

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES ^{1/16}

CORRECTIVE ACTION REQUEST

CAR No. 90-06

Associated AR,SR,NCR NO. N/A

PART 1: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

10CFR Part 50, Appendix B, Criterion 5, requires that activities affecting quality be accomplished as prescribed by documented instructions or procedures. TOP-001-02 was released as "Draft Rev. 1" on 9/13/89, however it has never been released as an effective document. In addition, significant changes to the methods of performing quality affecting SRA activities have been made without formal approval and controls that would assure proper communication of the changes to affected personnel.

Initiated by: R. D. Brient *RDB*

Date: 11/2/90 *SEM*

PART 2: PROPOSED ACTION

Responsible Element Manager: A. Whiting/T. Romine

a) Root Cause:
(See Attached Sheet)

Response due 12/2/90 RDB

b) Corrective Action to Preclude Recurrence:

In between procedure revisions, timely change notices will go forward to all users of the procedure, reflecting modifications and how they are to be implemented. Procedure will be re-issued as a Rev. 2 end of January 1991 incorporating all included changes.

Target Date for Completion: 1/31/91 *extended per attached memo and RDB 2/12/91*

Response provided by: Allen R. Whiting

Date: 11/28/90

PART 3: APPROVAL

Comments/Instructions: NONE.

Director of QA: [Signature]

Date: 11/29/90

PART 4: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

TOP-001, Rev 2 issued 1/4/91 TOP-001-03, -04, & -05 superseded by TOP-001-Rev 2. TOP-001-02 will be superseded by other TOPs as needed by the activities conducted

Verified by: [Signature]

Date: 12/18/91

CORRECTIVE ACTION REQUEST

CAR No. 90-06

PART 2: PROPOSED ACTION

a) Root Cause:

The above referenced "Draft Rev.1" of TOP-001-02 was released as an effective document on September 11, 1989 as indicated by the attached Effectivity and Approval Sheet. At the client's specific request the TOP-001-02 Rev.1 was issued as a "Draft" Controlled Document on September 11, 1989 for the purpose of being used as a "proof-of-system" test as so indicated by the incorporated "note" on the attached effectivity and approval sheet for said procedure. Consistent with the "note" caption, and subsequent to the delivery of several items and many ensuing discussions with the client, we received the two attached letters dated January 31, 1990 and February 15, 1990 indicating conditional "acceptance" of the procedure. Prior to and subsequent to the receipt of the above letters, insignificant changes were made to the "draft" procedure by red-line insertion to the controlled copy of the Manager of WSE&I with subsequent transfer of information made to appropriate users. This transfer of information was provided in various forms of communication with the appropriate users of the procedure. Implementing guidance was provided by the Manager of WSE&I in verbal, written and training modes. Currently a change form notification is being prepared to be sent to each "holder" of the "controlled document" procedure TOP-001-02 Rev. 1 Draft, that will indicate that the "master copy" containing all the red-lined inserts made since September 11, 1989 will be maintained in the Manager of WSE&I's office as the official copy of the procedure to be referenced and used until a Revision 2 is officially issued (currently scheduled for end of January 1991).

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

TECHNICAL OPERATING PROCEDURE

Proc. TOP-001-02

DRAFT

Revision 1

Page 1 of 12

& Attachments

Title PROGRAM ARCHITECTURE RELATIONAL DATABASE CONTENT AND
DEVELOPMENT INSTRUCTIVE DRAFT REV. 1

EFFECTIVITY AND APPROVAL

DRAFT

Revision 1 of this procedure became effective on Sept. 11, 1989. This procedure consists of the pages and changes listed below.

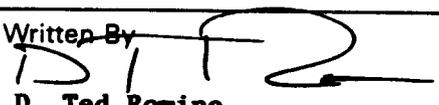
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	-	9/11/89

NOTE: This draft document is being used as a "proof-of-system" test. The NRC has been notified that work in process will be accomplished to this procedure to determine its effectiveness. If this test proves the procedure provides the required information to the NRC and the Center, it will be published in Rev. 1 status. It may be changed to meet NRC comments and published/controlled as Rev. 1 to TOP-001-02 at a later date.

