

## CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## CORRECTIVE ACTION REQUEST

CAR No: 95-03

Associated AR, SR, NCR No:

CNWRA AR 95-01

## PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

QAP-013 requires a Quality Requirements Application Matrix be generated defining specific operating procedures applicable to an activity. The QRAM for EBS/Investigation of Issues Related to EBS indicates QAP-015 applies to the qualification of EQ3/6 data. No documentation of qualification (or exclusion exemption) was available.

Initiated by: D. W. Dunavant

DWD 6/28/95

Date: 06/09/95

## PART B: PROPOSED ACTION

Responsible EM: B. Sagar

Response Due: 07/24/95

## 1) Extent of Condition:

At the current time, no existing data have been qualified by the CNWRA, and two exemptions have been granted. With the exception of the exemptions issued, all other activities whose QRAMs indicate that QAP-015 needs to be addressed are without qualified or exempted data.

## 2) Root Cause:

The QRAMs had only been completed a few weeks before the audit, so the staff had no opportunities to develop plans to qualify data to obtain exemptions. In addition, reassessment of the QRAMs suggests very conservative applications of the existing data requirements. In the case of EQ3/6, this is DOE data which is excluded from qualification requirements by QAP-015, paragraph 5.1.3, second bullet. The exclusion criteria of QAP-015 do not appear to have been appropriately applied in the QRAM. Also, much of the data identified in QRAMs do not appear to be used in licensing, which is necessary to meet the inclusion criterion of QAP-015, 5.1.2, second bullet.

## 3) Remedial Action:

Proposed Completion Date: 8/31/95

After revision of CNWRA Operations Plans and Project Plans for FY96, the QRAMs will be reevaluated fully using the appropriate inclusion and exclusion criteria. To facilitate the exemption process, the QRAM will be modified to include a data qualification exemption on the form itself, with approvals of the Technical Director and QA Director, as required by QAP-015.

## 4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 08/31/95

A "White Paper" discussing data uses and qualification requirements shall be prepared and distributed to the CNWRA staff. This guidance shall be applied in the revision of the QRAMs after planning document revision.

Element Manager:

B. Sagar

Date: 6/28/95

## PART C: APPROVAL

Comments/Instructions

Director of QA:

B. Mabrito

Date:

7/3/95

## PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

1. QAP-017, The QRAM, was changed in June 1995.
2. A CNWRA existing data "White Paper" was completed 8/10/95.
3. Awaiting approval from NRC on Ops Plans/Project Plans as of 8/21/95.
4. REV. 1 TO QAP-015, Qualification of Existing Data, was issued to staff 8/24/95.
5. QRAMs completed for new FY96 Ops Plans (AT New, lower funding levels) 3/13/96.

Verified by:

B. Mabrito

Date:

3/14/96

Distribution:

W. Patrick  
B. Mabrito  
Directors  
Element Managers  
W. Murphy  
P. Lichtner  
R. Brient

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REGULATORY ANALYSES**

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**QUALITY REQUIREMENTS APPLICATION MATRIX**

Task/Subtask Title: EBS/Investigation of Issues Related to EBS  
Project No: 20-5702-523 Element Manager: Narasi Sridhar  
Principal Investigator: Peter Lichtner

Task/Subtask Description:

*See Page 3 of 6.*

*only modeling  
SC 5/18/95*

**1. Generally Applicable Quality Requirements:**

QAP-001 Scientific Notebook Control

QAP-002 Review of CNWRA Documents, Reports, Papers, and Presentation Materials

(QAPs that describe Quality Assurance department functions are also universally applicable)

**2. Quality Requirements Applicable to specific Activities:**

**2.1 Systematic Regulatory Analysis:**

TOP-001-07	Procedure for High-Level Waste Functional Analysis
TOP-001-11	Development of Compliance Determination
TOP-001-12	Development of Technical Review Components
TOP-001-13	Development of Compliance Determination Methods
TOP-001-15	PADB Loading, Version, and Change Control

*N/A*  
↓

**2.2 Laboratory and Field Investigations:**

TOP-012	Identification, Control, Storage, Handling, Shipping, and Archiving of Samples
CQAM Ch. 12	Control of Measuring and Test Equipment

*N/A*  
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## QUALITY REQUIREMENTS APPLICATION MATRIX

### 2.3 Development and Use of Scientific and Engineering Software:

For software that are expected to be used directly in license application reviews:

