CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-07 Associated AR, SR, NCR No: Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY: Quality Planning

There is no documentation that all QRAMs are evaluated for need for revision when Operations Plans are revised as required by QAP-013, 3.1.5. Of the ones for which the impact determination was made, not all three signatures required by QAP-013, 3.1.6 were available. Also see CAR 99-01 from the 1999 audit.

Initiated by: D.W. Dunavant Date: 06/30/00

PART B: PROPOSED ACTION

Responsible Individual: B. MARRITO/B. SAGAR
Response Due: 7/31/2000

1) Extent of Condition:
See attached pages.

2) Root Cause:
See attached pages.

3) Remedial Action: Proposed Completion Date: 8/11/2000
See attached pages.

4) Corrective Action to Preclude Recurrence: Proposed Completion Date: 8/18/2000
See attached pages.

Element Manager: B. SAGAR Date: 7/31/2000 7/31/2000

PART C: APPROVAL
Comments/Instructions

President

Director of QA: Date: 8/03/00 1/31/2000

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

Revised procedure was distributed 8/23/2000. Procedure incorporates activities described in the area "Corrective Action to Preclude Recurrence". No further action required.

Verified by: Date: 8/23/2000

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
PRINCIPAL INVESTIGATORS
ELEMENT MANAGERS
TECHNICAL DIRECTOR
CNWRA PRESIDENT
D. Dunavant/T. Tabovich ATLS
R. Webb SwRI QA Manager

2/14/

Corrective Action Request 2000–07

PART B: PROPOSED ACTION

1) Extent of Condition:

Part A of Correction Action Request (CAR) 2000–07 describes the condition adverse to quality in the area of planning. "There is no documentation that all QRAMs are evaluated for need for revision when Operations Plans are revised as required by QAP-013, 3.1.5. Of the ones for which the impact determination was made, not all three signatures required by QAP-013, 3.1.6 were available. Also, see CAR 99-01 from the 1999 audit."

Due to several requests by the NRC in early FY2000, a total of three HLW Repository Operations Plans changes were made. In these specific cases, a review of the changes was made by the appropriate Element Managers, Technical Director, and QA Director. In no case did any of the Ops Plans changes force a modification in the quality requirements for the proposed work. This was a case of a limited number of instances, however the QRAM documentation was not clearly shown.

The Quality Requirements Application Matrix (QRAM) form does not currently have a review box to provide evidence when a QRAM form has been evaluated when Operations Plans, Project Plans and proposals are revised.

2) Root Cause:

Although all revisions and changes to CNWRA Operations Plans and proposals for the past year were checked for specific quality requirements as shown on the QRAM forms, there was no convenient method for the cognizant Element Manager, the Technical Director, and the QA Director to show their review. Therefore, while all reviews were accomplished, there was insufficient documentation of the reviews. More specifically, signature and date blocks for plan and proposal revisions/changes on the QRAM simply did not exist. In some cases where the Technical Director and QA Director signed the QRAM form, it was not clear that the signatures were for a specific planning document change.

3) Remedial Action:

All FY2000 QRAM forms have been reviewed by CNWRA QA and it has been verified that the changes to the HLW Repository Operations Plans did not require changes to the quality requirements on the QRAM forms.

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Before August 11, 2000, the QRAM form will be revised to accommodate the additional signatures and dates required during the re-evaluation process for plan and proposal revisions/changes. Whenever planning documents are to be revised or changed, the QRAM form will be evaluated by the Element Manager, Technical Director and QA Director.

Proposed Completion Date: August 11, 2000

4) Corrective Action to Preclude Recurrence:

The new QRAM form will provide spaces at the bottom of the second page for documenting the review of the changes against the QRAM requirements. This new QRAM form will be utilized for any planning document revisions/changes for the remainder of FY2000. The revised QRAM form will assist in documenting the required reviews and approvals of the Element Manager, Technical Director, and the QA Director whenever planning documents have been changed. The Technical Director and QA Director will enforce the use of QRAM forms and will make all CNWRA and other staff cognizant of their responsibilities within the CNWRA Quality system. Please see the attached sample copy of the revised QRAM form.