CNWRA
CONTROLLED
COPY 11

Supersedes Procedure No. TOP-001-02 Revision 0

Approvals

Written By  D. Ted Romine	Date 9/11/89	Technical Review  M. Miklas	Date 9/11/89
Quality Assurance  Bruce Mabrito	Date 9/11/89	Cognizant Director  Allen R. Whiting	Date 9/11/89

4

RDB *LD*

Ben *Ben*



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

most interesting,
Somewhat of an
"Approval document."
Ben

JAN 31 1990

MEMORANDUM FOR: Mary Mace, ADM/CAB
THRU: Shirley Fortuna, PMDA
FROM: Philip Altomare, HLEN/DHLWM
SUBJECT: FINAL TECHNICAL OPERATING PROCEDURE (TOP) 001-02

As a test of the revised Technical Operating Procedure (TOP) 001-02 for development and preparation of information for the Program Architecture Support System, the CNWRA provided completed input forms and Synopsis of information for two worked Regulatory Requirement Topic examples - Erosion and Substantially Complete Containment (Allen Whiting letter to Phil Altomare of November 2, 1989). This was considered a "baselining" of the Program Architecture and a number of discussions and meetings on the subject matter have been held since the receipt of these example cases. The basic process and modifications for database content, as presented in the TOP-001-02 and Attachment A, are acceptable with incorporation of the changes noted in the attachment and should now be formalized in a controlled procedure. Noting, however, that it has been the conclusion of both the NRC and the CNWRA, that further experience should be gained with the intent to streamline the process and the procedures and to establish resource efficient operability and maintainability of the Program Architecture Support System.

!!

Philip Altomare
Philip Altomare
WSE&I Program Elements Manager

Enclosure:
As stated

NRC COMMENTS ON TECHNICAL OPERATING PROCEDURE (TOP) 001-02

GENERAL COMMENT

The Technical Operating Procedure (TOP) 001-02 and Attachment A are very thorough and provide detailed explanation for the preparation of input for the Program Architecture Support System (PASS). Unfortunately, in obtaining completeness, the resulting quantity of information has had a negative effect on the reviewers in that it leaves a perception of complexity and detail that may be difficult to implement. Although this may be a false impression, possible problems in following or implementing the TOP should be carefully observed in the coming months and simplification of the process and/or instructions proposed, as appropriate. Also, the operability and maintainability of the PASS is very important, particularly as regards minimizing resources required for information collection, input preparation, and update. In general, information collection should be part of the normal work activities. Also, the TOP should state that DOE, State and others program and technical information is only for reference purposes. Instructions should be given to not expend special effort collecting DOE program or technical information for the Program Architecture, particularly in view of the changing DOE program, but to concentrate upon preparation of NRC technical and program information for input to the Program Architecture. The PASS should not be perceived as a means to record and track all DOE activities.

It is requested that the implementation of the TOP 001-02 procedures continue to be monitored with the intent of further streamlining the process and procedures and developing resource efficient operability and maintainability.

SPECIFIC COMMENTSTechnical Operation Procedure

Page 2, first paragraph under 2.2, first sentence beginning with "The PASS ___": change the sentence to read as follows, "The PASS is a management tool for ___ use in recording and monitoring the extensive information and activities that comprise the NRC HLW repository licensing program."

Attachment A

1. Page A5: request that we do not introduce a new acronym, NWMS.
2. Page A9: recommend that site characterization include all site investigations prior to Construction Authorization (including surface exploration) rather than just those between Exploratory Shaft Construction and Construction Authorization.