TOP-018 Development and Control of Scientific and  
Engineering Software

YES

List of software subject to these requirements and approximate schedule for implementation:

*EBSAAC (?) - MAY become a suite of codes, currently being redefined - no date established. } Developed Software*  
*MULTIFLO - SRD WAITING; under development - TOP-018 implementation started } Developed Software*  
*GEM - A sub-routine of MULTIFLO, documented in EBSAC report, Oct 1994, NOT currently controlled. - Developed Software*  
*SCCEX - USER manual published Jan. 1995 - Developed Software*

### 2.4 Data and Data Analyses:

For data that are expected to be used directly in license application reviews:

QAP-015 Qualification of Existing Data

YES

QAP-014 Documentation and Verification of Routine  
Calculations

YES

List data subject to qualification and approximate schedule for implementation:

*MULTIFLO will utilize EQ3/6 Database, electrochemical processes data, kinetic data from open literature, material properties data (rock density, Thermal data, etc), waste package design data. The above data will become subject to identified procedures. 5/19/95*

### 3.0 Approval:

*PCL*

*PJ*  
Technical Director

*5/19/95*  
Date

*Burns*  
Director QA

*5/19/95*  
Date

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## QUALITY REQUIREMENTS APPLICATION MATRIX

Task/Subtask Title: \_\_\_\_\_  
 \_\_\_\_\_  
 Project No: \_\_\_\_\_ Element Manager: \_\_\_\_\_  
 Principal Investigator: \_\_\_\_\_  
 Task/Subtask Description: \_\_\_\_\_

### 1. Generally Applicable Quality Requirements:

QAP-001 Scientific Notebook Control

QAP-002 Review of CNWRA Documents, Reports, Papers, and Presentation Materials

(QAPs that describe Quality Assurance department functions are also universally applicable)

### 2. Quality Requirements Applicable to specific Activities:

#### 2.1 Systematic Regulatory Analysis:

TOP-001-11	Development of Compliance Determination Strategies	<input type="checkbox"/> Yes	<input type="checkbox"/> No
TOP-001-13	Development of Compliance Determination Methods	<input type="checkbox"/> Yes	<input type="checkbox"/> No
TOP-001-15	PADB Loading, Version, and Change Control	<input type="checkbox"/> Yes	<input type="checkbox"/> No

#### 2.2 Laboratory and Field Investigations:

TOP-012	Identification, Control, Storage, Handling, Shipping, and Archiving of Samples	<input type="checkbox"/> Yes	<input type="checkbox"/> No
CQAM Ch.12	Control of Measuring and Test Equipment	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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## QUALITY REQUIREMENTS APPLICATION MATRIX

### 2.3 Development and Use of Scientific and Engineering Software:

For software that are expected to be used directly in license application reviews:

TOP-018 Development and Control of Scientific and Engineering Software

☐ Yes ☐ No

List of software subject to these requirements and approximate schedule for implementation:

### 2.4 Data and Data Analyses:

For data that are expected to be used directly in license application reviews:

QAP-015 Qualification of Existing Data

☐ Yes ☐ No

QAP-014 Documentation and Verification of Routine  
Calculations

☐ Yes ☐ No

List data subject to qualification and approximate schedule for implementation:

List data exempted from qualification in accordance with QAP-015, 5.1.3:

Exemption Approvals: \_\_\_\_\_  
 Technical Director Date Director QA Date

### 3.0 Approval:

\_\_\_\_\_  
 Technical Director Date Director QA Date


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# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## MEMORANDUM

August 18, 1995

**TO:** CNWRA Directors, Element Managers, Technical Staff

**FROM:** Bruce Mabrito, Director of Quality Assurance 

**SUBJECT:** CNWRA Position on Qualification and Use of Existing Data in the HLW Regulatory Process

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The purpose of this memorandum is to convey to you a position paper which carefully explains the basic principles utilized in controlling the qualification and use of existing data within the CNWRA.

The subject of existing data control was raised during the quality assurance audit in April, 1995, which resulted in a change to Quality Assurance Procedure-015, "Qualification of Existing Data." In conjunction with the QAP-015 change, the attached CNWRA statement and flowchart were developed by Wes Patrick, Budhi Sagar, Pat Mackin, Bob Brient, and myself to explain existing data policies and controls in a more simplified fashion.

