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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 96-04

Associated AR, SR, NCR No: CNWRA AR 96-01

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY
 Several procedural requirements of QAP-008 have not been complied with in the area of control of documents.

 See attached.
 Initiated by: Donald W. Dunavant *[Signature]* Date: 7/26/96

PART B: PROPOSED ACTION
 Responsible EM: **B. Mabrito**
 Response Due: **8/15/96**

1) Extent of Condition: See attached.

2) Root Cause: See attached.

3) Remedial Action: See attached. Proposed Completion Date:

4) Corrective Action to Preclude Recurrence: See attached. Proposed Completion Date:

Element Manager: *[Signature]* Date: 8/15/96

PART C: APPROVAL
 Comments/Instructions: Reviewed and discussed with center QA Dept 9/12/96

Director of QA: *[Signature]* Date: 9/12/96

[Signature] 8/23/96

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

See 12/15/96 memo from B. Mabrito to CAR 96-04 Folder. 12/15/96

Verified by: *[Signature]* Date: 12/15/96

Distribution:
 B. Sagar, Tech Director
 H. Garcia, Dir. of Admin
 B. Mabrito, Cognizant EM
 W. Antrick, CNWRA President

H. Garcia Took it upon himself to "make up" previous documents in his review. We are leaving documents "as is" and this CAR is closed. *[Signature]* 12/18/96

- **Updates are not being made to the Master Documents List to recognize in-process changes and revisions to procedures.**
- **No objective evidence was available to demonstrate that the Master Documents List was distributed.**
- **Recipients of controlled documents are not all acknowledging receipt within the allotted time period.**
- **No record copies of previous Master Documents Lists were available.**

NOTE: H. Garcia reviewed this 3 document and (in error) marked it up. Please disregard the handwritten notes on this document.

Open Marked
12/18/96

RESPONSE TO CORRECTIVE ACTION REQUEST 96-04

EXTENT OF CONDITION:

mark-up of
In considering the extent of the condition identified in this Corrective Action Request (CAR), Quality Assurance Procedure-008, Document Control, was reviewed in its entirety. The purpose of the review was to identify any other nonconformances or inconsistencies internal to the QAP. The review included investigation in the following areas: *check of* identification of controlled documents; revisions and changes to controlled documents; assignment of unique numbers, *examination of* where required, CNWRA Quality Assurance Manual, QAPs, and TOPs meeting the format requirements; document approval and effectivity actions; distribution of documents; additions of documents to the Controlled Document Distribution List; ~~marking~~ marking of controlled and uncontrolled documents; and maintenance of controlled document records. The implementation of QAP-008 was determined to be complete, except for those areas identified by the auditor during the audit. The extent of the condition in QAP-008 appears limited to those findings identified by the auditor as bullet items attached to CAR 96-04.

ROOT CAUSES:

The root causes of the identified nonconformances are listed below, ~~after they are restated and more detail is provided in each paragraph.~~

(i) Updates are not being made to the Master Document List to recognize in-process changes and revisions to procedures. In-process changes and revisions were not being logged on the Master Document List until they were issued, in accordance with the CNWRA Quality Assurance Manual (CQAM), Section 6.4.6(1). It has become apparent during this CNWRA audit that QAP-008 did not comport precisely with the CQAM in this area. The CQAM was being complied with rather than QAP-008.

(ii) No objective evidence was available to demonstrate that the Master Document List was distributed. Distribution of the Master Document List was *made* through circulation to the CNWRA President, Directors, Element Managers, and Principal Investigators. The objective evidence for the distribution of the Master Document List was apparently lost in the process of circulation.

(iii) Recipients of controlled documents are not all acknowledging receipt within the allotted time period. "Controlled Document Transmittal & Acknowledgement Record" Forms (DC-1-2) for controlled documents were available for review, however, a small number of them were not returned, or not returned in a timely manner. These were, for the most part, attributable to a lack of responsiveness on the part of our *in returning the DC-1-2 forms* client's staff *not returning the DC-1-2 forms* over which the CNWRA has no authority. *Sponsor's* There were a few such forms which were not returned to the CNWRA Document Control area within the 30 days specified in QAP-008, and no follow up was accomplished to obtain the forms.

(iv) Two copies of previous Master Document Lists were available, but were not sufficient to satisfy procedural requirements. Some record copies of the previous Master Document Lists were not available because they were eliminated from the QA Records, *since they*

3/16/96

are not kept more than one year, in accordance with QAP-012, Quality Assurance Records Control. We may have been a bit too enthusiastic in cleaning out the working copies of QA Records prior to the audit.

