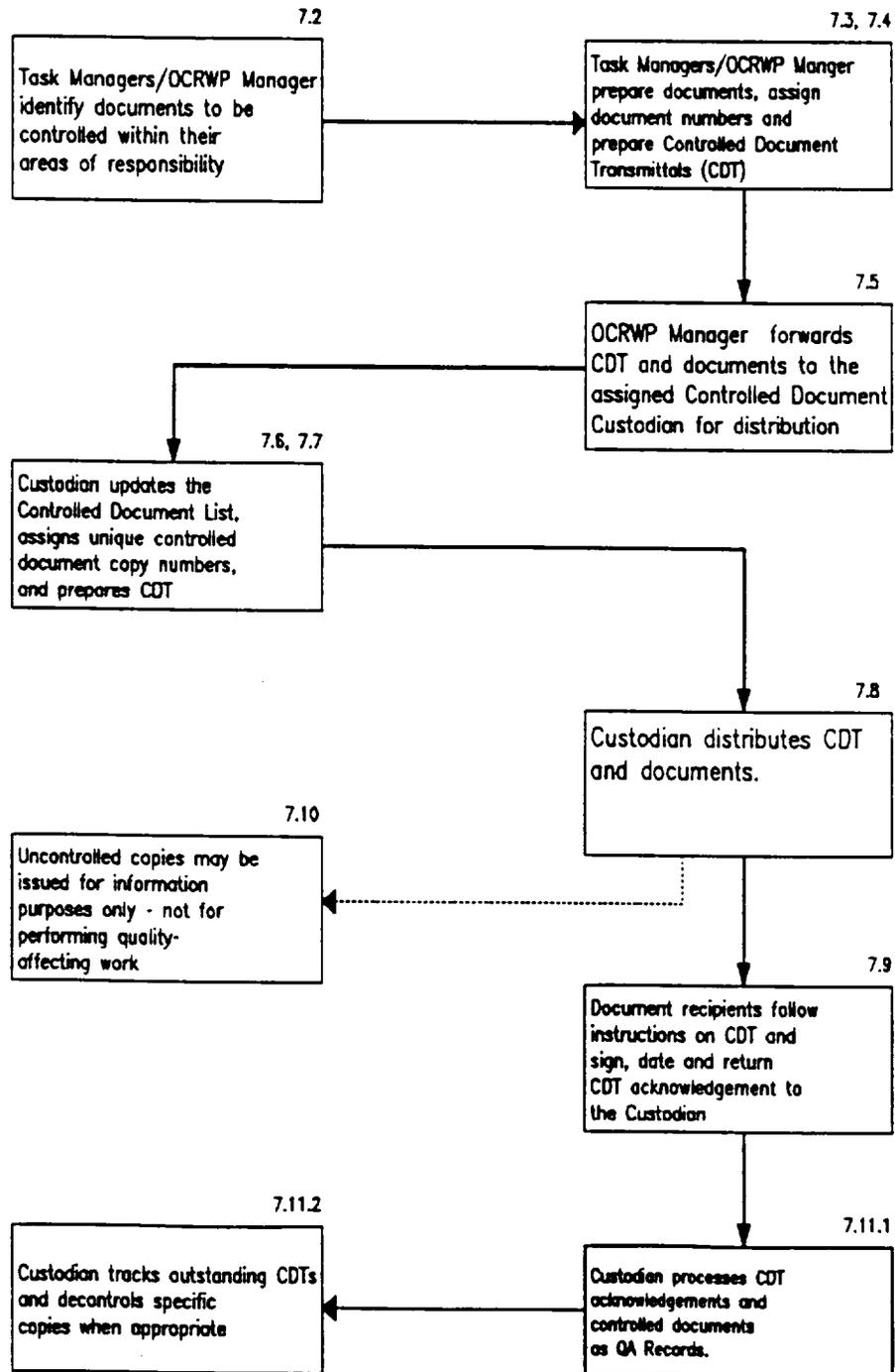
9.2 Attachment II - Controlled Document Transmittal

9.3 Attachment III - Controlled Document Transmittal - Continuation

FILE: DOCUMENT CONTROL

Attachment I

DOCUMENT CONTROL FLOWSHEET



TITLE: DOCUMENT CONTROL

Attachment II

SYSTEMS INTEGRATION PROGRAMS  
CONTROLLED DOCUMENT TRANSMITTAL

(Page 1 of )

Controlled Document: \_\_\_\_\_  
Document No.: \_\_\_\_\_ Date: \_\_\_\_\_  
Transmitted By: \_\_\_\_\_ Return by Date: \_\_\_\_\_

REVISIONS & COMMENTS

DISTRIBUTION

COPY NO.

RECEIPT INSTRUCTIONS: Protect the attached Controlled Document and/or insert revisions (if applicable), destroy superseded material, sign this receipt form and return it to the Controlled Document Custodian named below.

\_\_\_\_\_  
Signature of Recipient

\_\_\_\_\_  
Date

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

FILE: DOCUMENT CONTROL

Attachment III

SYSTEMS INTEGRATION PROGRAMS

CONTROLLED DOCUMENT TRANSMITTAL - CONTINUATION

(Page of )

Controlled Document: \_\_\_\_\_  
 Document No.: \_\_\_\_\_ Date: \_\_\_\_\_  
 Transmitted By: \_\_\_\_\_ Return by Date: \_\_\_\_\_

REVISIONS & COMMENTS

DISTRIBUTION

COPY NO.