If you have any questions regarding implementation of QAP-015 or any other QA procedure, please contact Bob Brient at extension 5537, or myself at extension 5149.

cc: W. Patrick  
QA Records Folder 304

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## **Existing Data Use in the HLW Regulatory Process**

The DOE is required to support their license application for a HLW repository with data that have been either (i) collected under an NRC accepted QA program, or (ii) if not collected under an NRC accepted QA program, qualified in accordance with established QA procedures.

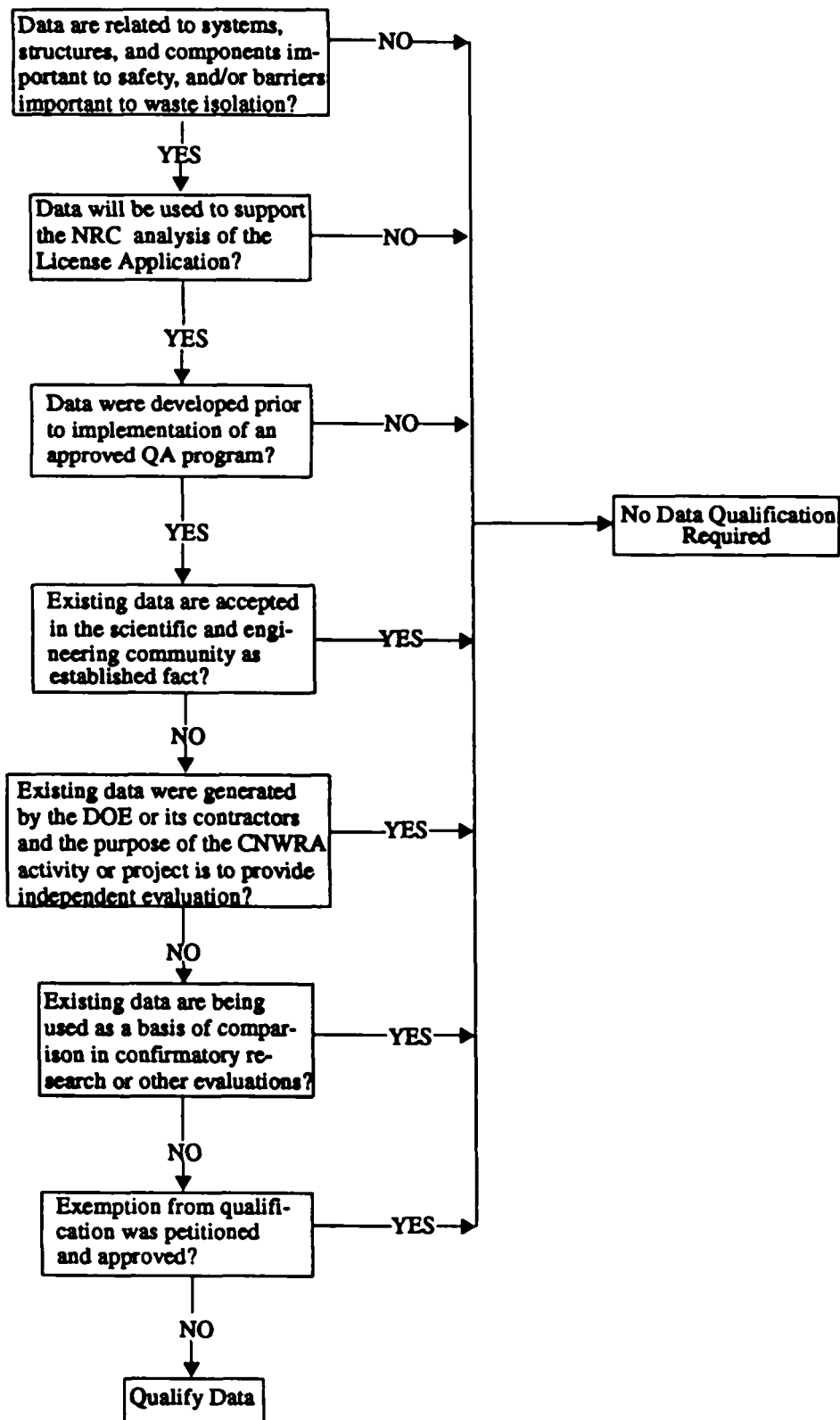
In its review of DOE's license application, NRC may choose to utilize data other than that submitted in DOE's license application. As with the license application, some of the data to be utilized by NRC may be collected under QA programs of the NRC or its contractors. Other data, if not collected directly by NRC or its contractors under an approved QA program, may require qualification. However, in many cases, the data used by NRC in the license application review will be excluded or may be exempted from qualification.