Proposed Completion Date: August 18, 2000

Element Manager: Bruce Mabrito July 31, 2000

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

December 14, 2000

MEMORANDUM

TO: Corrective Action Folder for Audit 2000-1

FROM: Bruce Mabrito, Director of Quality Assurance

SUBJECT: Evaluation of Proposed Corrective Action Responses

A review was performed on responses originally composed in July 2000 on the Corrective Actions Requests (CARs) which resulted from the annual CNWRA audit performed in June of the same year. During the review it became apparent that as further evaluation and work was performed in closing out the CARs, some of the originally described actions were no longer appropriate or applicable. It is the goal of this memorandum to explain some of the changes which occurred between what was originally planned and what actions were performed to close out the CARs. These changes are in line with CNWRA business practices and, in a sense, more in line with the performance-based quality program we at the CNWRA are implementing.

Most of the differences occur on the CARs in the areas identified as "Remedial Action" and/or in the area identified as "Corrective Action to Preclude Recurrence." We will discuss the differences between what was originally agreed to and what was actually performed in more detail below.

CAR 2000-01 Subject: Procurement Controls identified in NQA-1, 1986 were not addressed in QAP-016, and have not been followed.

In the 5th paragraph under Corrective Action to Prevent Recurrence a statement is made to "implement adequate formal training for all affected CNWRA staff and, if required, consultants and subcontractors on the provisions of 10 CFR 50, Appendix B, Criterion VII and, if necessary, those related to ANSI/ASME NQA-1, Element 7 concerning the acquisition of items and services." The statement goes on to state that this training can be part of the regular QA indoctrination for CNWRA staff members and, if appropriate, consultants and subcontractors. It also requires that the training will be documented on attendance/participation records.

Upon further evaluation it was recognized that consultants and subcontractors do not purchase items and materials effecting quality for the CNWRA, so therefore, training on critical procurement requirements is not appropriate or warranted. CNWRA staff were issued a revised QAP-016 procedure with a transmittal and receipt form in August 2000. The transmittal and receipt form provides documentation that CNWRA staff have read and understand the procedure containing the more recent procurement requirements. Although formal attendance records were originally required, the strategy of using transmittal and receipt records

provides documented objective evidence that CNWRA staff had received and read the required procedure and understand the procedure contents.

CAR 2000-02 Subject: Scientific Notebooks were not compliant to the requirements of QAP-001.

Corrective Action to Preclude Recurrence state that Element Managers (EMs) are to do occasional informal checking of the Scientific Notebooks; QA will follow-up when Scientific Notebooks are issued to new employees, consultants, and subcontractors; and that EMs and the Director of QA will review scientific notebooks in the process of being archived at approximately six month intervals as they are submitted to QA records.

It will be difficult to produce objective evidence documentation showing that all these activities are being completed. As part of their managerial activities, EMs should be informally reviewing scientific notebooks of staff who work in areas for which they are responsible. During the extensive review of CNWRA scientific notebooks completed after the June 2000 audit, a heightened sense of ownership and responsibility was shown by CNWRA staff personnel for scientific notebooks and compliance to QAP-001. This commitment was also transferred to consultants and subcontractors who maintained notebooks for work being performed by them for the CNWRA Principal Investigators and EMs. CNWRA QA staff will continue to evaluate scientific notebooks during the periodic surveillances which are routinely performed in accordance with the CNWRA Surveillance Schedule. During the next 6 month recall of scientific notebooks, EMs and the Director of QA will continue their close review of scientific notebooks that are in the process of being archived.

CAR 2000-03 Subject: Documentation/Verification of Calculations

Corrective Actions to Preclude Recurrence contained five distinct recommendations of which two will be discussed here. The first area for discussion is contained in paragraph (iv) and states the requirements for performing a QAP-014, Documentation and Verification of Scientific and Engineering Calculations, should be made as early as possible. The recommendation also states that the required checks should be performed as "calculations proceed." Paragraph (v) of the recommendations states that EMs , the Technical Director, and the reviewers should be provided refresher training on the revised QAP-014.

