

SNL WIPP Corrective Action Request (CAR) Status Report

CAR Number	Issue Date	Status	Estimated Completion Date	Responsible Staff
IA-04-01-CAR-01	9 /2 /2004	Open	10/29/2004	J. Long, D. Rudeen, A. Gilkey

Deviation

1. Contrary to the requirements of NP 19-1, Section 2.3.7.1, the Implementation Document for CCDFGF 5.00A and 5.01 had the same version number.
2. Two test case 4 files (DRS_TC41_SPLVOL_GROPE.INP and DRS_QE0100_TC41_SPLVOL_GROPE.OUT) in the Verification and Validation Plan/Validation Document for DRSPALL Version 1.00 (ERMS #524782) were not the correct files.

Corrective Action Plan

Remedial Action:

The Implementation Document for CCDFGF 5.00A and 5.01 which had the same version number will be corrected. Two Test Case 4 files in the Verification & Validation Plan/Validation Document for DRSPALL Version 1.00 were not the correct files. The correct files will be placed in CMS.

Investigative Action:

The incorrect identification of CCDFGF versions started with a change from version 4.0 to 5.0 while the baseline documents were being changed back to version 1.0. Subsequent changes were implemented to correct the problem, but the later changes inadvertently resulted in the version numbers being replicated. The extent of the condition is limited to the documents for CCDFGF. The impact to configuration identification is minor since unique identification of the baseline artifacts can also be traced by Record Center ERMS number.

The missing DRSPALL test files occurred during transfer of the files from the Code Sponsor to the SCM Librarian. The files were re-named prior to being placed in the CMS library, and the two files in question were mislabeled. The extent of this condition is limited to Test Case 4 files. The impact to reproducibility and traceability is minor since the files would be needed to reproduce the same results but the same files could be generated in a fairly quick time frame.

Status of Corrective Actions | CAP submitted and approved.

CAR Number	Issue Date	Status	Estimated Completion Date	Responsible Staff
W-03-11	8 /29/2003	Open	9 /30/2004	Amy B. Rein

Deviation

- 1) One SNL WIPP personnel does not have a Qualification and Training form completed and in records.
- 2) The job titles and/or job descriptions is not specific for the position, descriptive for the position or not correct for the current responsibilities of the individuals.
- 3) In most cases there has not been an annual review performed of Qualification and Training records by management.
- 4) In two cases, it appears that SNL WIPP personnel received NWMP QA Training six months after starting work on the WIPP project. It should be noted that at the time both individuals were Student Interns with SNL and not directly performing or responsible for work on the WIPP project. In some cases job specific procedures/documents required for the position are not identified.
- 5) There is not evidence that Document Control is being notified of new or transferred personnel to the SNL WIPP program.

Corrective Action Plan

Remedial Actions:

1. Generate/Update Q&T forms for SNL WIPP personnel as identified.
2. Complete evaluation and impact statement for Student Employee involved in WIPP work with no Q&T form.

Investigative Actions:

1. Review procedure NP 2-1 for adequacy, clarity, effectiveness, and usability.
2. Review additional samples of Q&T forms for compliance to requirements of NP 2-1.

Actions to Preclude Recurrence:

1. Devise ways of tracking current SNL WIPP staff and their qualification status.
2. Assign specific personnel to implement Q&T initiation, including new and updates, SNL or Contractor.
3. Revise procedure NP 2-1 as applicable.
4. Require personnel training to revised procedure on qualification and training process.
5. Conduct surveillance of Q&T process after implementation.

Status of Corrective Actions | Corrective actions have been completed. Awaiting verification.

SNL WIPP Corrective Action Request (CAR) Status Report

CAR Number	Issue Date	Status	Estimated Completion Date	Responsible Staff
W-03-12	9 /3 /2003	Open	1 /31/2005	Y. Xiong, N. Wall

Deviation

Scientific Notebooks, WIPP-MgO-CBD-8, WIPP-MgO-CBD-9, and WIPP-MgO-CBD-10 did not provide sufficient detail to retrace or repeat the experiment. A comment dispute was not brought to the attention of the QA team lead (notebook WIPP-MgO-CBD-9). Detail of deviations are provided by Dr. Donald Wall. See Form NP 16-1-1 for full details.

