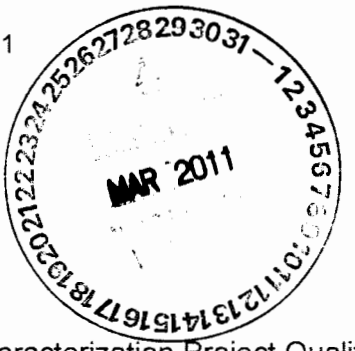
Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221
March 28, 2011



Mr. D. K. Ploetz, Manager
Central Characterization Project
Washington TRU Solutions, LLC
P.O. Box 2078
Carlsbad, NM 88221 – 2078

Subject: CBFO Audit Report for Audit A-11-06, Central Characterization Project Quality Assurance Program

Dear Mr. Ploetz:

The Carlsbad Field Office (CBFO) performed the subject audit March 1-3, 2011. The audit team concluded that the Central Characterization Project (CCP) Quality Assurance Program (QAP) continues to adequately address the upper-tier requirements of the CBFO *Quality Assurance Program Document.* Furthermore, the audit team concluded that the CCP QAP and implementing procedures evaluated were satisfactorily and effectively implemented. The audit report is enclosed.

As described in the report, the audit team identified two Conditions Adverse to Quality (CAQ), one isolated CAQ that was corrected during the audit, and four Observations. The team offered two Recommendations for your consideration in enhancing the program.

If you have any questions concerning this report, please contact me at (575) 234-7491.

Sincerely,

D. S. Miehls

Dennis S. Miehls
Senior Quality Assurance Specialist

Enclosure

cc: w/enclosure

M. Navarrete, CBFO	*ED	R. Lee, EPA	ED
J. R. Stroble, CBFO	ED	S. Zappe, NMED	ED
N. Castaneda, CBFO	ED	S. Holmes, NMED	ED
C. Fesmire, CBFO	ED	J. Kieling, NMED	ED
D. Haar, WTS/CCP	ED	T. Kesterson, DOE OB WIPP NMED	ED
V. Cannon, WTS/CCP	ED	D. Winters, DNFSB	ED
A. Fisher, WTS/CCP	ED	G. Lyshik, LANL-CO	ED
M. Walker, WTS/CCP	ED	P. Gilbert, LANL-CO	ED
Y. Salmon, WTS/CCP	ED	P. Hinojos, CTAC	ED
T. Peake, EPA	ED	P. Y. Martinez, CTAC	ED
M. Eagle, EPA	ED	WIPP Operating Record	ED
E. Feltcorn, EPA	ED	CBFO QA File	
R. Joglekar, EPA	ED	CBFO M&RC	
S. Ghose, EPA	ED	*ED denotes electronic distribution	

CBFO:OQA:DSM:MAG:11-0503:UFC 2300.00

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U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE

AUDIT REPORT

OF THE

WASHINGTON TRU SOLUTIONS (WTS)

CENTRAL CHARACTERIZATION PROJECT (CCP)

CARLSBAD, NEW MEXICO

AUDIT NUMBER A-11-06

CCP QUALITY ASSURANCE PROGRAM

March 1 - 3, 2011

Prepared by: Priscilla Y Martinez **Date:** 3-28-11
Priscilla Y. Martinez, CTAC
Audit Team Leader

Approved by: Martin P. Navarrete **Date:** 3-28-11
Martin P. Navarrete, CBFO
Acting Director, Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-11-06 was conducted at the Washington TRU Solutions (WTS) Central Characterization Project (CCP) offices in Carlsbad, NM, March 1 - 3, 2011. The purpose of the audit was to evaluate the sustained adequacy, implementation, and effectiveness of the WTS CCP Quality Assurance Program (QAP), established for controlling quality-affecting activities associated with CCP characterization and certification of transuranic (TRU) waste destined for disposal at the Waste Isolation Pilot Plant (WIPP).