Calculation verification reviews are performed when required as identified on the QAP-12-4 Form, Instructions To Technical Reviewers, which is signed by the cognizant EM. This form is initiated at the beginning of the review process and is just about as early as anyone would want to review calculations used to support data and/or conclusions contained in a deliverable document. Performing calculation reviews prior to work being completed on a deliverable product would be unproductive. The revised QAP-014 (dated 8/30/2000) was sent to appropriate CNWRA technical staff to replace their earlier version and to other CNWRA staff needing the procedure. Electronic training was sent out to technical staff to inform them of the changes to QAP-014. Again, formal CNWRA transmittal and receipt forms were used to document that staff personnel have received, read and understand the revised procedure.

CAR 2000-05 Subject: Training Issues

The only change concerning this CAR is that the remedial action required copies of an e-mail from EMs to the Director of QA documenting the results of an assessment by the EMs be placed in each consultant's file. The EMs performed their assessment and informed the Director of QA but these e-mails, one e-mail from each EM, will be placed in the training file and not in each consultant's file.

CAR 2000-06 Subject: Ineffective Corrective Action

Since the 2000 audit in June, no corrective actions have been written and therefore it is too early to determine compliance with the responses described in the CAR. Some of the actions to preclude recurrence will have to be evaluated during the 2001 audit. A significant number of procedures have been revised to prevent recurrence of the unsatisfactory findings.

CAR 2000-07 Subject: Quality Planning

The Director of CNWRA QA, by attending the weekly management meetings and by making presentations at quarterly staff meetings, is continually keeping the staff aware of their individual responsibilities within the CNWRA quality assurance system. This individual responsibility is first presented to each employee during their Indoctrination to the Quality System as part of their new employee training.

In summary, significant changes have occurred within the quality assurance system, including the revision 4 to the CNWRA QA Manual (CQAM). These changes primarily addressed the modification of work routines and parts of the quality system which were not adequately described in the CQAM. Revisions to some of the most commonly used procedures at the CNWRA have also been made. With these and other changes implemented, it is our belief that the quality system is stronger, and more flexible, in the areas that were found deficient during the 2000 audit and the actions taken should prevent similar deficiencies from occurring again.

cc: QA Memos Folder
Each QA Audit 2000 CAR

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

6/1/00

QUALITY REQUIREMENTS APPLICATION MATRIX

OPS Plan/Proposal Title: _____

Revision & Change: _____ Date: _____

Project/Proposal No: (if available) _____ Element Manager: _____

Principal Investigator: _____

Task/Subtask Description:

1. Project/Task Specific Quality Requirements:

AP-005	Obtaining Subcontract Services	☐ Yes	☐ No
AP-006	Obtaining Consultant Services	☐ Yes	☐ No
QAP-001	Scientific Notebook Control - Determined by EM or Project Manager	☐ Yes	☐ No
QAP-016	Procurement - will there be any quality-affecting procurement during this work?	☐ Yes	☐ No
QAP-017	Drawing Control - are there going to be any drawings?	☐ Yes	☐ No

Additional QAPs required:

QAP-002	Review of CNWRA Documents, Reports, Papers, and Presentation Materials - All
QAP-004	Surveillance Control
QAP-005	Quality Indoctrination
QAP-007	Professional Personnel Qualification
QAP-008	Document Control
QAP-009	Nonconformance Control
QAP-010	Corrective Action
QAP-012	QA Records Control
QAP-013	Quality Planning

2. Quality Requirements Applicable to specific Activities:

2.1 Systematic Regulatory Analysis:

TOP-001-11	Development of Compliance Determination Strategies	☐ Yes	☐ No
TOP-001-13	Development of Compliance Determination Methods	☐ Yes	☐ No
TOP-001-15	PADB Loading, Version, and Change Control	☐ Yes	☐ No

2.2 Laboratory and Field Investigations:

TOP-012	Identification, Control, Storage, Handling, Shipping, and Archiving of Samples	☐ Yes	☐ No
CQAM Ch.12	Control of Measuring and Test Equipment	☐ Yes	☐ No

DRAFT SAMPLE, before final in QAP-013, Quality Planning Procedure

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY REQUIREMENTS APPLICATION MATRIX

2.3 Development and Use of Scientific and Engineering Software:

For software that are expected to be used directly in regulatory 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:

If non-controlled Scientific and Engineering Software are used, a copy of the software itself and input/output files for specific applications in a deliverable will be maintained as a QA Record; if controlled software are used in this task, all input files and appropriate sample output files will be provided to the QA Records folder and retained as a QA Record.

