

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2005-4

Associated AR, SR, NCR No: AR 2005-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Contrary to the requirements of TOP-018, Rev. 9, Chg. 0, the following discrepancies were found:

1. Version control and software documentation package discrepancies
 - a. No objective evidence available to verify ProShake Version 1.11 used for Preclosure - SA was controlled in accordance with Section 4
 1. ProShake Version 1.1 was listed as controlled on CNWRA Controlled Software Directory
 2. Disks included with package indicated Version 1.10
 3. Users manual included with package indicated Version 1.1
 4. Screenshot of "About" indicated Version 1.11
 - b. No objective evidence was available for EarthVision to verify that:
 1. Version 7.0 was listed on the CNWRA Controlled Software Directory prior to retirement as required by Section 4.1.4
 2. Version 7.0 was retired with the issuance of a Software Release Notice(SRN) as required by Section 4.3
 3. Version 7.0.1 used for Preclosure - SA was controlled in accordance with Section 4.
 - c. Of 19 software documentation packages reviewed, all having had a QA verification:
 1. 7 packages contained media that did not include all of the required media label information per Section 4.1.3
 2. 2 packages did not include any media as required by Section 4.1.2
 3. 4 packages did not include documentation or reference to documentation of installation testing as required by Section 4.1.1
2. TPA Code Discrepancies
 - a. No objective evidence was available to verify code reviews were being conducted of the TPA Code v 5.0.1 in accordance with Section 5.4.7
 - b. No objective evidence was available to verify a user's manual was developed for the TPA Code v 5.0 as required by Section 5.5
3. Findings on TOP-018
 - a. Section 4.2.9 references Section 3.4.4 that does not exist in the procedure
 - b. Section 5.3.1 and 5.4.1 reference Section 5.1 for guidance; no guidance is available in Section 5.1
 - c. Section 5.1 references criteria for determination of development of a SRD and/or SDP; no criteria are listed
 - d. Section 6 does not list CNWRA Controlled Software Directory or acceptance test results as records

Initiated by: R. Weber

Date: May 18, 2005

Responsible Individual: B. Brient/R. Janetzke


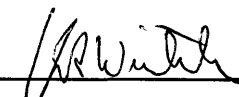
Response Due: June 15, 2005

PART B: PROPOSED ACTION

See Attached.

1) Extent of Condition:**2) Root Cause:****3) Remedial Action:****Proposed Completion Date:****4) Corrective Action to Preclude Recurrence:****Proposed Completion Date:**

Manager/Director:

Date:

5/27/2005 / 5-27-05

CAR 2005-4 Proposed Action

Issue 1 - Version control and software documentation package discrepancies

Discussion:

- a: CAR 2004-1, initiated July 12, 2004, identified use of uncontrolled software versions in reports. While CAR 2004-1 identified the preclosure seismic analysis report as using uncontrolled Earthvision 7.0.1, ProShake 1.11 (used in the same report) was inadvertently not included in CAR 2004-1. This oversight was recognized in early January 2005 and ProShake 1.11 was in process of being placed under control during the audit. A validation plan and report for ProShake version 1.11 was approved May 19, 2005. (CAR 2004-01 is attached ^{with 5/21/05} no reference)
- b. Earthvision 7.0 had already been superceded by version 7.5 when version 7.0 was released. Earthvision 7.0 was placed under control only for the purpose of remedial action for CAR 2004-1 and was retired shortly thereafter, so posting on the controlled software listing was not necessary or desirable. SRN 323 indicates Earthvision 7.0 was placed under control on 8/31/2004 and was annotated as retired on 9/21/2004. A separate SRN for retiring this version was not necessary. As described in the QA verification documentation for Earthvision 7.0 A (SRN 323), this version was placed under control to only address CAR 2004-1. Corrective action for CAR 2004-1 was adequate to address the configuration identification issues.
- c. 1. Archive copies of software are labeled with at least the software name and version, and the additional information required by TOP-018 is available on the Software Release Notice. The media information requirement of TOP-018 were considered to be addressed by Software Release Notices, which are in the same software folders as the archive copy of the software.
 2. FLAC 4.00 was retired in 1/2005 and un-retired in 3/2005. The archive copy of the software and installation test information was in the QA records under retired software. The Division Information Management Services group held the archive copy of ArcView version 3.2a.
 3. Of the four software items identified during the audit, installation testing for FLAC 4.00 was located in the retired software file. For the other three, installation testing was described on the Software Release Notice. This was considered to meet the intent of TOP-018, 4.1.1 although evidence was not literally attached to the release notice or in a scientific notebook.

1. Extent of Condition:

- a. The analysis for CAR 2004-1 included determining the extent of condition. Other than ProShake 1.11, no use of unqualified software has been identified subsequent to CAR 2004-1.
 b. The analysis for CAR 2004-1 included determining the extent of condition.
 c. The extent of conditions was limited to the software noted during the audit.

2. Root Cause:

- a. CAR 2004-1 adequately identified the root cause of the use of uncontrolled software.
 b. CAR 2004-1 adequately identified the root cause of the use of uncontrolled software.
 c. Software configuration control practices met the intent of TOP-018, however did not meet the literal interpretation of a few requirements.