The audit resulted in the identification of nine concerns in the areas of documents, personnel qualification and training, procurement, and software quality assurance (SQA). Two concerns were identified that necessitated the generation of a corrective action report (CAR) (see section 6.1). One condition adverse to quality (CAQ) was identified in the area of SQA, which was determined to be minor and isolated in nature, and was corrected during the audit (CDA) (see section 6.2). Four concerns were identified in the areas of personnel qualification and training and documents, which were determined to be Observations (see section 6.3). Two concerns were identified in the areas of procurement and SQA, which were determined to be Recommendations (see section 6.4).

Overall, the audit team concluded that the CCP QAP continues to adequately address applicable upper-tier requirements and remains satisfactorily implemented and effective.

2.0 SCOPE AND PURPOSE

2.1 Scope

The scope of the audit included evaluations of the CCP QAP plans, procedures, and resulting documents and records demonstrating the performance of quality-affecting activities associated with the characterization and certification of TRU waste.

The following areas were evaluated:

Quality Assurance

- Organization and QA Program
- Personnel Qualification and Training
- Quality Improvement (CARs, Nonconformance Reports [NCRs], and Trending Analysis)
- Documents
- Records
- Work Processes
- Procurement and Graded Approach
- Inspection and Testing
- Assessments
- SQA

Evaluation of the CCP QAP was based on current revisions of the following documents:

- DOE/CBFO-94-1012, *Quality Assurance Program Document* (QAPD)
- CCP-PO-001, *CCP TRU Waste Characterization Quality Assurance Project Plan* (QAPjP)
- CCP-PO-002, *CCP Transuranic Waste Certification Plan*
- Applicable CCP and WTS quality assurance implementing procedures

2.2 Purpose

The audit was conducted to determine the degree to which the CCP QAP continues to provide adequate controls governing the characterization and certification of TRU waste destined for disposal at the WIPP.

3.0 AUDIT TEAM AND INSPECTORS

AUDITORS/TECHNICAL SPECIALISTS

Dennis S. Miehls	Audit Team Management Representative, CBFO Quality Assurance Office
Priscilla Y. Martinez	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC)
Jack Walsh	Auditor, CTAC
Mario Chavez	Auditor, CTAC
Tammy Bowden	Auditor, CTAC
Katie Martin	Auditor, CTAC
BJ Verret	Auditor, CTAC
Harley Kirschenmann	Auditor, CTAC
Greg Knox	Auditor, CTAC
Lea Chism	Auditor, CBFO

4.0 AUDIT PARTICIPANTS

CCP personnel involved in the audit process are identified in Attachment 1. A pre-audit conference was held in the CBFO Skeen-Whitlock Building in Carlsbad, NM, on March 1, 2011. Daily audit briefings were held with CCP management and staff to discuss issues, potential deficiencies, and audit progress. The audit was concluded with a post-audit conference held in the CBFO Skeen-Whitlock Building on March 3, 2011.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The following sections identify each of the QAP elements evaluated during the course of this audit. For each element, the audit team evaluated the associated implementing plans and procedures to verify the adequate flow-down of upper-tier requirements, conducted interviews with responsible personnel, and reviewed randomly selected documents and records to determine the degree to which the CCP QAP is effectively implemented.

Nine concerns were noted during the audit and are further described in the respective areas in which they were identified. The audit team evaluated these concerns and determined that the CCP QAP continues to be adequately established, satisfactorily implemented, and effective in achieving the desired results.

Attachment 1 identifies the CCP personnel contacted during the audit. Attachment 2 is a Summary of the Audit Results. Attachment 3 lists the documents reviewed.

5.2 Quality Assurance Activities

Organization and QA Program

The audit team reviewed the CCP QAPjP, CCP Waste Certification Plan, and QA implementing procedures established for documenting the CCP QAP to ensure that they adequately address the applicable upper-tier requirements of the CBFO QAPD. The audit team interviewed management and QA management personnel and reviewed documentation, including organization flow charts. Interviews with QA management were conducted to ensure the independence of the QA organization, direct access to responsible management at a level where appropriate action could be effected, and independence from cost and schedule considerations.