3. Page 24, Related Issues: 1) It should be clarified that DOE issues are intended to be the DOE Issue Hierarchy; 2) "State" issues should be changed to "State and others" issues and it should be clear these issues are for information purposes not NRC action. (If NRC adopts the issues of others, they are included as open items or uncertainties and then subject to NRC action.)
4. Page A30, Section 5.6, second sentence: "methods and models" should not be indicated to be included in the Format and Content Guide.
5. Page A66, item 10.1: the General Guidelines and Criteria should be moved to the NRC Compliance Determination Methods.
6. Page A77, Compliance Determination Strategy: the Erosion and SCC Regulatory Requirement, examples each used different approaches to describing the strategy. The record description should be modified to describe a consistent approach that can assist in establishing the level of detail for the regulatory requirement and will be consistent with the NRC License Application Review Strategy.
7. Page A78, first paragraph: recommendations should be submitted to the WSE&I Program Element Manager (PEM) and cognizant technical PEM for review and concurrence or redirection. The WSE&I PEM has coordination responsibility and the cognizant technical PEM has responsibility for the specific technical area. The HLWM Technical Sponsor has overall responsibility for HLWM technical direction.
8. Page A99, second paragraph, item 2: delete this item. An uncertainty on "how to reduce a previous uncertainty" is still the same uncertainty.
9. Page A119, Uncertainty Component: It is not clear that this set of records continue to serve a useful purpose. I suggest that this be considered for removal from the database.
10. Page A129 Composite Uncertainty Reduction Methods Analysis and Page A161, Composite Rank Ordering: Consider treating attribute ranking as off-line activities (see Ted Romine letter to Phil Altomare of 8/22/89).
11. Page A144, item 19f: "Other" should be included under the uncertainty reduction method types. It is not clear that a complete set is given.
12. Page A173, second paragraph, second sentence: delete "for recommendation to the NRC" and replace with "in consultation with NRC."

13. Page A193, Recommended NRC Overall Research Program Plan, Section 24.1.4: the following should be included:
- (a) A clear simple statement of the research need,
 - (b) Technical reason the research is needed,
 - (c) Regulatory reason the research is needed,
 - (d) Reference to NRC programs that will use the research results,
 - (e) Associated NRC research and Technical Assistance, and
 - (f) Associated DOE research or investigations
14. Page A201, Open Items, first paragraph: delete "DOE compliance demonstration methods." NRC will not track uncertainties related to DOE compliance demonstration methods in the PASS as open items. If it is of sufficient concern to NRC it would become an NRC uncertainty to be tracked as an open item. Note, the open item described here is that related to the Program Architecture. At some future time, the open items as defined in the NRC Site Characterization Analysis are to be included, or accessible, from the PASS.

Technical Content of Erosion and SCC Example Regulatory Requirement Topics

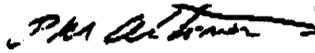
The example Regulatory Requirement Topics served to demonstrate the Program Architecture process and application of the PASS database content description, i.e., they served to "Baseline" the Program Architecture. There is still a need to refine and update the technical content of the example cases. Also, this exercise indicated a need for a standardized hardcopy report for Regulatory Requirement Topics in addition to access to the computer database. Accordingly, consideration should be given to preparing a standard report for Erosion and Substantially Complete Containment to be used as a guide for future PASS data preparation.

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To NEXT
PAGE

- 2 -

The action taken by this Technical Direction is considered to be within the scope of the current contract NRC-02-88-005. No changes to cost or delivery of CONTRACTED SERVICES and products are authorized. Please notify me immediately if you believe that this Direction would result in changes to cost or delivery of contracted services or products.

Sincerely,



Philip Altomare, WSE&I
Program Element Manager

Enclosure:
As stated

cc: Mary Mace, ADM/CAB



9
P. Altman HLEN 7 H3
UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 02 1990

Mr. Alan Whiting, Director
Systems Engineering and Integration
Center for Nuclear Waste Regulatory Analysis
P. O. Box 28510
6220 Culebra Road
San Antonio, Texas 78284

Dear Mr. Whiting:

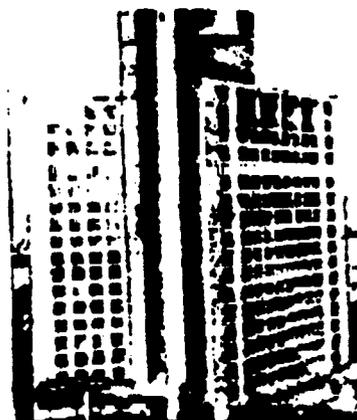
SUBJECT: NRC Staff Comments on Draft Report CNWRA 90-003

NRC staff have previously provided and discussed comments on the CNWRA 90-003 report (see CNWRA Meeting Reports for January 11, 1990, and January 18, 1990). Additional comments are attached from the geoscience, performance assessment, engineering and legal staff for your information (these were informally provided at the January 29, 1990 meeting). Please note that the comments or regulatory analysis provided do not represent an agency position but are the individual views or analysis of the commentors. The intent is to provide the CNWRA with the knowledge and experience gained by a number of the NRC staff by providing input as if it were a contribution to one of the CNWRA technical working groups. The CNWRA still has the responsibility for final analysis and preparation of the report. It is expected that the CNWRA will consider the NRC input in their analysis but it is not expected that a response will be required for each NRC comment. Records of the disposition of each comment should be handled the same manner as that presently used for working groups and maintained at the CNWRA. Where an important consideration is identified, it is expected that it would be incorporated in the rationale statement. No further comments are to be expected from the NRC, however, please feel free to contact me or the specific staff person if clarification is needed.