SUMMARY OF ROOT CAUSES: (a) QAP-008 had not been reviewed and updated in about four years and through the introduction of newer office tools (including updated E-mail systems which allows attachments to be sent electronically), some of the QAP requirements were being complied with ^{in a way} ~~which did not provide~~ the needed objective evidence; (b) not all aspects of QAP-008 were being fully complied with, specifically those related to the Master Document List, partially because it was in conflict with the CQAM; and (c) insufficient training had been provided to the QA Clerk.

REMEDIAL ACTIONS:

The actions to remediate each of the findings are listed below.

- (i) The Master Document List is being installed ~~and maintained~~ on the CNWRA Local Area Network (LAN) accessible to all CNWRA staff, and it will reflect the current controlled documents in effect at all times. This will be a "read-only" document and all the CNWRA staff will be advised of its location.
- (ii) Hard copy distribution of the Master Document List will not be required upon implementation of the above-described approach.
- (iii) Since the audit, recipients of controlled CNWRA documents who have not returned their acknowledgement forms are being identified and will be instructed to return their acknowledgements.
- (iv) The most recent and current copy of the Master Document List (dated 8/15/96) has been printed and will be put in the appropriate QA Record Working File. The Master Document Lists shown to the auditor (dated 7/17/96 and 7/18/96) were available during the audit, but earlier copies were not available for review. See below for corrective action to preclude recurrence.

Proposed Completion Date: August 30, 1996

CORRECTIVE ACTION TO PRECLUDE RECURRENCE:

QAP-008, Records Control, is being revised to reflect changes that had gradually occurred during the past four years at the CNWRA. The QA Records Clerk has taken the initiative to rewrite the procedure, utilizing her knowledge of the current CNWRA records and processes, ^{plus} suggestions made by CNWRA QA staff, ^{those} made during the audit by the auditor, and taking into consideration the specific findings of this audit. This corrective action will preclude recurrence of the nonconformance situations identified during the audit.

adding the

Other CNWRA QAPs will be reviewed for current need and applicability, ^{to} ~~as~~ an additional corrective action ~~to preclude recurrence.~~

to evaluate the need for

Proposed Completion Date: September 13, 1996

SEE CNWRA memorandum to CNA 96-02 folder dated 9/13/96



CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

MEMORANDUM

September 13, 1996

TO: QA Records Corrective Action Request 96-04 File

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

SUBJECT: Status of Corrective Actions on CAR 96-04 as of 9/13/96

REFERENCE: CAR 96-04, From Annual CNWRA QA Audit

This memorandum to the CAR 96-04 file is to document progress to date to complete corrective actions.

The CNWRA Records Control Procedure, QAP-008, has been revised and distributed to key CNWRA staff as of August 22, 1996. Formal and informal comments received during the CNWRA 1996 QA Audit were included in Revision 2 of the QAP. The QA Support Staff member wrote the procedure to ensure that the document correctly reflects the methods currently utilized in the Document Control area.

During the week of September 9, 1996, a review was conducted of the current suite of Quality Assurance Procedures, ~~now active in the CNWRA~~ ^{CNWR}. Based partially on that review, ~~there was~~ ^{there was} initiation of a revision to QAP-014, Documentation and Verification of Routine Calculations. Discussions were held with the CNWRA Technical Director to determine the most effective method to conduct and document such verification of routine calculations.

Other QA Procedures have been suggested for change, revision or deletion, however at this time a complete list has not been assembled. The proposed completion date of corrective actions to preclude recurrence of September 13, 1996 is therefore being changed to September 27, 1996. *h*

If there are any questions regarding this change, please contact me at ext. 5149.

*Please disregard mark ups
made by H. Gmuis.
B. E. 12/18/96*

**SURVEILLANCE ON CONTROLLED DOCUMENTS
ACKNOWLEDGEMENT RECORDS NOT RETURNED
AUGUST 16, 1996**

CNWRA QUALITY ASSURANCE MANUAL, Revision 2, Change 10, issued 5/29/96

- D. Ferrill
- S. Fortuna (NRC)
- A. Holt (SwRI)
- H. Manaktala **RETURNED**
- B. Meehan (NRC)
- W. Murphy **RETURNED 8/19**
- B. Stiltenspole (NRC) **RETURNED**

CNWRA QUALITY ASSURANCE MANUAL, Revision 2, Change 9, issued 12/5/95

- M. Ahola
- M. Conway
- D. Ferrill **RETURNED 8/21/96**
- H. Manaktala **RETURNED**
- B. Meehan (NRC)