It was concluded that the QA organization has the required authority, independence, access to work areas, and organizational freedom necessary to perform assigned responsibilities.

The audit team interviewed the CCP QA Manager and reviewed documentation to verify the implementation and effectiveness of the QAP. Established adequacy was verified for the technical and QA training for personnel performing activities subject to the QAPD. This is documented in CCP-QP-002, *CCP Training and Qualification Plan.*

In addition to training and qualification, the CBFO QAPD requires that QA programs address and establish provisions for tracking and performing trend analysis of quality problem areas. The audit team interviewed the individual responsible for trending analysis and reviewed associated records, and determined that sufficient trending is performed, documented, and reported as required. This is documented in CCP-QP-014, *CCP Quality Assurance Trend Analysis and Reporting.*

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.1 governing the establishment of the CCP Organization and Quality Assurance Program are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

Personnel Training and Qualification

The audit team conducted interviews with responsible personnel and reviewed training procedures and personnel training records consisting of qualification cards covering a broad spectrum of CCP operational disciplines performed at each host site where CCP performs characterization and certification activities. This included evidence of training for acceptable knowledge (AK), nondestructive examination (NDE), real-time radiography (RTR), nondestructive assay (NDA), headspace gas (HSG), visual examination (VE), and helium leak testing. Also reviewed were table-top job analyses, appointment letters for subject matter experts (SMEs) and visual examination experts (VEEs), and verification of approvals where required. Additionally, reviews were performed, based on documented evidence, to confirm that processes were performed in accordance with approved procedures and that changes/revisions to procedures are communicated and acknowledged, where required, by personnel.

During the course of interviews and reviews of documentation, the audit team identified a potential problem that was communicated to the auditees: not all Qualified Helium Leak Test (HLT) Level III (L) personnel are listed on the List of Qualified Individuals (LOQI). HLT Level III (L) personnel are required by CCP-QP-002 and CCP-QP-030, *CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel*, to be requalified at a minimum every 3 years. Records indicate that there are three approved HLT Level III (L) individuals, but only one of these is identified on the current LOQI. The LOQI is used at the appropriate host sites, for qualification of individual's position and training due dates. (see section 6.3, Observation 4).

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.2 governing personnel qualification and training are adequately addressed, satisfactorily implemented, and effective.

Quality Improvement (CARs, NCRs, and Trend Analysis)

The audit team conducted interviews with responsible personnel and reviewed procedures established for NCRs and corrective action management. Reviews of randomly selected CARs, NCRs, and trend analysis reports were performed to verify that deficiencies were documented, tracked, and resolved, and that trend analysis is conducted and reported as required.

The audit team observed and reviewed the Nonconformance Reporting Module (NCRM) and the Corrective Action Report Module (CARM), which are used in support of tracking and trending conditions adverse to quality.

The audit team reviewed reconciliation reports for NCRs and CARs. Documentation was reviewed to ensure that annual reconciliation reports are submitted to CCP Records in accordance with CCP-QP-008, *CCP Records Management*.

A random sample of NCRs, voided NCRs, CARs, and voided CARs were reviewed. The team verified that both NCRs and CARs are handled in accordance with procedural requirements. A random sample of CBFO reportable NCRs were reviewed and verified to have been processed as required.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.3 governing quality improvement are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

Documents

The audit team conducted interviews with responsible personnel and reviewed randomly selected CCP procedures/documents and resulting records to verify that appropriate preparation, review, approval, issuance, distribution, control and changes are being performed. Reviews also included verifications that procedures used were current and that, where appropriate, obsolete procedures are managed to preclude their use.

During this portion of the audit, four concerns were identified regarding document control processes. The first concern involved procedures that could impact data quality or performance criteria as defined in CCP-PO-001 and CCP-PO-002. Such procedures are required to be submitted to CBFO for approval within five days of project-level review and prior to issuance. Though the site project manager (SPM) is directing the Document Writer to submit documents to CBFO, the SPM is not advising the Document Writer of the five-day time requirement (see section 6.3, Observation 1).

