

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

NONCONFORMANCE REPORT

Project No. 20-5702-031

NCR No. 92-05

PART 1: DESCRIPTION OF NONCONFORMANCE

TOP-001-11 has not been revised to reflect changes in the CDS method that have come about since the procedure was originally issued. CDS's have been developed and approved that do not reflect current TOP-001-11 requirements.

Initiated by: R.D.P. — J

Date: 12/12/92

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

Disposition:

(SEE ATTACHED SHEET)

Basis of Disposition:

(SEE ATTACHED SHEET)

Action to correct nonconformance:

(SEE ATTACHED SHEET)

Target date for completion: Procedure revision 4/15/93
CDS Revision 3/31/93

Proposed by: P.C.M.

Date: 12/15/92

PART 3: APPROVAL

Element Manager: [Signature] Date: 12/15/92

Director of QA: [Signature] Date: 12/15/92

Comments/Instructions: NONE. GEN

PART 4: CLOSE OUT

Comments:

TOP 001-11, Rev 1, was issued 1/12/93. Revised 3/30/93
Based on memo from P. Mackin to B. Mabeito on 3/29/93 a
request for extension to modify existing "approved" CDSs was granted.
See documentation in this folder. GEN 3/30/93 Final close out 3/30/94

Verified by: [Signature] Date: 3/31/94.

SEE ATTACHED DOCUMENTATION.

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

Disposition:

- 1. Efforts involving CDS type selection and the preparation of draft CDSs will be allowed to continue. This effort includes the briefing of NRC and Center management on the results of type selection.
- 2. Within the NRC DHLWM, no CDSs may be formally concurred in by the cognizant Branch Chief and transmitted to the CNWRA for review until item number 1 of the action to correct the nonconformance, as detailed below, is completed.
- 3. Within the CNWRA, no CDSs may be reviewed or approved in accordance with QAP-002 until item number 1 of the action to correct the nonconformance, as detailed below, is completed.
- 4. Previously approved CDSs will be modified and reviewed as necessary to verify compliance with the revised TOP-001-11.

Basis of Disposition:

- 1. While the nonconformance report correctly reflects that TOP-001-11 is no longer consistent with certain details of the final product of the procedure, the basic nature and purpose of the CDS remain unchanged. Examples of the inconsistencies include the removal of PASS identification numbers, modification of the definition and criteria for a Type 2 review, and revisions to standard language for review type rationales. Selection of CDS type and draft CDS preparation are actions which are still generally valid with respect to TOP-001-11 and which take place before any formalized approval or concurrence is recorded. As such, these actions are not "quality affecting" and may be allowed to continue during the period in which corrective action is being implemented.
- 2. Concurrence in and approval of CDSs have inherent in them the verification that the associated development procedure was adhered to. Since the currently accepted versions of CDSs are not consistent with this procedure, the concurrence and approval processes should not take place until the procedure and its products are brought into agreement. This situation will exist when the corrective action detailed below is completed.

Action to correct nonconformance:

- 1. Revise TOP-001-11 to ensure consistency with the CDS development process and its products as they have evolved. The revision will include measures designed to help preclude the repetition of the problem addressed by this nonconformance report. Training of the appropriate staff on the revised procedure must be completed prior to submission of any CDSs for review or approval. Procedure revision to be completed by January 15, 1993.

3/11

2. Modify existing "approved" CDSs for conformance with the revised TOP-001-11. Action to be completed by March 31, 1993.

3. Progress on corrective action will be documented by inserting appropriate Administrative Item entries in the CNWRA Commitment Control Log.

MEMORANDUM

February 14, 1993

TO: CNWRA Director of Quality Assurance

FROM: P. Mackin 

SUBJECT: Request for Modification to Correct Nonconformance for NCR 92-005

NCR 92-005 was issued because some Compliance Determination Strategies (CDS) were not prepared in accordance with the governing procedure (TOP-001-11: Development of Compliance Determination Strategies). Corrective action included revising the affected CDSs.

In my memo to you on this subject dated December 20, 1993, I requested a delay until February 15, 1994 to complete the corrective action. This delay was necessitated by the need to subject all the revised CDSs to the required formal review under QAP-002. While element managers have concurred in the changes to the affected CDSs, the process will not be completed until formatting of references and entry into the Regulatory Program Database has been accomplished. It was expected that these actions would be finished by February 15; however, the NRC project officer did not complete his review of the material until February 11. We have committed to submitting a major milestone report documenting completion of 93 CDSs by March 31, 1994.