MANAGEMENT PLAN, Revision 5, Change 1, issued 6/28/96 (not on MDL)

- S. Fortuna (NRC) **RETURNED**
- B. Meehan (NRC)
- B. Stiltenspole (NRC) **RETURNED**

MANAGEMENT PLAN, Revision 5, Change 0, issued 5/24/96

- S. Fortuna (NRC) **RETURNED**
- B. Meehan (NRC)
- B. Stiltenspole (NRC) **RETURNED**

This internal surveillance was conducted 8/16/96. A copy of an enclise list was sent to each CERCLA element manager with their Element staff member's name who did not return their respective acknowledgement sheet. Each Elm was requested to have the acknowledgement sheets returned to QA Document Control. This list documents those acknowledgement sheets returned in August, 1996. James Mahoney

**SURVEILLANCE ON CONTROLLED DOCUMENTS
ACKNOWLEDGEMENT RECORDS NOT RETURNED
AUGUST 16, 1996
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CNWRA OPERATIONS PLAN FY96, Revision 7, Change 2, issued 7/3/96

- A. DeWispelare **RETURNED**
- D. Ferrill
- S. Fortuna (NRC)
- R. Green
- B. Meehan (NRC)
- S. Mohanty **RETURNED**
- J. Russell **RETURNED 8/21**
- B. Stiltenspole (NRC) **RETURNED**
- S. Stothoff **RETURNED 8/20**
- C. Tschoepe **RETURNED**

CNWRA OPERATIONS PLANS FY97, Revision 8, Change 0, issued 7/26/96

- C. Connor
- G. Cragolino **RETURNED**
- D. Ferrill
- S. Fortuna (NRC)
- S. Hsiung **RETURNED 8/27**
- L. McKague
- B. Meehan (NRC)
- S. Mohanty **RETURNED**
- S. Rowe (SwRI)
- J. Russell **RETURNED 8/21**
- B. Stiltenspole (NRC)
- S. Stothoff

**OPERATIONS PLANS FOR WASTE SOLIDIFICATION SYSTEMS, Revision 5, Change 4, issued
7/2/96**

- G. Comfort (NRC) **RETURNED**
- S. Fortuna (NRC)
- H. Karimi
- B. Meehan (NRC)
- B. Stiltenspole (NRC) **RETURNED**

**SURVEILLANCE ON CONTROLLED DOCUMENTS
ACKNOWLEDGEMENT RECORDS NOT RETURNED
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OPERATIONS PLANS FOR WASTE SOLIDIFICATION SYSTEMS, Revision 6, Change 0, issued 07/30/96

- G. Comfort (NRC) RETURNED**
- G. Cragnolino RETURNED**
- S. Fortuna (NRC)
- R. Johnson
- H. Karimi
- L. McKague
- B. Meehan (NRC)
- S. Rowe (SwRI)
- J. Russell **RETURNED 8/21**
- B. Stiltenspole (NRC) **RETURNED 8/20**

QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, AND PAPERS, Revision 5, Change 1, issued 10/27/95

- D. Ferrill
- M. Jarzempa
- P. Lichtner
- H. Manaktala
- R. Martin
- B. Meehan (NRC)
- S. Mohanty **RETURNED**
- D. Woodson

QAP-005 QUALITY INDOCTRINATION AND TRAINING, Revision 1, Change 0, issued 10/11/95

100%

QAP-015 QUALIFICATION OF EXISTING DATA, Revision 1, Change 0, issued 8/16/95

- R. Chen
- C. Connor
- D. Ferrill
- S. Fortuna (NRC)
- B. Henderson **RETURNED 8/26**
- M. Jarzempa
- R. Martin
- B. Meehan (NRC)

**SURVEILLANCE ON CONTROLLED DOCUMENTS
ACKNOWLEDGEMENT RECORDS NOT RETURNED
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AP-001 EVALUATION OF POTENTIAL CONFLICT OF INTEREST, Revision 3, Change 0, issued 5/31/96

S. Fortuna (NRC)
B. Meehan (NRC)
B. Stiltenspole (NRC) **RETURNED**

AP-010 LABORATORY CHEMICAL HYGIENE PLAN AND STANDARD OPERATING PROCEDURES FOR CNWRA LAB, Revision 1, Change 0, issued 4/16/96

S. Mohanty **RETURNED**

AP-015 DIFFERING PROFESSIONAL VIEWS, Revision 0, Change 0, issued 5/10/96

S. Fortuna (NRC)
B. Meehan (NRC)

[56] From: Linda Hearon 8/23/96 5:43PM (1042 bytes: 22 ln)
To: Bruce Mabrito
cc: Robert Brient
Subject: CAR 96-04

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----- Message Contents -----

Text item 1: Untitled

The following remedial actions have been completed in connection with CAR 96-04.