### **Basic Principles**

1. Data submitted in DOE's license application do not require qualification by the NRC or CNWRA for use in support of NRC's license application review.
2. While qualified data are preferred for use in direct challenges to the validity (e.g., accuracy, adequacy, representativeness, etc.) of DOE's data, the staff should not be constrained to using only qualified data. In circumstances such as this, exemption from existing data qualification may be granted in accordance with QAP-015, paragraph 5.3.
3. Validation of the analysis methods (i.e., the mathematical models) used in NRC's license application review should be accomplished using qualified data. The preferred sources of data for validation are those that do not require qualification by the CNWRA, such as (i) data collected under the CNWRA QA program; (ii) data from DOE's license application or precicensing documents that were collected under an approved QA program; and (iii) data generally accepted as fact by the scientific or engineering communities, and excluded from qualification requirements under QAP-015, paragraph 5.1.3.
4. Data not directly used in the license application review need not be qualified. Uses of data include the general development of license review capabilities and development of staff capabilities and analysis methods.

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## EXISTING DATA QUALIFICATION DECISION TREE







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# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## MEMORANDUM

August 31, 1995

**TO:** Corrective Action Request 95-03 File

**FROM:** Bruce Mabrito, Director of Quality Assurance   
Budhi Sagar, Technical Director 

**SUBJECT:** CAR Number 95-03 Progress and Delay of Completion

**REFERENCE:** CNWRA CQAM and QAP-013

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Corrective Action Request 95-03 was generated during the annual CNWRA quality assurance audit. The Remedial Action stated was to reevaluate and review the Quality Requirements Application Matrix (QRAM) form after revision of the CNWRA FY96 Operations Plans and Project Plans, using the appropriate inclusion and exclusion criteria. It was further stated that the QRAM was to be modified to include a data qualification exemption on the form itself with approvals of the Technical Director and the Director of QA, as required by QAP-015. The Corrective Action to Preclude Recurrence was to issue a position paper discussing existing data and qualification requirements to the CNWRA staff and that guidance will be applied in revising QRAMs.

To date, the following has been accomplished and is documented on the CAR 95-03 form:

(i) Form QAP-017, the Quality Requirements Application Matrix, was changed in June, 1995 to include a special section on exemption from qualification of existing data;

(ii) a CNWRA position paper entitled "Existing Data Use in the HLW Regulatory Process" was developed and issued to the CNWRA staff August 18, 1995; and

(iii) a new revision of QAP-015, Qualification of Existing Data, was completed and issued to the CNWRA staff on August 22, 1995.

The revision of the QRAMs could not be initiated until the CNWRA Operations and Project Plans were accepted by NRC. On August 30, 1995, advance notification (by fax) was received from NRC on the conditional approval (with changes required by the CNWRA) of the CNWRA FY96 Operations Plans, however, FY96 Research Project Plans have not yet been accepted.

To allow for NRC full acceptance of the FY96 Operations Plans/Project Plans and for sufficient time to complete the new QRAM forms, the due date for this corrective action is extended to December 15, 1995.

cc: Henry Garcia  
Robert Briant



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# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## MEMORANDUM

November 8, 1995

**TO:** Corrective Action Request 95-03 File

**FROM:** Bruce Mabrito, Director of Quality Assurance   
Budhi Sagar, Technical Director 

**SUBJECT:** CAR Number 95-03 Progress and Delay of Completion

**REFERENCE:** CNWRA CQAM and QAP-013

---

Corrective Action Request 95-03 was generated during the annual 1995 CNWRA quality assurance audit. The Remedial Action stated was to reevaluate and review the Quality Requirements Application Matrix (QRAM) form after revision of the CNWRA FY96 Operations Plans and Project Plans, using the appropriate existing data qualification requirement inclusion and exclusion criteria. It further stated that the QRAM form was to be modified to include a data qualification exemption with approvals by the Technical Director and the Director of QA for more convenient implementation of QAP-015 (Quality Planning). The stated Corrective Action to Preclude Recurrence was to issue a position paper discussing existing data and qualification requirements to the CNWRA staff and that guidance will be applied in revising QRAMs.