3. Remedial Action:

- a. ProShake 1.11 is being placed under control and is being validated. CAR 2004-1 provided the necessary remedial action to address Earthvision 7.0.
 b. Necessary remedial action was taken for CAR 2004-1.
 c. Revise TOP-018, 4.1.3 and 5.7.5 to require software media to be labeled with the software name and version number (only). Move FLAC version 4.00 records from retired software files to active files. Revise TOP-018, 4.1.1 and 5.6.1 to allow installation testing to be documented on the Software Release Notice.

Target Date for Completion: (TOP-018 revision) July 30, 2005

4. Corrective Action to Preclude Recurrence:

- a. CAR 2004-1 provided adequate corrective action to preclude recurrence.
- b. CAR 2004-1 provided adequate corrective action to preclude recurrence.
- c. For the next revision to TOP-018, reviewers will be instructed to interpret requirements literally and to carefully evaluate control features to verify consistency with actual practices.

Target Date for Completion: (TOP-018 revision) July 30, 2005

Issue 2 - TPA Code Discrepancies

Discussion:

a. As was explained during the audit, TOP-018 Section 5.4.7 applies to formal reviews only and as such does not apply to informal code reviews of the TPA code. Thus, objective evidence for informal reviews is not required. However, to make a clear distinction between the requirements for the reviews, TOP-018 will be modified.

b. TOP-018 does not require that a User's Manual be produced for each version of the software. In concordance with this, the client provided instructions not to produce a User's Manual for TPA version 5.0. However, a clarifying statement in this regard will be added to TOP-018.

1. Extent of Condition:

The condition was limited to the specific audit observations.

2. Root cause: The authors and reviewers of TOP-018 did not interpret the requirements to imply that any code review must meet the documentation criteria or that user manuals were required for every version.

3. Remedial action: Revise TOP-018 sections 5.4.7 to add an exception to documenting informal comments and section 5.5.1 indicating that user manuals will be developed when required by the client or as determined by Division management.

Target Date for Completion: (TOP-018 revision) July 30, 2005

4. Corrective Action to Preclude Recurrence: For the next revision to TOP-018, reviewers will be instructed to interpret requirements literally and to carefully evaluate control features to verify consistency with actual practices.

Target Date for Completion: (TOP-018 revision) July 30, 2005

Issue 3 - Findings on TOP-018

Discussion:

a. When TOP-018, rev 9 was prepared, this cross reference was not revised.

b. and c. When TOP-018, rev 9 was prepared, a portion of the text relating to the option to waive the requirement for Software Requirements Descriptions and Software Development Plans was inadvertently left in.

d. Although revision 9 and previous revisions of TOP-018 have not specifically identified the CNWRA Controlled Software Directory or acceptance test results as QA records. these documents have been retained as QA records.

1. Extent of condition:

The conditions are limited to those identified during the audit.

2. Root cause:

- a, b & c. The authors and reviewers of TOP-018, did not recognize the few editorial errors identified in the audit. The editorial errors did not cause any nor would the errors be likely to cause deviations from the intent of TOP-018.
- d. Authors and reviewers of TOP-018, revision 9 and earlier revisions did not recognize the omission of these records.

3. Remedial action:

- a. Revise TOP-018, 4.2.9 to change the cross reference to 4.2.3.
- b and c. Revise TOP-018, 5.1 deleting the second paragraph, and sections 5.2.1 and 5.3.1 deleting the portion of the first sentence relating to waiver in 5.1.
- d. Revise TOP-018, 6.1 to add (i) software development files (that will contain acceptance test results) and (ii) the Controlled Software Directory.

Target Date for Completion: (TOP-018 revision) July 30, 2005

4. Corrective Action to Preclude Recurrence: For the next revision to TOP-018, reviewers will be instructed to carefully evaluate changes and to verify consistency with actual practices.

Target Date for Completion: (TOP-018 revision) July 30, 2005

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CORRECTIVE ACTION REQUEST

CAR No: 2005-4

Associated AR, SR, NCR No: AR 2005-1

PART C: APPROVAL
Comments/Instructions

Director of QA:



Date:

5/27/2005

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
PRINCIPAL INVESTIGATOR
MANAGER
TECHNICAL DIRECTOR
CNWRA PRESIDENT

Verified by:

Date:

Verification Of Corrective Action Implementation (Remedial Actions)

Issue 1 C. Paragraphs 4.2.2 and 5.7.5 in TOP-018 Revision 10 now only require the software medium to identify the name and version of the software. FLAC Version 4.00 has been moved to the active file area. TOP-018 Revision 10 (Rev10) now allows for installation testing to be documented on the Software Release Notice.

Issue 2. Rev10 paragraph 5.4.7 now states that informal reviews are not required to be documented. Paragraph 5.5.1 now states that a user's manual will be prepared when required by the software development plan or by Client direction.

Issue 3. A Para. 4.39. now contains the correct reference back to 4.3.3.

B. The second paragraph 5.1 has been deleted.

C. References to the waiver have been removed in paragraphs 5.7.1+5.3.1.

D. Paragraph 6.1 now contains references to software development files (including installation and acceptance test results) and the controlled software listings.

Corrective Action to Preclude Recurrence (The same response was stated for all 3 issues.)

The technical reviewer of TOP-018 Revision 10 contributed to the response to CAR 2005-4 and the programmatic reviewer approved the response to CAR 2005-4. Therefore these reviewers were well aware of the need to interpret requirements literally and to carefully evaluate control features to verify consistency with actual practices.

(R) 8/10/05