The second concern was identified regarding the procedures that are cross-referenced with CCP-QP-011, *CCP Laboratory Logbooks*. Twenty procedures that are cross-referenced with CCP-QP-011 were reviewed for verification. Four had a freeze file in place to update when revised. Five procedures were already changed and 11 procedures had not necessitated the need for review or updating. These procedures have not been updated in the applicable sections to reflect title changes. References in procedures are not changed until the procedure is revised (see section 6.3, Observation 2). The next concern is regarding the completeness of the CCP Document Control QA records packages. Twelve out of 20 records packages were found to contain incomplete information, obliterated text, misfiled pages, and parts of two different procedures in one file. As required by CCP-QP-010, records generated during the performance of the procedure are maintained as QA records in accordance with CCP-QP-008, which requires records to be legible, accurate, and complete (see section 6.1, CAR 11-020). Also observed during the audit, eight of 18 requested completed records packages had not been created after the document was issued. There is no required

timeframe for creating these documents; however, a potential for loss of information required in the records package exists (see section 6.3, Observation 3).

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.4 governing documents are adequately addressed, satisfactorily implemented, and effective.

Records

The audit team conducted interviews and reviewed procedures for the control of records. Randomly selected records were examined, including record submittals, retrieval requests, transmittal/receiving forms, records inventory and disposition schedules (RIDS), records inventory worksheets, operational logbooks, and laboratory logbooks. Records storage arrangements were evaluated to verify compliance with requirements for the preservation of in-process and completed records. Further, reviews of records were performed to verify accuracy, completion, legibility, and appropriate annotations for corrections when necessary.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.5 governing records are adequately addressed, satisfactorily implemented, and effective. Two concerns were identified in the Documents section pertaining to preparation of records. (see section 6.1, CAR 11-020 and section 6.3, Obs. 3).

Work Processes

The audit team conducted interviews and reviewed various CCP program implementing procedures to verify compliance with work process requirements. Although this audit was conducted at the project office in Carlsbad, NM, evidence (submitted records) of CCP work completed at various TRU waste generator sites was also examined to the extent possible. The few instances where certain work process elements could not be fully verified (such as proper handling, storage and shipping of items, item identification and control, labeling of measuring and test equipment (M&TE), and software version installation) will be included in the scope of future recertification audits performed at the various TRU waste generator sites where the work is performed.

Overall, the audit team concluded that the upper-tier requirements of CBFO QAPD Section 2.1 governing work processes, both at the project office and host sites (evaluated to the extent possible), were adequately addressed, satisfactorily implemented, and effective. No concerns were identified.

Procurement and Graded Approach

The audit team conducted interviews with responsible personnel and reviewed procedures established for the control of procurement activities and graded approach. Review of the procurement process included graded approach as described in CCP-QP-001, *CCP Graded Approach*, and procurement processes identified in CCP-QP-015, *CCP Procurement*; WP 15-PC3609, *Preparation of Purchase Requisitions*; and WP 15-PC3044, *Quality Credit Card Purchases*. Specific documents reviewed included

CCP QA grading level checklists (Attachment 1 to CCP-QP-001), Purchase Requisitions (PRs), Purchase Orders (POs), CCP Receipt Inspection Verification Sheets (Attachment 1 to CCP-QP-026), Quality Credit Card Purchase Logs and forms, and Training Status Reports. In addition, procurement package information such as Integrated Financial Management System (IFMS) information, email, internal memo, or other written correspondence, was reviewed.

The audit team verified that the CCP Graded QA Database is established, up-to-date, and contains the requisite information. QA Grading Determination Checklists are generated if an item to be procured has not previously been graded, and QA Grading Level Determination Checklists are submitted to and maintained in Records Management in fire-rated file cabinets at the CBFO Administrative Building.

