

United States Government

Department of Energy

memorandumCarlsbad Field Office
Carlsbad, New Mexico 88221

DATE: October 28, 2003

REPLY TO
ATTN OF: CBFO:QA:MPN:GS:03-2928:UFC 2300.00

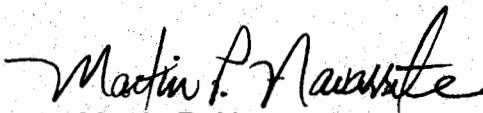
SUBJECT: Closure of Corrective Action Reports 03-072, 03-073, 03-074, 03-075, 03-076 and 03-077

TO: Brian Edgerton, DOE-ID
Richard Cullison, DOE-ID

The Carlsbad Field Office (CBFO) performed verification of corrective action completion for Corrective Action Reports (CARs) 03-072 through 03-077. The corrective actions taken and implemented for these CARs have been evaluated by review of documents received and observed during a site visit on October 15-16, 2003. The results of the evaluation indicate that AMWTP has adequately addressed the issues identified in CARs 03-072 through 03-077 and has adequately implemented the corrective actions for these issues. Based upon this evaluation it has been determined the AMWTP has satisfactorily implemented the necessary corrective actions and actions to preclude recurrence to close these CARs.

CARs 03-072 through 03-077 have been closed based on the CBFO verification of the corrective actions. The CAR continuation sheets documenting verification of corrective action completion and closure of the CARs is attached.

If you have any questions or comments, please contact me at (505) 234-7483.


Martin P. Navarrete
Quality Assurance Specialist



Attachments

cc:

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031033



CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-072

2. Activity Report No. A-03-05

3. Page 1 Of 2

Block 18: Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were evaluated based on closure documentation package provided by the AMWTP during the site visit that occurred on October 15 and 16, 2003. The corrective actions and objective evidence reviewed and found to be satisfactory are as follows:

A. Remedial Action

Establish the format of report forms for the Waste Tracking System (WTS) to ensure "all data" in each field are legible, and complete. These actions will ensure a complete quality record can be produced in hard copy from the Waste Tracking System container screens. These forms will then be assembled into reworked BDRs and submitted to revalidation.

All affected Batch Data Reports associated with AMWTP will be reworked using the revised WTS Data report forms and revalidated. NCR 3492 has been issued and identifies the affected BDR's. Specific BDR's identified on the NCR for rework will be identified to enable demonstration through the entire project process and be available for re-assessment by CBFO. The complete rework/revalidation of all remaining BDRs will be managed as documented on NCR 3492 and will be a work in process at the time of CBFO reassessment.

All revalidation will be performed manually using the Manual Batch Data reports produced from the implementation of NCR 3492. Note that for Assay Batches, an Independent Technical Review signature will be applied in WTS for drum movement criticality purposes only. All Assay Batches will undergo full Manual Batch Data review.

Verification Results

Verified that AMWTP established a format for the WTS data report forms that ensure that all data fields are legible, complete and adequately addresses the quality record requirements. Refer to the attached checklist for verification of this CAR for more details.

B. Extent and Impact of the Deficiency

The extent and impact of this deficiency related specifically to truncated data fields. In WTS, all the data was complete, if a field affecting data quality was truncated, a comment was noted on the form to clarify the data entry. Some fields that were not related to data quality were truncated, which is the deficient condition. Therefore, there were no data fields with truncation that had any relevance to "data quality".

Verification Results

Verified that AMWTP performed an investigation of the condition adverse to quality and determined that the extent and impact specifically relates to truncated data fields in the hardcopy BDRs. The investigation determined that the data fields are complete within the WTS. AMWTP issued NCR 3492 to complete the rework of the BDRs. Refer to the attached checklist for verification of this CAR for more details.