2.4 Data and Data Analyses:

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

QAP-015 Qualification of Existing Data ☐ Yes ☐ No

QAP-014 Documentation and Verification of Scientific & Engineering Calculations ☐ Yes ☐ No

List data subject to qualification and approximate schedule for implementation:

List data exempted from qualification in accordance with QAP-015, 5.3:

Exemption Approvals: _____

Technical Director Date QA Director Date

3.0 Approval: **Plan/Proposal Revision** _____ **Change** _____ **Date** _____

_____

Element Manager Date

_____

Technical Director Date QA Director Date

4.0 Approval: **Plan/Proposal Revision** _____ **Change** _____ **Date** _____

_____

Element Manager Date

_____

Technical Director Date QA Director Date

5.0 Approval: **Plan/Proposal Revision** _____ **Change** _____ **Date** _____

_____

Element Manager Date

_____

Technical Director Date QA Director Date

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-013 Revision 4 Page 1 of 5

Title

QAP-013 QUALITY PLANNING

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on 8/22/2000. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
All	0	8/22/2000

UNCONTROLLED

Supersedes Procedure No. QAP-013, Rev. 3, Chg 1

Approvals

Written By	Date	Concurrence Review	Date
BRUCE MABRITO	8/22/2000	NARASI SRIDHAR N.S.	8/24/2000
Quality Assurance	**Date**	**Cognizant Director**	**Date**
MARK EHNSTROM	8/22/2000	HENRY GARCIA	

QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify the methods of applying the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance Manual (CQAM) and Operating Procedures to specific CNWRA activities, and to provide for scheduling of quality verification. This procedure implements the requirements of CQAM Sections 2, 3, and 18.

2. RESPONSIBILITY

2.1 The Director of Quality Assurance (QA) is responsible for implementation of this procedure.

2.2 The Element Managers (EMs) and Principal Investigators (PIs) are responsible for identifying QA requirements applicable to Operations Plans, Research Project Plans, proposals and Internal Research and Development projects (IR&D) as specified by this procedure.

3. PROCEDURE

3.1 Initial quality planning shall be accomplished through the preparation of Quality Requirements Application Matrices (QRAM), CNWRA Form Quality Assurance Procedure (QAP-17) (Figure 1).

3.1.1 For each element of the work breakdown structure (Key Technical Issue, Integrated Subissue, project) identified in Operations Plans, Project Plans, projects and proposals, a QRAM shall be jointly prepared by the cognizant EM and PI, the Technical Director and QA Staff.

3.1.2 The QRAM shall provide a brief description of the scope of work and shall identify procedures or actions that are applicable to the activity. The basis for applicability shall be: (i) the nature of the activity (e.g., the type of work to be performed), and (ii) the use of the products (e.g., their importance to licensing). Products, such as data and analysis methods (including software) which are expected to be used directly in license application reviews are of the highest importance, and more stringent requirements apply. Otherwise, and in the absence of specific Operating Procedures, good scientific and engineering practices apply to all CNWRA technical activities.

3.1.3 The QRAM shall reference the revision and change number of the Operations Plan, Project Plan, project or proposal for which the QRAM was written.

3.1.4 The QRAM shall indicate Operating Procedures which need to be developed when no existing controls have been established.

3.1.5 Whenever Operations Plans, Project Plans, and proposals have been revised, it is the responsibility of the EM to determine if the corresponding QRAM should be re-evaluated as described in Section 3.1.1. The basis for re-evaluation shall include: (i) new tasks, (ii) substantially revised tasks, and (iii) change in the importance of products with respect to their potential use. If the re-evaluation determines that the existing QRAM is acceptable, this review will be documented by the EM, Technical Director and Director of QA on the existing QRAM form.

3.1.6 The QRAM and QRAM revisions shall be approved by the Element Managers, Director of QA and the Technical Director, and shall be distributed to CNWRA management and the cognizant PI.

3.2 Quarterly QA Status Reports shall be prepared by the QA staff to provide for QA verification activities based on the schedule of activities affecting quality and long term surveillance plans.

3.2.1 The Quarterly QA Status Report shall identify hold points, notification points, and witness points for surveillance. In addition, this report shall document current Nonconformance Reports and Corrective Action Requests and the status of their resolution.