The audit team verified that procurement requisitioners have received required training. PRs contain the applicable quality-related information required by WP 15-PC3609. This includes identification of the Quality Level (QL), statement of work, M&TE calibration requirements, and appropriate quality clauses, for example, Certificates of Conformance (C of C). All PRs reviewed were verified not to contain a mixture of QLs. The identification of appropriate personnel reviewing and approving each PR was verified through access to the PeopleSoft database. PeopleSoft is the controlling software for processing PRs. CCP QA initiates Receipt Inspection Verification Sheets and inspection planning. Inspection results are recorded on the CCP Receipt Inspection Verification Sheets, including receipt of C of C/analysis when National Institute of Science and Technology (NIST) traceability is a requirement.

There is only one CCP Q Card holder. This individual was verified to have had the required training. Review of the Q Card Log indicated that calibration services were the only type of Q Card procurements performed during the past year. An approved inspection plan is in place for calibration services.

One concern was identified during this review. Procedure CCP-QP-001, *CCP Graded Approach,* Attachment 1 and WP 15-PC3609, Section 1.2 need clarification regarding whether items procured as Commercial Grade Items or as formal Dedicated Commercial Grade Items are processed in accordance with WP 09-CN3040. Current wording of the procedure does not clearly identify if an item identified as commercial grade from Attachment 1 is subject to the formal Dedicated Commercial Grade Item process. Definitions are provided in WP 09-3040 for Dedicated Commercial Grade Items and Commercial Grade Items (see section 6.4, Recommendation 1).

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.3 governing procurement are adequately addressed, satisfactorily implemented, and effective.

Inspection and Testing

The audit team conducted interviews with responsible personnel and reviewed procedures for the control of inspection and testing activities. Randomly selected

Receipt Inspection Verification Sheets were reviewed to verify compliance with requirements for inspection. This review included evaluations to determine proper inspection planning, performance, review, and acceptance of required documents. As a result, the audit team determined that inspection activities performed are compliant with requirements.

The audit team reviewed CCP-QP-027, *CCP Test Control*, addressing requirements and responsibilities for testing activities. The audit team also reviewed CCP-CM-030, *CCP High Energy Real-Time Radiography (Equipment #HE-RTR-01) Site Acceptance Test Plan for Hanford.* Verification was performed to confirm compliance with requirements.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.4 governing inspection and testing are adequately addressed, satisfactorily implemented, and effective. No concerns were identified.

Control of Measuring and Test Equipment

The audit team conducted interviews with responsible personnel and reviewed procedures for the control of M&TE. Evaluations of evidence included identification and labeling, establishment of recalibration intervals, use of an M&TE recall system, controls for managing out-of-tolerance M&TE, methods for extending recalibration due dates when necessary, and the content of M&TE certificates of calibration. All were verified to be compliant.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.4.5 governing the control of M&TE are adequately addressed, satisfactorily implemented, and effective. No concerns were identified.

Assessments

The audit team interviewed responsible personnel and reviewed procedures established for the performance of both management assessments and quality surveillances. As described in the interface document CCP-PO-008, internal independent assessments of the CCP QAP are performed by the WTS QA organization to provide independent results. Reviews of assessment records and interviews with the CCP QA Manager and the surveillance coordinator confirmed that required assessments are being performed.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 3 governing assessments are adequately addressed, satisfactorily implemented, and effective.

Software QA

The audit team conducted interviews of CCP personnel responsible for software control, witnessed a demonstration of the software problem report/software change control electronic management and tracking system, and reviewed a sample of records to verify implementation of CCP procedures with respect to control of software.

Implementation of the CCP Software QA Processes was evaluated. The execution of the requirements for the development, procurement, maintenance and control of computer software for vendor software, applications within commercial-off-the-shelf (COTS), and CCP-developed applications were evaluated. The evaluation included a review of the development and control of software baselines implemented for several processes including Headspace Gas (HSG), HSG for Transportation (HSG-TRANS), Remote-handled Dose-to-Curie (RH DTC), NDA, and the Project Office Data Center (PODC).