C. Root Cause Determination – 6B Management Problem, Work Organization/Planning Deficiency.

The generation of these BDRs was a decision made just prior to the audit due to the inability of WTS to consistently function correctly through the electronic data validation process. It was determined that data was being collected technically correct and complete during the actual operator examination or measurement process, and was accurately being signed electronically in WTS by the responsible operator. However, the project was not fully prepared to produce paper copies of container examinations into assembled Manual BDRs, and the decision was made to use print screens from WTS.

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-072

2. Activity Report No. A-03-05

3. Page 2 Of 2

Block 18: Verification of Corrective Action Completion (Continued)

Verification Results

Verified that AMWTP determined that the cause or the condition adverse to quality was a last minute decision to assemble manual BDRs from WTS screen prints that caused the data fields to be truncated. This decision was based on the inability of WTS to consistently function correctly through the electronic validation process. AMWTP prepared an Investigation and Root Cause Analysis Report AMWTP RCA-03-009, August 28, 2003. Refer to the attached checklist for verification of this CAR for more details.

D. Corrective Actions to Preclude Recurrence:

- a. Complete revision of WTS Reports to eliminate possibility of truncating data.
- b. Provide training on WAP B3 requirements for ITR, TS/QA, SQAOS, and SPM responsibilities (specific to the Validation process) to those respective individuals in AMWTP who are responsible for performing these reviews of BDR's.
- c. Rework the Batch Data Reports (BDR's) used for Audit Objective Evidence using the revised WTS report format. Complete the validation to authenticate the data quality through the "review process".

Verification Results

Verified that AMWTP completed the revision of the WTS report forms via Software Change Request (SCR), SCR-194, Batch Data Reports for Manual Validation - Audit Issue and provided training to the ITRs, TS/QA, SQAOS and SPM on the WAP B3 validation requirements. AMWTP reworked the BDRs original used for Audit A-03-05 objective evidence and will rework the remaining containers prior to closure of NCR-3492. Refer to the attached checklist for verification of this CAR for more details.

Based on the above supporting documentation and actions, the recommendation is for closure of this CAR.

Block 19a: Verifier:


Jeff May

Date: 10/27/03

Block 19b: Trend Cause Code: 3.2

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-073

2. Activity Report No. A-03-05

3. Page 1

Of 2

Block 18: Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were evaluated based on closure documentation package provided by the AMWTP during the site visit that occurred on October 15 and 16, 2003. The corrective actions and objective evidence reviewed and found to be satisfactory are as follows:

A. Remedial actions:

Headspace gas batch data reports HSG03-00208, HSG03-00209, HSG03-00211 have been completed through SPM review and will be revised and updated with the surrogate analyses form. Headspace gas batch data reports that have been through level 1 validation will be returned to the data generator and be revised with surrogate analyses. Headspace gas data quality is in no way affected by the addition of surrogate analysis added to all batch data reports. All headspace gas batch data reports affected in this CAR shall contain revised data verification and validation checklists.

Verification Results

Verified that AMWTP revised the affected BDRs to include the surrogate form and revised the QA checklists that address retention times windows and completed the validation to authenticate the data quality. Refer to the attached checklist for verification of this CAR for more details.