In our meeting of January 29, 1990, you informed me that the CNWRA will deliver the final report CNWRA 90-003 on February 28, 1990. Accordingly, I will inform our contracts office, by copy of this letter, to proceed to establish that date as the contract deliverable date (reference the Mary Mace letter to John Latz of January 10, 1990).



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20545



FAX NO'S 301 - FTS - 492-0269, 492-0260, 492-1137

VERIFICATION NO. 301 - FTS - 492-0262

LOCAL () OR FTS ()
PLEASE CHECK ONE

PLEASE TYPE OR USE BOLD FELT TIP PIN. TELECOPIES WILL NOT BE RETURNED.

- | | TO | LOCATION |
|----|---------------------------|----------------------------------|
| 1. | <u>Allen Whittam</u> | <u>San Antonio TX (CNWRA)</u> |
| | FAX # <u>512-522-5155</u> | VERIFICATION <u>512-522-5160</u> |
| 2. | <u>R. Adley (CNWRA)</u> | <u>Crystal City Va.</u> |
| | FAX # <u>920-2189</u> | VERIFICATION <u>979-9129</u> |
| 3. | _____ | _____ |
| | FAX # _____ | VERIFICATION _____ |
| 4. | _____ | _____ |
| | FAX # _____ | VERIFICATION _____ |
| 5. | _____ | _____ |
| | FAX # _____ | VERIFICATION _____ |
| 6. | _____ | _____ |
| | FAX # _____ | VERIFICATION _____ |

OF PAGES 6 AND COVER SHEET

FROM _____ PHONE EXT. _____



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 15 1990

11
ROB LXS
BEAN [Signature]

Bob - Think of a way
to have this available
to check the completely
CNWRA Revised
document against
[Signature]

John E. Latz, President
Center for Nuclear Waste
Regulatory Analyses
Post Office Box 28510
6220 Culebra Road
San Antonio, Texas 78228-0510

Dear Mr. Latz:

Subject: Technical Operating Procedure (TOP) 001-02 Under the "Waste Systems Engineering and Integration" Program Element Under Contract No. NRC-02-88-005

Revised TOP-001-02 entitled "Program Architecture Relational Database Content and Development Instructions", and synopses of information for two worked regulatory requirement topic examples entitled "Extreme Erosion" and "Substantially Complete Containment" which are considered a "baselining" of the Program Architecture are acceptable with the incorporation of the enclosed comments.

Should you have any questions, please contact me on area code 301-492-4291.

Sincerely,

Mary H. Mace

Mary H. Mace, Contracting Officer
Contract Administration Branch
Division of Contracts
and Property Management
Office of Administration

cc: J. Funches, NMSS

cc: Dir/El. Mgrs.

NRC COMMENTS ON TECHNICAL OPERATING PROCEDURE (TOP) 001-02

GENERAL COMMENT

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Attachment A

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14

January 29, 1991

TO: Bruce Mabrito
 Director - QA

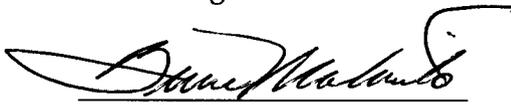
FROM: Allen Whiting
 Element Manager - WSE&I

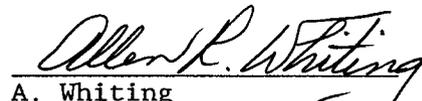
SUBJECT: Scheduled Action on Attached CAR No. 90-06

Based on the unavailability of proper resources to re-issue the TOP-001-02 by the committed date of January 31, 1991, as well as the unknown future role of the document being considered for revision, I am requesting an extension of time to complete the agreed to corrective action.

I am requesting a new target date of April 8, 1991 for completion of the CAR. This request is made on the basis that quality related work performed utilizing this procedure during this requested delay period will not be adversely affected.