The following has been accomplished to date and is documented on CAR 95-03: (i) Form QAP-017, the Quality Requirements Application Matrix, was changed in June, 1995 to include a special section on exemption from qualification of existing data; (ii) a CNWRA position paper entitled "Existing Data Use in the HLW Regulatory Process" was developed and issued to the CNWRA staff August 18, 1995; and (iii) a new revision of QAP-015, Qualification of Existing Data, was completed and issued to the CNWRA staff on August 22, 1995.

The revision of the QRAMs could not be initiated until the CNWRA FY96 Operations and Project Plans were accepted by NRC. On September 29, 1995, the NRC approved all CNWRA Research Project Plans and on October 3, 1995 the NRC approved the Operations Plans (after first requiring some changes). During the time since the Operations and Project Plans were submitted, the U.S. Congress has reduced the amount of HLW funds available to the NRC and, in effect, to the CNWRA. New CNWRA FY96 Operations and Project Plans will be required by the NRC shortly to reflect the change in size and scope of the CNWRA program. Some of the earlier scheduled work will obviously not be accomplished because of the reduced budget and must be reflected in the Operations and Project Plans.

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Due to the anticipated changes to Operations and Project Plant, a decision has been made by the Technical Director and the Director of Quality Assurance to not complete the FY96 QRAMs. To prepare the QRAMs on the current FY96 Operations and Project Plans would be unproductive inasmuch as they would have to be immediately revised for the new FY96 Plans (which will reflect the reduced budget for the CNWRA). Those new FY96 Plans are currently expected to be completed by the end of December, 1995, however, this may not be an accurate date.

In an effort to focus the important QRAM planning activities on the Operations and Project Plan development, it has been agreed that the QRAM interview process will be accomplished during development of the Plans. In this way the quality planning requirements will be fully integrated into the development of the scope of the technical activities.

To allow for sufficient time to complete this process, the due date for this corrective action is extended to January 15, 1996.

Please contact either Bruce Mabrito at ext. 5149 or Budhi Sagar at ext. 5252 if you have questions regarding this approach.

cc: W. Patrick  
Directors  
Element Managers  
R. Brient



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# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## MEMORANDUM

January 15, 1996

**TO:** Corrective Action Request 95-03 File

**FROM:** Bruce Mabrito, Director of Quality Assurance   
Budhi Sagar, Technical Director 

**SUBJECT:** CAR Number 95-03 Progress and Delay of Completion

**REFERENCE:** CNWRA CQAM and QAP-013

---

The Corrective Action Request (CAR) 95-03 was generated during the annual 1995 CNWRA quality assurance audit. The Remedial Action stated was to reevaluate and review the Quality Requirements Application Matrix (QRAM) form after revision of the CNWRA FY96 Operations (Ops) Plans (Project Plans have now been eliminated), using the appropriate existing data qualification requirement inclusion and exclusion criteria. It further stated that the QRAM form was to be modified to include a data qualification exemption with approvals by the Technical Director and the Director of QA for more convenient implementation of QAP-015 (Quality Planning). The stated Corrective Action to Preclude Recurrence was to issue a position paper discussing existing data and qualification requirements to the CNWRA staff and that guidance will be applied in revising QRAMs. The following has been accomplished to date and is documented on CAR 95-03: (i) Form QAP-017, the Quality Requirements Application Matrix, was changed in June, 1995 to include a special section on exemption from qualification of existing data; (ii) a CNWRA position paper entitled "Existing Data Use in the HLW Regulatory Process" was developed and issued to the CNWRA staff August 18, 1995; and (iii) a new revision of QAP-015, Qualification of Existing Data, was completed and issued to the CNWRA staff on August 22, 1995.

The new QRAMs for FY96 Ops Plans have not been initiated as yet because of the delay in changing them to reflect lower funding levels associated with a recently reduced budget. The delay is partially due to a later-than-expected submittal date specified by NRC, and the CNWRA is also awaiting final budgetary information from the sponsor. Due to the required changes to Ops Plans, a decision has been made by the Technical Director and the Director of Quality Assurance to not complete the new FY96 QRAMs until the CNWRA Ops Plans are at least finalized within the CNWRA. It was expected that the Ops Plan change would be completed by this date, but that has not occurred. To allow for sufficient time to complete this process, the due date for this corrective action is hereby extended to March 15, 1996.