Eleven software artifacts were sampled, covering CCP-QP-022, *CCP Software Quality Assurance Plan*, software Categories 1 through 6, excluding Category 4, which had no activity during the past year. Fifty-nine software artifacts submitted to software configuration management (SCM) from February 2010 to March 2011 were all uniquely identified with a software change order (SCO) number. Thus, of the Category 1 through 6 artifacts, the audit covered roughly 18% of the available population. The following table gives a breakdown of the sampled software artifacts presented in order of the software categories and unique SCO number, as defined in CCP-QP-022.

Category No.	Category Name	SCO #	Software Name
1	COTS	1148	Dicksonware v15.0.0
2	Application within COTS or System Software	1142 1133 1135	FGA Attachment R-L v0 ORNL DTC HFIR 16 gal v0 Report # 342 ORNL DTC HFIR 16 gal v0 Report # 343
3	Qualified Supplier Software	1128 1129	NDA 2000 v 4.0 DNUCE.WSC v 1.0
4	Non-Qualified Supplier Software	NA	NA
5	CCP Software	1091 1102	HAN-AK v2.0 P-TS RL Candidate v1.0
6	Exempt	NA	RadviewHAN.xls v100111 RadviewHAN.xls v100308 RadviewHAN.xls v100429

Several concerns were identified during the audit. One concern over the completeness of the Software Inventory List (SIL) and the SQA-TRU Software Quality Assurance Database were noted and corrected during the audit (see section 6.2, CDA 1). A

Recommendation was provided to management identifying that the SIL and the SQA-TRU QA Database should be assessed for consistency (see section 6.4, Recommendation 2). Two other documented concerns covering the traceability of functional requirements through to the testing and design documentation are noted in CAR 11-021 (see section 6.1).

Overall, even with the noted deviations, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 6 governing software are adequately addressed, satisfactorily implemented, and effective.

6.0 CORRECTIVE ACTIONS, OBSERVATIONS, AND RECOMMENDATIONS

6.1 Corrective Action Reports

During the audit, the audit team may identify Conditions Adverse to Quality (CAQ) and document such conditions on Corrective Action Reports (CARs).

Condition Adverse to Quality (CAQ) – An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies.

Significant Condition Adverse to Quality (SCAQ) – A condition which, if uncorrected, could have a serious effect on safety, operability, waste confinement, TRU waste site certification, regulatory compliance demonstration, or the effective implementation of the QA program.

Two conditions adverse to quality necessitating the generation of CARs were identified as a result of this audit, as described below.

CAR 11-020

CCP Document Control QA records packages are not being completed in accordance with CCP-QP-008. Twelve of 20 records packages were found to contain incomplete information, obliterated text, misfiled pages, and parts of two different procedures in one file. As required by CCP-QP-010, records generated during the performance of the procedure are maintained as QA records in accordance with CCP-QP-008, which requires records to be legible, accurate, and complete.

CAR 11-021

No objective evidence was provided to verify that all functional requirements for Software Change Order (SCO) #1102 (P-75 candidate/supplemental listing module) and SCO #1091 (RL AK module) have been tested. SCO #1091, Attachment 2, block 15 requires regression testing; however, no objective evidence was provided to verify the testing was performed. Also, there is a loss of traceability between the requirements documentation in Section 3.0, which identifies 15 requirements, and the Design Documentation in Section 7.0 for SCO #1091 (RL-AK Module), which lists only seven.

6.2 Deficiencies Corrected During the Audit

During the audit, the audit team may identify CAQs. The audit team members and the Audit Team Leader (ATL) evaluate the CAQs to determine if they are significant. Once a determination is made that the CAQ is not significant, the audit team member, in conjunction with the ATL, determines if the CAQ is isolated requiring only remedial action and therefore can be Corrected During the Audit (CDA). Deficiencies that can be classified as CDA are those isolated deficiencies that do not require a root cause determination or actions to preclude recurrence, and those for which correction of the deficiency can be verified prior to the end of the audit.

Upon determination that the CAQ is isolated, the audit team member, in conjunction with the ATL, evaluates/verifies any objective evidence/actions submitted or taken by the audited organization and determines if the condition was corrected in an acceptable manner. Once it has been determined that the CAQ has been corrected, the ATL categorizes the condition as a CDA.