Accordingly, I request a delay until March 31, 1994 for completion of this corrective action.

cc:
W. Patrick
CNWRA Directors
CNWRA Element Managers
A. DeWispelare
S. Spector
R. Brient
NCR 92-005 File

Approved:



Bruce Mabrito
Director of Quality Assurance

MEMORANDUM

March 29, 1993

TO: CNWRA Director of Quality Assurance

FROM: P. Mackin

SUBJECT: Request for Modification to Action to Correct Nonconformance for Nonconformance Report **92-005**

In the "Proposed Disposition and Corrective Action" for Nonconformance Report **92-005**, it was stated that approved Compliance Determination Strategies (CDS) would be updated to conform to the revised **TOP-001-11** by March 31, 1993.

The Program Element Manager for the Repository Licensing and Quality Assurance Project Directorate of the Division of High-Level Waste Management has requested that revision to the approved CDSs be delayed until the end of fiscal year '93. His request is based on avoiding interference with the extensive effort which is ongoing to complete all the remaining CDSs. He also desires that members of the NRC staff prepare the drafts for the revised CDSs. The NRC will be informing us formally of this direction in a letter which will transmit Revision 0 of the License Application Review Plan to the CNWRA. I expect to receive this letter in the near term and will distribute a copy of it to you.

The requested change will not impact quality affecting work, since the revised CDSs will be concurred in by both CNWRA and NRC staffs. It has not yet been determined whether the License Application Review Plan will be published as a joint CNWRA/NRC document.

Accordingly, I request a change in the date for completion of this corrective action to September 24, 1993.

cc:

J. Latz
W. Patrick
CNWRA Directors
CNWRA Element Managers
A. DeWispelare
S. Spector
R. Brient

SEM
3/30/93

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3/30/93

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

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NCR 92-05

MEMORANDUM

March 30, 1993

TO: Pat Mackin ,

FROM: Bruce Mabrito *Bruce Mabrito*

SUBJECT: Request for Modification to Action to Correct Nonconformance for Nonconformance Report 92-05

REFERENCE: Your Memo of 3/29/93, Same Subject

I have read your request to extend the required date to complete CNWRA Nonconformance Report 92-05 to September 24, 1993. Based upon my knowledge of the CDS development process and the importance given by the NRC to completing this effort without this additional diversion, I am approving your request for the extension.

You indicated that the letter you expect to receive from the NRC regarding Revision 0 of the License Application Review Plan will include a reference of this direction to the CNWRA. Please ensure that a copy of that correspondence is directed to the CNWRA QA Nonconformance Report Tracking Log folder/NCR 92-05, where documentation on this NCR is currently maintained.

cc: W. Patrick
CNWRA Directors
CNWRA Element Managers
J. Latz
A. DeWispelare
S. Spector
R. Brient

FILE IN
NCR # 92-005 7/11

MEMORANDUM

September 21, 1993

TO: CNWRA Director of Quality Assurance
FROM: P. Mackin *PM*
SUBJECT: Request for Modification to Correct Nonconformance for NCR 92-005

This memorandum requests a further delay in the completion of corrective action for subject NCR.

In your memorandum dated March 30, 1993 you concurred in my request to delay revisions to CDSs which had been in nonconformance with TOP-001-11 until September 24, 1993. Since that time, extensive effort **has** been made by NRC and CNWRA technical staffs to complete the initial preparation of all other CDSs. Responding to NRC-established priorities, revision of those previously approved CDSs which are not in conformance with the procedure has been delayed. The NRC Project Officer has been furnished copies of the applicable CDSs for his mark-up. After he **has** completed that mark-up, CNWRA staff will review, comment **as** necessary, and then revise the CDSs in accordance with TOP-001-11, Rev 1 and QAP-002.

By separate note to you, the NRC Project Officer has stated that he will complete his mark-up by September 30, 1993. Accordingly, allowing time for the CNWRA to complete its review action, I request a delay until November 15, 1993 for completion of CDS revision under subject NRC.

cc:
W. Patrick
CNWRA Directors
CNWRA Element Managers
A. DeWispelare
S. Spector
R. Brient

Approved *Bruce Mabruto* 10/8/93
BRUCE MABRUTO

8/11

MEMORANDUM

November 8, 1993

TO: CNWRA Director of Quality Assurance

FROM: P. Mackin *PM*

SUBJECT: Request for Modification to Correct Nonconformance for NCR 92-005

In my memo to you dated September 21, 1993 I requested a delay until November 15, 1993 to complete action to update CDSs which had been in nonconformance to TOP-001-11. This delay was necessitated by the need for the NRC project officer to mark-up copies of these CDSs for that purpose.