Please contact either Bruce Mabrito at ext. 5149 or Budhi Sagar at ext. 5252 if you have questions regarding this approach.

cc: W. Patrick  
Element Managers

Directors  
R. Brient


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# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## MEMORANDUM

March 8, 1996

**TO:** QA Records File 204, "Periodic QA Status Review & QA Requirements Matrix"

**FROM:** Bruce Mabrito, Director of Quality Assurance 

**SUBJECT:** CNWRA FY96 Surveillance Schedule, Dated 3/7/96

**REFERENCE:** CNWRA Quality Assurance Procedure-004, Surveillance Control


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The attached Surveillance Schedule for the remainder of FY96 was developed to facilitate an effective method to verify an action has been or is being accomplished in conformance with the specified requirements.

This Surveillance Schedule was derived from the Quality Requirements Application Matrixes which were completed through detailed interviews of the Principal Investigators, Element Managers, QA staff, and the Technical Director. This Surveillance Schedule replaces the plan based on the earlier FY96 Operations Plans. As stated on this schedule, these surveillances are based on the revised Operations Plans which were made effective January 20, 1996.

There may be changes to this schedule, based on interfaces with CNWRA Element Managers, meetings, travel commitments, etc., however, this schedule represents a planned and considered approach to provide a workable schedule for all involved CNWRA parties.

Attachment/

cc: W. Patrick  
Directors  
Element Managers  
Principal Investigators  
R. Brient  


**CNWRA MONTHLY SURVEILLANCE SCHEDULE FY96**  
**Based on Revised Operations Plans Effective 1/20/96**

Date	Number	Task	Principal Investigator
March	No general surveillance activities planned, to allow work to begin under new Operations Plans. Quality planning and software control activities will be conducted.		
April	20-5708-871	Radionuclide Transport: Technical Assistance	David Turner
	20-5708-761	TSPA and Technical Integration: Technical Assistance	Randy Manteufel
May	20-5708-861	Isothermal Flow Technical Assistance	Gordon Wittmeyer
	20-5708-862	Isothermal Flow Code Development—SUFLAT	Ross Bagtzoglou
	20-5708-863	Isothermal Flow Applied Technical Investigations	Ross Bagtzoglou
	20-5708-864	Isothermal Flow Code Development—BREATH	Stu Stothoff
	20-5708-571	Container Life & Source Term Technical Assistance	Gustavo Cragolino
	20-5708-572	Container Life & Source Term Code Development—EBSPAC	Sitakanta Mohanty
	20-5708-573	Container Life & Source Term Applied Technical Investigations	Gustavo Cragolino
June	20-5708-561	Near-Field Environment Technical Assistance	Bill Murphy
	20-5708-562	Near-Field Environment Code Development—MULTIFLO	Peter Lichtner
	20-5708-563	Near-Field Environment Applied Technical Investigations	Bobby Pabalan
	20-5708-661	Thermal Effects on Flow Technical Assistance	Ron Green
	20-5708-663	Thermal Effects on Flow Applied Technical Investigations	Stu Stothoff

**CNWRA MONTHLY SURVEILLANCE SCHEDULE FY96 (Cont'd)**  
**Based on Revised Operations Plans Effective 1/20/96**

<b>Date</b>	<b>Number</b>	<b>Task</b>	<b>Principal Investigator</b>
July	20-5708-771	Revision to EPA & NRC Regulations Technical Assistance	Pat Mackin
August	20-5708-461	Igneous Activities Technical Assistance	Britt Hill
	20-5708-462	Igneous Activities Code Development—Volcanic Hazard	Chuck Connor
	20-5708-463	Igneous Activities Applied Technical Investigations	Britt Hill
	20-5708-471	Structural Deformation Technical Assistance	John Stamatakis
	20-5708-472	Structural Deformation Code Development—3DStress	David Ferrill
	20-5708-473	Structural Deformation Applied Technical Investigations	John Stamatakis
September	20-5708-671	Repository Design & TM Effects Technical Assistance	Simon Hsiung
	20-5706-001	Waste Solidifications Systems: Vitrification	Chuck Tschoepe
	20-5706-002	Waste Solidifications Systems: High-Level Waste Tank Storage	Gustavo Cragnolino
	20-5706-003	Waste Solidifications Systems: Environmental Issues	Chuck Tschoepe

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