One deficiency, determined to be minor and isolated in nature, was identified and corrected during the audit, as described below.

CDA 1

During the review of the SIL, a few minor issues were identified. Examples included an incorrect software version number, spreadsheet version was not noted, and software name was not updated on an SCO. This CAQ was not significant and was isolated to the SIL, requiring only remedial action. CCP corrected the issues during the audit and the audit team verified the corrections.

6.3 Observations

During the audit, the audit team may identify potential problems that should be communicated to the audited organization. The audit team members, in conjunction with the ATL, evaluate these conditions and classify them as Observations using the following definition.

Observation – A condition that, if left uncorrected, could result in a CAQ.

Once a determination is made, the audit team member, in conjunction with the ATL, categorizes the condition appropriately.

Four Observations were noted by the audit team, as described below.

Observation 1

A potential problem exists concerning procedures that could impact data quality or performance criteria as defined in CCP-PO-001 and CCP-PO-002. Such procedures are required to be submitted to CBFO for approval within five days of project-level

review and prior to issuance. Though the SPM is directing the Document Writer to submit documents to CBFO, the SPM is not advising the Document Writer if there is a five-day time requirement.

Observation 2

The procedures that are cross-referenced with CCP-QP-011, *CCP Laboratory Logbook,* have not been updated in the applicable sections to reflect the title changes. Twenty procedures that are cross-referenced with CCP-QP-011 were reviewed for verification. Four had freeze file in place to update when revised. Five procedures were already changed and 11 procedures had not necessitated the need for review or updating. These procedures have not been updated in the applicable sections to reflect title changes. Even though this condition has not affected implementation of the QA program, if left uncorrected could result in a CAQ.

Observation 3

While requesting completed records packages in CCP Document Services, it was noted that eight of the 18 requested records packages were not yet created. There is no required timeframe for creating these documents; however, a potential exists for losing all information required in the records package.

Observation 4

Not all Qualified HLT Level III (L) personnel are listed on the LOQI. HLT Level III (L) personnel are required by CCP-QP-002 and CCP-QP-030 to be requalified at a minimum every 3 years. Records indicate that there are three approved HLT Level III (L) individuals, but only one of these is identified on the current LOQI. The LOQI is used at the appropriate host sites, for qualification of individual's position and training due dates.

6.4 Recommendations

During the audit, the audit team may identify suggestions for improvement that should be communicated to the audited organization. The audit team members, in conjunction with the ATL, evaluate these conditions and classify them as Recommendations using the following definition.

Recommendations – Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing requirements.

Once a determination is made, the audit team member, in conjunction with the ATL, categorizes the condition appropriately.

Two Recommendations were provided as a result of this audit, as described below.

Recommendation 1

Procedure CCP QP-001, *CCP Graded Approach,* Attachment A needs clarification regarding if items are procured as a Commercial Grade Items or as formal Dedicated Commercial Grade Items processed in accordance with WP 09-CN3040. Definitions are provided in WP 09-3040 for a Dedicated Commercial Grade Item and Commercial Grade Item.

Recommendation 2

The audit team recommends that the SIL and the SQA-TRU QA Database be assessed together for consistency.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary of Audit Results
Attachment 3: Documents Audited