B. Investigative Actions Extent and Impact of Deficiency:

- 1) Retention time (RT) windows shall be determined for Mass Spectrometer (MS) analyzed compounds except the internal standards, ethylbenzene, m&p xylene, and o-xylene. These (RT) windows shall be ± 0.400 minutes of the average retention time of the initial calibration. Internal standard retention time windows shall be ± 0.250 minutes of the average retention time of the initial calibration and ethylbenzene, m&p xylene, and o-xylene retention time windows shall be ± 0.150 minutes of the average retention time of the initial calibration. The justification for this procedural revision is based on the SW-846 8000B method stating that ± 3 times RSD of initial calibration retention times is only one way to determine RT windows and is recommended for non-MS detectors. In addition for justification the Varian GCMS Saturn software used at the AMWTP will only allow a minimum retention time window of ± 0.05 minutes which is greater than ± 3 times Standard Deviation of the initial calibration retention time. Headspace gas batch data reports that are affected by this CAR shall implement the above-described methodology of retention time window determination and batch data validation and verification checklists shall be updated to reflect a QC/QA performance check of the determined retention time windows. Retention time window determinations for hydrogen and methane shall be determined using the SW-846 8000B methodology, which uses $\pm 3 \times SD$ of the initial.
- 2) Internal standards shall be used as surrogates as stated in the current revision of INST-OI-13. This requirement shall be performed and the calculation shall be inserted into all effected headspace gas batch data reports. For future BDR's performed by AMWTP the current revision of INST-OI-13 will be revised to eliminate the performance of Surrogate analysis and SPCC analysis. Procedures shall be clarified that a modified 8260B method shall be the basis of requirements along with Section B3-5 of the (Gas Volatile Organic Analysis) and all pertained tables in that section. Percent recoveries of internal standards shall be within 70% to 130% recovery of the original calibration. A NCR will be initiated to document the failure of the internal standards to meet the percent recovery windows outlined above. The disposition will be an evaluation to determine acceptability to use the data "as is" due to the fact no TIC's were detected in any of the affected batches.

Verification Results

Verified that AMWTP performed an investigation of the condition adverse to quality and determined that EPA Method SW-846 does not specify retention time (RT) window determination for mass spectrometer detectors and the AMWTP procedure INST-OI-13 required internal standards to be used as surrogates. Refer to the attached checklist for verification of this CAR for more details.

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-073

2. Activity Report No. A-03-05

3. Page 2 Of 2

Block 18: Verification of Corrective Action Completion (Continued)

C. Root Cause Determination:

(1) Procedure Problem 2A Defective or Inadequate Procedure

The operational instruction for determination of the RT windows did not correctly consider the instrument used for measurements when identifying the acceptance criteria.

(2) Personnel Error 3B Inattention to Detail

The chemist performing the initial calibration used the incorrect criteria in the WIPP WAP instead of using the information in the approved AMWTP procedure. This is also a contributing cause since the inadequate conditions had not been appropriately dispositioned during technical data review.

Verification Results

Verified that AMWTP determined that the cause of the condition adverse to quality was that the operational procedure for determination of the RT windows did not correctly consider the instrument used for measurements when identifying the acceptance criteria and the chemist performing the initial calibration used incorrect criteria instead of following the approved procedure. AMWTP prepared an Investigation and Root Cause Analysis Report AMWTP RCA-03-009, August 28, 2003. Refer to the attached checklist for verification of this CAR for more details.

D. Corrective Action to Preclude Recurrence:

1) The corrective action plan for CAR # 03-073 will be implemented by BNFL Inc. to correct HSGS procedural noncompliance. Document Change Requests (DCR's) shall be initiated for procedure revisions of INST-TRUW-8.2.1 and INST-OI-13. BNFL Inc will review and internally approve these procedure modifications. Upon acceptance by CBFO, training shall be performed to the approved procedure revisions per BNFL Inc. approved training program.

2) All chemists shall undergo supplemental training designated by the SPM and SQAQO. This training will be documented by BNFL Inc. AMWTP training department and added to each chemist's qualification package.

Verification Results

Verified that AMWTP modified procedure INST-OI-13 and INST-TRW-8.2.1 to correct the procedure noncompliance. In addition, verified that the chemists completed supplemental training. Refer to the attached checklist for verification of this CAR for more details.

Based on the above supporting documentation and actions, the recommendation is for closure of this CAR.