3.2.2 The Quarterly QA Status Reports shall be distributed to CNWRA management.

4. RECORDS

The QRAM and revisions, and Quarterly QA Status Reports shall be controlled as QA Records in accordance with CQAM Section 17, and shall be permanently retained.

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY REQUIREMENTS APPLICATION MATRIX

OPS Plan/Proposal Title: _____

Revision & Change: _____ Date: _____

Project/Proposal No: (if available) _____ Element Manager: _____

Principal Investigator: _____

Task/Subtask Description:

1. Project/Task Specific Quality Requirements:

AP-005	Obtaining Subcontract Services	☐ Yes	☐ No
AP-006	Obtaining Consultant Services	☐ Yes	☐ No
QAP-001	Scientific Notebook Control - Determined by EM or Project Manager	☐ Yes	☐ No
QAP-016	Procurement - will there be any quality-affecting procurement during this work?	☐ Yes	☐ No
QAP-017	Drawing Control - are there going to be any drawings?	☐ Yes	☐ No

Additional QAPs required:

QAP-002	Review of CNWRA Documents, Reports, Papers, and Presentation Materials - All
QAP-004	Surveillance Control
QAP-005	Quality Indoctrination
QAP-007	Professional Personnel Qualification
QAP-008	Document Control
QAP-009	Nonconformance Control
QAP-010	Corrective Action
QAP-012	QA Records Control
QAP-013	Quality Planning

2. Quality Requirements Applicable to specific Activities:

2.1 Systematic Regulatory Analysis:

TOP-001-11	Development of Compliance Determination Strategies	☐ Yes	☐ No
TOP-001-13	Development of Compliance Determination Methods	☐ Yes	☐ No
TOP-001-15	PADB Loading, Version, and Change Control	☐ Yes	☐ No

2.2 Laboratory and Field Investigations:

TOP-012	Identification, Control, Storage, Handling, Shipping, and Archiving of Samples	☐ Yes	☐ No
CQAM Ch.12	Control of Measuring and Test Equipment	☐ Yes	☐ No

CNWRA FORM QAP-17 (8/2000)

Sample Figure 1

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-013 Revision 4 Chg 0 Page 5 of 5

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY REQUIREMENTS APPLICATION MATRIX

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

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

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2.4 Data and Data Analyses:

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

QAP-015 Qualification of Existing Data ☐ Yes ☐ No

QAP-014 Documentation and Verification of Scientific & Engineering Calculations ☐ Yes ☐ No

List data subject to qualification and approximate schedule for implementation:

List data exempted from qualification in accordance with QAP-015, 5.3:

3.0 Approval:

_____
Element Manager Date

_____
Technical Director Date QA Director Date

4.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

_____
Element Manager Date

_____
Technical Director Date QA Director Date

5.0 Approval: Plan/Proposal Revision _____ Change _____ Date _____

_____
Element Manager Date

_____
Technical Director Date QA Director Date

CNWRA FORM QAP-17 (8/2000)

Sample

Figure 1 (Cont'd)

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Subject: TRAINING: QAP-013 QUALITY PLANNING
Date: Wed, 23 Aug 2000 16:18:14 -0500
From: Bruce Mabrito <bmabrito@gargol.cnwra.swri.edu>
Organization: CNWRA
To: STAFF_GROUP <STAFF_GROUP@gargol.cnwra.swri.edu>

Revision 4 of CNWRA Quality Assurance Procedure-013 (Quality Planning) has been distributed. This document mandates that elements of CNWRA work be planned for and the need for subcontract services, consultant services, procurement of certain items, drawing control, scientific notebooks and other key activities/issues are identified prior to start of work. Also identified is the need to identify the development and use of scientific and engineering software, the need for qualification of existing data, and the need for documentation and verification of scientific and engineering calculations.

The primary change to this QAP-013 revision is a new Quality Requirements Application Matrix (QRAM) form which allows for multiple revisions of Ops Plans, Project Plans, etc., and the visibility of the EM, Technical and QA Director signatures for each revision.

If you have specific questions regarding QAP-013, please call me at 522-5149.

Bruce Mabrito Director of CNWRA Quality Assurance