PERSONNEL CONTACTED DURING AUDIT A-11-06				
NAME	**ORG/Title**	**PREAUDIT MEETING**	**CONTACTED DURING AUDIT**	**POST AUDIT MEETING**
Billet, Michele	CCP/Training Coordinator	X	X	
Burns, Scott	RCT/WTS/Engineer Software QA		X	
Cannon, Val	CCP/QA Mgr	X	X	
Fisher, A. J.	CCP/Training Manager		X	X
Golden, Jerry	CCP/Engineer Software QA		X	
Gomez, Chris	CCP/QA NCR Coordinator		X	X
Hayes, Jack	CCP/Procurement		X	
Hinojos, Felicia	CCP/Doc Svc Manager	X	X	X
Jones, Laura	CCP/QA Engineer	X	X	
Martin, Ryan	CCP/Records		X	
Morrison, Jim	WITS/Software Dev.		X	
Orr, Derek	RCT/WTS/NDA Support		X	
Pearcy, Mark	CCP/Site Project Mgr	X	X	X
Pearcy, Sheila	CCP/Records Mgr	X	X	X
Ploetz, D. K.	CCP/Mgr		X	
Punchios, Sheri	CCP/Records		X	
Roberts, Nick	CCP/Engineering/Software QA	X	X	X
Rostro, Leslie	RCT/WITS/Administrative Specialist		X	
Sensibaugh, Michael	CCP/Projects Mgr	X	X	X
Smith, Tyrone	CCP/M&TE Custodian		X	
Wade, Louis	CCP/QA Engineer	X	X	X
Walker, Jim	CCP/Projects Control Mgr	X		X
Walker, Mak	CCP/QA CAR Coordinator	X	X	X

Summary of Audit Results

Documents	Concern Classification				QA Evaluation		Technical
	CARs	CDAs	Obs	Rec	Adequacy	Implementation	Effectiveness
Activity					A	S	E
Organization & QA Program					A	S	E
Personnel Qualification & Training			1		A	S	E
Quality Improvement					A	S	E
Documents	1		3		A	S	E
Records					A	S	E
Work Processes					A	S	E
Procurement & Graded Approach					A	S	E
Inspection & Testing				1	A	S	E
Assessments					A	S	E
Software QA	1	1		1	A	S	E
TOTALS	2	1	4	2	A	S	E

Definitions			
E = Effective		CAR = Corrective Action Report	Rec = Recommendation
S = Satisfactory		CDA = Corrected During Audit	A = Adequate
I = Indeterminate		NE = Not Effective	NA = Not Adequate
M = Marginal		Obs = Observation	

Documents Audited During Audit A-11-06

ID	Description	Rev
CCP-CM-030	CCP High Energy Real-Time Radiography (Equipment # HE-RTR-01) Site Acceptance Test Plan for Hanford	0
CCP-PO-001	CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAPjP)	19
CCP-PO-005	CCP Conduct of Operations	21
CCP-PO-008	CCP Quality Assurance Interface with the WTS Quality Assurance Program	9
CCP-QP-001	CCP Graded Approach	5
CCP-QP-002	CCP Training and Qualification Plan	30
CCP-QP-004	CCP Corrective Action Management	10
CCP-QP-005	CCP TRU Nonconforming Item Reporting and Control	19
CCP-QP-006	CCP Corrective Action Reporting and Control	9
CCP-QP-008	CCP Records Management	17
CCP-QP-010	CCP Document Preparation, Approval and Control	21
CCP-QP-011	CCP Laboratory Logbooks	10
CCP-QP-014	CCP Quality Assurance Trend Analysis and Reporting	3
CCP-QP-015	CCP Procurement	10
CCP-QP-016	CCP Control of Measuring, Testing, and Data Collection Equipment	15
CCP-QP-017	CCP Identification and Control of Items	3
CCP-QP-018	CCP Management Assessment	8
CCP-QP-019	CCP Quality Assurance Reports to Management	6
CCP-QP-021	CCP Surveillance Program	7
CCP-QP-022	CCP Software Quality Assurance Plan	12
CCP-QP-023	CCP Handling, Storage and Shipping	3
CCP-QP-026	CCP Inspection Control	10
CCP-QP-027	CCP Test Control	5
CCP-QP-028	CCP Records Filing, Inventorying, Scheduling, and Dispositioning	12
CCP-QP-030	CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel	8
WP 09-CN3040	Commercial Grade Item Dedication	0
WP 13-QA.03	Quality Assurance Independent Assessment Program	17
WP 15-PC3044	Quality Credit Card Purchases	6
WP 15-PC3609	Preparation of Purchase Requisitions	20