Block 19a: Verifier: 

Jeff May

Date: 10/27/03

Block 19b: Trend Cause Code: 2.1

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-074

2. Activity Report No. A-03-05

3. Page 1

Of 2

Block 18: Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were evaluated based on closure documentation package provided by the AMWTP during the site visit that occurred on October 15 and 16, 2003. The corrective actions and objective evidence reviewed and found to be satisfactory are as follows:

A. Remedial Action:

All (three hundred eighty-three) affected debris containers associated with CAR 3454 will be reworked using the revised WTS Data report forms and revalidated. CAR 3454 has been issued and identifies the affected containers. At least five container batches identified on CAR 3454 will be available to enable demonstration through the entire project level process for re-assessment by CBFO. The complete rework/revalidation of all remaining containers will be managed as documented on CAR 3454 and will be a work in process at the time of CBFO reassessment. CAR 3454 will not be closed until all noted drums have been re-worked.

Initiate a revision to INST-OI-12, Real Time Radiography to provide clear instruction for entering an inventory of waste items and description of any objects that cannot be identified in a step rather than a note.

Verification Results

Verified that AMWTP modified procedure ^{MCN 10-28-03} INST-OI-12 _{IN} to provide clear instructions for entering an inventory of waste item and a description of any objects that can't be identified in a step rather than a note. Refer to the attached checklist for verification of this CAR for more details.

B. Extent and Impact of the Deficiency:

RTR batches have been reviewed; three hundred eighty-three debris drums will be evaluated and reworked. Sludge drums adequately provide a description of the waste items in the waste material parameters.

Verification Results

Verified that AMWTP performed an investigation of the condition adverse to quality and determined that 383 debris drums require rework. AMWTP issued CAR 3454 and NCR 3492 to complete the rework of the BDRs. Refer to the attached checklist for verification of this CAR for more details.

C. Root Cause Determination:

Procedure Problem 2A Defective or Inadequate Procedure

The operational procedure did not clearly communicate the WIPP WAP requirements to the operator for recording the full inventory of waste items identified in the waste container within the comments section of the examination screen. Notes in operational procedures are not used to communicate operator actions, but to provide additional information, thus there was no clear instruction within the procedure directing the operator to document the full inventory of items seen in the examination.

Verification Results

Verified that AMWTP determined that the cause or the condition adverse to quality was that the operational procedure did not clearly communicate the WIPP WAP requirements to the operator for recording the full inventory of waste items identified in the waste container within the comments section of the WTS screen. AMWTP prepared an Investigation and Root Cause Analysis Report AMWTP RCA-03-009, August 28, 2003. Refer to the attached checklist for verification of this CAR for more details.

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-074

2. Activity Report No. A-03-05

3. Page 2 Of 2

D. Corrective Actions to Preclude Recurrence: (Continued)

1. Operators will be trained on the revision made to INST-OI-12, *Real Time Radiography Operations*.
2. Rework the "debris" Batch Data Reports (BDR's) originally used for Audit Objective Evidence, which implements the revised WTS report format. Complete the validation to authenticate the data quality through the "review process".

Verification Results

Verified that AMWTP provided operators with training on the changes to INST-OI-12. In addition, AMWTP reworked the BDRs original used for Audit A-03-05 objective evidence and will rework the remaining containers prior to closure of CAR 3454 and NCR-3492. Refer to the attached checklist for verification of this CAR for more details.

Based on the above supporting documentation and actions, the recommendation is for closure of this CAR.

Block 19a: Verifier: _____



Jeff Mas

Date: 10/27/03

Block 19b: Trend Cause Code: 2.1

CBFU CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-075

2. Activity Report No. A-03-05

3. Page 1

Of 1

Block 18: Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were evaluated based on closure documentation package provided by the AMWTP during the site visit that occurred on October 15 and 16, 2003. The corrective actions and objective evidence reviewed and found to be satisfactory are as follows. Refer to the attached checklist for verification of this CAR for more details.

A. Remedial Action:

Verification Results

CAR 3420 was issued to document the procedure violation identified by NCR 3369 and a corrective action plan has been approved.

Procedure INST-OI-13 was modified to correct the procedure noncompliance.

Procedure INST-TRUW-8.2.1 was modified to correct the procedure noncompliance.

Supplemental training was provided for all chemists.