The NRC project officer forwarded the marked-up copies to me on November 4th. While it would be possible physically to make the necessary changes by November 15th, additional changes have been identified for the affected CDSs which should be entered concurrently for purposes of efficiency. Namely, (i) the CDS procedure, and consequently the CDSs themselves, must be further refined to incorporate comments received from the NRC OGC; (ii) OGC comments on the regulatory structure need to be incorporated; and (iii) results of an NRC editorial review of the CDSs must be implemented.

A significant effort has commenced to refine all the CDSs for incorporation into the version of the LARP scheduled to be published at the beginning of CY94. Accordingly, I request a delay until December 31, 1993 for completion of this corrective action.

cc:
 W. Patrick
 CNWRA Directors
 CNWRA Element Managers
 A. DeWispelare
 S. Spector
 R. Brient

Approved :

Bruce E. Mabrito 11/9/93

 Bruce E. Mabrito
 Director of Quality Assurance

1 copy to NCR 92-005 file

9/11

MEMORANDUM

December 20, 1993

TO: CNWRA Director of Quality Assurance

FROM: P. Mackin *PM*

SUBJECT: Request for Modification to Correct Nonconformance for NCR 92-005

NCR 92-005 was issued because some Compliance Determination Strategies (CDS) were not prepared in accordance with the governing procedure (TOP-001-11: Development of Compliance Determination Strategies). Corrective action included revising the affected CDSs.

I my memo to you on this subject dated November 8, 1993, I requested a delay until December 31, 1993 to complete the corrective action. This delay was necessitated by the need to integrate the corrective action with other changes required to the CDSs and with the License Application Review Plan (LARP) development schedule. You concurred in my request.

It **has** again become necessary to request **a** delay in the completion of the corrective action. While **all** the necessary revisions have been made to the affected CDSs, the revised CDSs must be subjected to the same formal review and approval process in accordance with QAP-002. It is planned that all CDSs will be submitted to CNWRA management for review in early January, 1994 in order to meet a revised schedule for publishing the LARP. This review will be done more efficiently if all CDSs can be examined together rather than conducting a separate review for those which were specifically the subject of NCR 92-005.

Accordingly, I request a delay until February 15, 1994 for completion of this corrective action.

- cc:
- W. Patrick
- CNWRA Directors
- CNWRA Element Managers
- A. DeWispelare
- S. Spector
- R. Brient
- NCR 92-005 File

Approved:

Bruce Mabrito 12/20/93

Bruce Mabrito
Director of Quality Assurance

ncr92.005

MEMORANDUM

February 14, 1993

TO: CNWRA Director of Quality Assurance

FROM: P. Mackin 

SUBJECT: Request for Modification to Correct Nonconformance for NCR 92-005

NCR 92-005 was issued because some Compliance Determination Strategies (CDS) were not prepared in accordance with the governing procedure (TOP-001-11: Development of Compliance Determination Strategies). Corrective action included revising the affected CDSs.

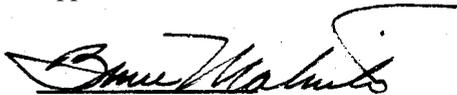
In my memo to you on this subject dated December 20, 1993, I requested a delay until February 15, 1994 to complete the corrective action. This delay was necessitated by the need to subject all the revised CDSs to the required formal review under QAP-002. While element managers have concurred in the changes to the affected CDSs, the process will not be completed until formatting of references and entry into the Regulatory Program Database has been accomplished. It was expected that these actions would be finished by February 15; however, the NRC project officer did not complete his review of the material until February 11. We have committed to submitting a major milestone report documenting completion of 93 CDSs by March 31, 1994.

Accordingly, I request a delay until March 31, 1994 for completion of this corrective action.

cc:

W. Patrick
CNWRA Directors
CNWRA Element Managers ✓
A. DeWispelare
S. Spector
R. Brient
NCR 92-005 File

Approved:



Bruce Mabrito
Director of Quality Assurance

11/11

MEMORANDUM

March 28, 1994

TO: CNWRA Director of Quality Assurance

FROM: P. Mackin 

SUBJECT: Completion of Corrective Action for NCR 92-005

NCR 92-005 was issued because some Compliance Determination Strategies (CDS) were not prepared in accordance with the governing procedure (**TOP-001-11**, Development of Compliance Determination Strategies). Corrective action included revising the affected CDSs.

On March 25, 1994 the Major Milestone "CDS Development Report FY '93 (5702-221-420)" was transmitted to the NRC. Submission of this Major Milestone signifies that all corrective action associated with NCR 92-005 has been completed.

Accordingly, I request that this NCR be closed.

cc:
W. Patrick
CNWRA Directors
CNWRA Element Managers
A. DeWispelare
S. Spector
R. Brient

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 3/29/94