Corrective Action Plan

Revised Corrective Action Plan:

During the Corrective Action Verification process, it was noted that the standards and methods used to calibrate instrumentation (ICP, PH Meter) are not always recorded in the scientific notebook. Therefore, remedial actions #1 and #2 of the CAR remain open pending correction of the omitted items. The first remedial action item is being re-worded to specifically address this omission; the second will not change, but will be included in this revision for completion. Actions to preclude recurrence have been verified and closed and will not be restated in this revision.

Remedial Action:

- 1). Create new Scientific Notebook to provide sufficient detail to retrace or repeat the experimental work documented in Scientific Notebooks WIPP-MgO-CBD-8, WIPP-MgO-CBD-9, and WIPP-MgO-CBD-10. Special attention should be given to providing traceability to standards for all calibrations performed. The lot number, manufacturer, and expiration date of all standards used to calibrate instrumentation will be recorded. The method of calibration will be recorded in the scientific notebook (i.e. chemicals used, dilutions used, how dilutions were created, results of calibration, calibration checks performed, how often calibration checks were performed). Details of the analysis performed will be included or referenced, including the results of the analysis.
- 2). An independent technical review of the new notebook and all associated notebooks will be performed to assess completeness of the information in the new notebooks for providing traceability and repeatability of the experiments performed in scientific notebooks WIPP-MgO-CBD-8, WIPP-MgO-CBD-9, and WIPP-MgO-CBD-10.

Status of Corrective Actions | Partial verification completed 7/22/04. CAR W-04-06 was issued.

CAR Number	Issue Date	Status	Estimated Completion Date	Responsible Staff
W-04-06	6 /17/2004	Open	9 /30/2004	Yongliang Xiong

Deviation

Chemical Standards stored in the WIPP chemical cabinet were expired. Calibration Standards created by the PI were not properly labeled and had expired. Certificates of Certification from the manufacturer were not on file in the records center for the Chemical Standards reviewed.

Corrective Action Plan

Investigative Actions:

The ICP-AES calibration standards contained two elements, i.e. Ca and Mg. The expiration date for Ca (LOT #V8-176CA) was 5/30/04, and the expiration date of Mg (LOT #S9-13MG) is to be 11/15/04. Only two data sets were produced after 5/30/04. One was on 6/2/04, and the other was on 6/14/04.

Remedial Actions:

To demonstrate that the above two data sets are usable, the above standards will be tested against new ICP-AES calibration standards containing Ca (LOT #U8-169CA, expiration date: 6/30/05) and Mg (LOT #S9-13MG, expiration date: 11/15/04). Specifically, new calibration standards will be used to construct the calibration curve. Then the above mentioned calibration standards of certain concentrations (e.g. 10mg/L of Ca and Mg standard) will be analyzed as samples for a number of times (e.g. 10 times). The analytical results will be used to compute the average value and associated standard deviation. Based upon the average value and the expected value (e.g. 10 mg/L), the discrepancy, which is the absolute value obtained by subtracting the average value from the expected value, will be computed. If the discrepancy falls between less than one standard deviation and 1.96 standard deviation, the discrepancy will be deemed to be acceptable, and therefore the validation of the above standards used on June 2 and 14, 2004 is established. If the values do not fall between less than one standard deviation and 1.96 standard deviation, then the two data sets produced on June 2, 2004 and June 14, 2004 will be reproduced using standards within their due dates.

Actions to Preclude Recurrence:

All laboratory personnel using the standards to calibrate the ICP-AES or used for other WIPP activities will be trained to re-enforce checking standards expiration date prior to use and removing standards from the WIPP Standards Cabinet if expiration date(s) has expired.

Status of Corrective Actions | Corrective actions have been completed. Awaiting verification.