- (i) The Master Document List has been moved to the LAN (read-only) and the CNWRA staff have been notified of its location.
- (ii) A survey was completed on the Controlled Documents issued in FY96. Recipients who had not returned their acknowledgement sheets were identified and instructed to return them to Document Control. Form DC-1-2, "Controlled Document Transmittal and Acknowledgement Record," was modified to include the words "within 30 days" and the return address was clarified.
- (iii) The Master Document List was updated and printed 8/15/96 and put in the QA Record Working Files.
- (iv) QAP-008 Document Control was revised and issued 8/22/96.

Copy to CAR 96-04 Folder



MASTER DOCUMENT LIST

1)

TO Mail List:#SA-WO STAFF
To: Mikko Ahola at CNWRA-SUN
To: A Bagtzoglou at CNWRA-SUN
To: Charles Connor at CNWRA
To: Mike Conway at CNWRA
To: David Ferrill at CNWRA
To: Amitava Ghosh at CNWRA-SUN
To: Ronald Green at CNWRA-SUN
To: Simon Hsiung at CNWRA-SUN
To: Ronald Janetzke at CNWRA-SUN
To: Mark Jarzempa at CNWRA
To: Peter Lichtner at CNWRA-SUN
To: Randall Manteufel at CNWRA
To: Ronald Martin at CNWRA
To: Larry McKague at CNWRA
To: Sitakanta Mohanty at CNWRA
To: William Murphy at CNWRA
To: Goodluck Ofoegbu at CNWRA-SUN
To: Roberto Pabalan at CNWRA
To: English Percy at CNWRA
To: David Pickett at CNWRA
To: James Prikryl at CNWRA
To: John Stamatakos at CNWRA
To: Stuart Stothoff at CNWRA-SUN
To: Gordon Wittmeyer at CNWRA-SUN
From: Linda Hearon
Subject: MASTER DOCUMENT LIST
08-19-96 03:51 PM

**The Master Document List is now being kept on the LAN under
g:\master.doc\masterdoc.tbl. This is a "read-only" file. It will be
maintained by Document Control.**


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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

MEMORANDUM

September 27, 1996

TO: QA Records Corrective Action Request 96-04 File

FROM: Bruce Mabrito, Director of Quality Assurance 

SUBJECT: Status of Corrective Actions on CAR 96-04 as of 9/27/96

REFERENCE: CAR 96-04, From Annual CNWRA QA Audit

This memorandum to the CAR 96-04 file is to document progress to date to complete corrective actions.

The CNWRA Quality Assurance Procedure-008, the Records Control Procedure, was revised and distributed to key CNWRA staff August 22, 1996.

A review of Quality Assurance Procedures was completed the week of September 27, 1996. Based partially on that review, a number of QAPs have been put into the "hopper" for change or revision.


At this time it is difficult to accurately predict the completion date for the corrective actions to preclude recurrence. However, this issue is being actively "worked" and the effectivity date of each procedure will provide the objective evidence of the completion of a changed or revised procedure.

If there are any questions regarding this change, please contact me at ext. 5149.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES¹³

MEMORANDUM

December 15, 1996

TO: QA Records Corrective Action Request 96-04 File
FROM: Bruce Mabrito, Director of Quality Assurance 
SUBJECT: Closure of Corrective Action Request 96-04
REFERENCE: CAR 96-04, From Annual CNWRA QA Audit

This memorandum to the Corrective Action Request 96-04 folder is to document closure of the CAR.

As identified in the audit, implementation of QAP-008 was determined to be complete, except for those areas identified by the auditor. Those areas of noncompliance were identified and QAP-008 was revised August 22, 1996 to address them and to also reflect changes within the CNWRA organization that had taken place. Formal and informal comments received during the CNWRA 1996 QA Audit were included in that Revision 2 of the QAP. The QA Support Staff member wrote the procedure to ensure that the document correctly reflected the methods currently utilized in the Document Control area.

During the month of September 1996, a review was conducted of the current group of Quality Assurance Procedures now active in the CNWRA. Several other QA Procedures have been changed or revised based on that review.

Several additional QA Procedures have been identified for possible change, revision or deletion. As time permits, those CNWRA QAPs will be reviewed and action will be taken on them; however, the actions to specifically address the CAR from the CNWRA annual audit have been completed and CAR 96-04 can now be closed.

If there are any questions regarding this action, please contact me at ext. 5149.