B. Corrective Actions to Preclude Recurrence:

Verification Results

Procedure MP-Q&SI-5.4, Section 5.3.1 was revised to clarify the requirement to document procedural violations on a corrective action report

Based on the above supporting documentation and actions, the recommendation is for closure of this CAR.

Block 19a: Verifier:


Jeff May

Date: 10/27/03

Block 19b: Trend Cause Code: 2.1

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-076

2. Activity Report No. A-03-05

3. Page 1 Of 1

Block 18: Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were evaluated based on closure documentation package provided by the AMWTP during the site visit that occurred on October 15 and 16, 2003. The corrective actions and objective evidence reviewed and found to be satisfactory are as follows. Refer to the attached checklist for verification of this CAR for more details.

A. Remedial Action:

Verification Results

Acting Notification Remedial Action Memorandum # BJT-01-2003, Dated: 09/04/03 was verified issued to the WWIS Manager (AMWTP Waste Certification Official) by the AK Expert. There was no data entered into the WWIS Production Database, therefore, no corrections required.

B. Corrective Actions to Preclude Recurrence:

Verification Results

AMWTP Procedure MP-TRUW-8.13, Rev. 6, Section 4.4.3.3 was verified to instruct the AK Experts to notify the AMWTP WCO when one of the WIPP tracked radioisotopes is identified, thus requiring AK resolution.

AMWTP Procedure MP-TRUW- 8.16, Rev. 6, "WWIS Data Transfer", Appendix "A" was verified to require WIPP tracked radioisotopes to be reported for every assay examination. When activity of a radionuclide is less than or equal to the minimum detectable activity (MDA), the value is reported as less than "LLD".

Based on the above supporting documentation and actions, the recommendation is for closure of this CAR.

Block 19a: Verifier: _____

Jeff May

Date: 10/27/03

Block 19b: Trend Cause Code: 2.1

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 03-077

2. Activity Report No. A-03-05

3. Page 1 Of 1

Block 18: Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were evaluated based on closure documentation package provided by the AMWTP during the site visit that occurred on October 15 and 16, 2003. The corrective actions and objective evidence reviewed and found to be satisfactory are as follows. Refer to the attached checklist for verification of this CAR for more details.

A. Remedial Action:

Verification Results

Documents submitted to the RMC without signed transmittals were segregated and placed on hold by the responsible custodian.

All document packages identified in question were reviewed and resubmitted to RMC using records transmittal form # 1044. The following record transmittals were verified signed and dated by the Records Custodian, as required. The document transmittals listed below, referenced those BDR packages previously identified in CBFO CAR 03-077.

- AM-BN-T-4718, Dated: 08/20/03
- AM-BN-T-4722, Dated: 08/21/03
- AM-BN-T-4723, Dated: 08/20/03
- AM-BN-T-4897, Dated: 09/29/03
- AM-BN-T-4776, Dated: 09/02/03
- AM-BN-T-4941, Dated: 10/15/03

B. Corrective Actions to Preclude Recurrence:

Verification Results

A briefing was presented to all RMC Custodians to ensure understanding of the requirements of the AMWTP Procedure MP-DOC-18.2 regarding the transmittal of documents as a QA record.

Record Custodians were also sent a memorandum with a subject of "Record Custodian Compliance Expectations" which transmitted a packet that each custodian was required to read and sign the memorandum indicating that they understand the record custodian requirements for their area and that records may not be submitted to the Record Center without an accompanying Form 1044.

These actions were verified via AMWTP Training Rooster, dated 08/19/03, of which reflected a briefing on the applicable sections of AMWTP Procedure MP-DOC-18.2. The Senior Document Specialist conducted the briefing and review of the signed memorandums.

Based on the above supporting documentation and actions, the recommendation is for closure of this CAR.

Block 19a: Verifier: 

Jeff Mar

Date: 10/27/03

Block 19b: Trend Cause Code: 2.1