Concurrence Signatures:


 B. Mabrito


 A. Whiting

ARW/mag
 F: ARW\CAR.mem

*DISTRIBUTION: J. LATZ
 Directors
 EWS
 R. BRENT
 CAR QA Folder*

MEMORANDUM

29 May, 1991

TO: Bruce Mabrito
Director - QA

FROM: D. T. Romine
Element Manager - WSE&I

SUBJECT: Request for Extension on Completion of Action Related to Corrective
Action Request (CAR) 90-06

During the period since CAR 90-06 was issued, significant development and working experience have taken place with respect to the evolution of the Systematic Regulatory Analysis (SRA) structure and the Program Architecture Database (PADB). This development continues, specifically with respect to defining the details of a procedure for developing Compliance Determination Strategies (CDS) and to incorporating the functions of the Program Architecture Review Committee into standard Center document review procedures.

An outgrowth of the development described above is the need to restructure the TOP-001 series instructions. This restructure will include revising TOP-001 and superseding the other TOP-001 series instructions, with the exception of TOP-001-02. TOP-001-02 will be revised to provide an accurate procedure for CDS development and will also be divided into a number of "second-tier" instructions in order to support the sequential and continuing refinement which will occur as the SRA structure matures.

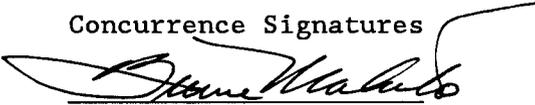
I am requesting an extension until 30 June 1991 in order to complete the following action in response to CAR 90-06:

- Revise TOP-001 and supersede TOPs 001-01, 001-03, 001-04, and 001-05
- Revise TOP-001-02, Attachment A, Section 11 (NRC Compliance Determination Strategy) to provide an accurate CDS procedure and to reflect its redesignation as a separate procedure subordinate to TOP-001

Revision of other sections of TOP-001-02 as instructions subordinate to TOP-001 will take place as SRA development dictates such that approved procedures will be in place prior to entry of the associated data into the PADB as approved data.

No PADB data entry will take place until the corrective action described above has taken place.

Concurrence Signatures



B. Mabrito



D. T. Romine

cc
Directors
Element Managers

R. Brient
P. Mackin

CAR QA Folder

MEMORANDUM

11 July, 1991

TO: Bruce Mabrito
Director - QA

FROM: D. T. Romine
Element Manager - WSE&I

SUBJECT: Request for Extension on Completion of Action Related to Corrective
Action Request (CAR) 90-06

A memorandum of 29 May, 1991 (same subject) requested an extension until 30 June, 1991 to complete the following action in response to CAR 90-06:

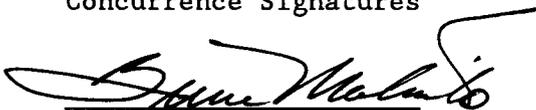
- Revise TOP-001 and supersede TOPs 001-01, 001-03, 001-04 and 001-05
- Revise TOP-001-02, Attachment A, Section 11 (NRC Compliance Determination Strategy) to provide an accurate CDS procedure and to reflect its redesignation as a separate procedure subordinate to TOP-001

A revision to TOP-001 is being reviewed in accordance with QAP-002. Several comments have been received concerning the revision, and concurrence in the resolution of those comments will be required from the Technical Director. The Technical Director will be absent from the Center until late in July. To allow time for comment resolution and concurrence by the Technical Director, I am requesting an extension until 30 August to complete the revision to TOP-001.

Development of a revision to TOP-001-02, Attachment A, Section 11 is occurring in coordination with the NRC staff. The NRC and Center staffs will test the proposed revision by using it to develop Compliance Determination Strategies for three example Regulatory Requirements. After reaching concurrence on the revision as a result of this process, the procedure will be formally approved in accordance with QAP-002. The NRC has committed to completing the Compliance Determination Strategies for the three examples by the end of this fiscal year (FY '91). Therefore, I am requesting an extension until 30 September, 1991 for completing the revision.

No PADB information will be approved until the corrective action described above has taken place.

Concurrence Signatures


B Mabrito


D. T. Romine

cc
Directors
Element Managers

R. Brient
P. Mackin

CAR QA Folder