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APR 2012

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

APR - 4 2012

Mr. Michael L. Sensibaugh, Manager
Central Characterization Project
Retrieval, Characterization, and Transportation
Washington TRU Solutions, LLC
P.O. Box 2078
Carlsbad, NM 88221-2078

Subject: Carlsbad Field Office Audit Report for Audit A-12-09, Central Characterization Project Quality Assurance Program

Dear Mr. Sensibaugh:

The Carlsbad Field Office (CBFO) performed Audit A-12-09 of the Central Characterization Project (CCP) Quality Assurance Program (QAP) Activities, March 6 – 8, 2012. The audit team concluded that the CCP QAP continues to adequately address the upper-tier requirements of the CBFO *Quality Assurance Program Document*. Further, the audit team concluded that the CCP implementing procedures evaluated were satisfactorily implemented and effective. The audit report is enclosed.

As described in the report, the audit team identified two Conditions Adverse to Quality (CAQs) and four Observations. The team offered three Recommendations for your consideration in enhancing your program.

If you have any questions, please contact me at (575) 234-7548.

Sincerely,

R. Unger

Randy Unger
Director, Office of Quality Assurance

Enclosure

CBFO:OQA:CF:CC:12-1358:UFC 2300.00

120403

cc: w/enclosure

J. R. Stroble, CBFO	*ED
C. Fesmire, CBFO	ED
R. Farrell, CBFO	ED
N. Castaneda, CBFO	ED
T. Morgan, CBFO	ED
M. Pinzel, CBFO	ED
D.K. Ploetz, WTS/CCP	ED
V. Cannon, WTS/CCP	ED
A. J. Fisher, WTS/CCP	ED
I. Quintana, WTS/CCP	ED
J. Carter, WTS/CCP	ED
M. Walker, WTS/CCP	ED
Y. Salmon, WTS/CCP	ED
J. Hoff, WTS	ED
M. Mullins, WTS	ED
T. Peake, EPA	ED
M. Eagle, EPA	ED
E. Feltcorn, EPA	ED
R. Joglekar, EPA	ED
S. Ghose, EPA	ED
R. Lee, EPA	ED
J. Kieling, NMED	ED
T. Kliphuis, NMED	ED
S. Holmes, NMED	ED
T. Hall, NMED	ED
R. Maestas, NMED	ED
T. Kesterson, NMED/DOE OB	ED
J. Marple, NMED/DOE OB	ED
D. Winters, DNFSB	ED
P. Gilbert, LANL-CO	ED
G. Lyshik, LANL-CO	ED
T. Bowden, CTAC	ED
M. Mager, CTAC	ED
WIPP Operating Record	ED
CBFO QA File	
CBFO M&RC	

*ED denotes electronic distribution

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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-12-09

CCP QUALITY ASSURANCE PROGRAM

March 6 – 8, 2012

Prepared by: Tamara D. Bowden **Date:** 3/21/12
Tamara D. Bowden, CTAC
Audit Team Leader

Approved by: R. Unger **Date:** 3 APR 12
Randy Unger, CBFO
Director, Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-12-09 was conducted at the Washington TRU Solutions (WTS) Central Characterization Project (CCP) offices in Carlsbad, NM, March 6 – 8, 2012. 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 personnel qualification and training, documents, records, and software quality assurance (SQA). Two concerns were identified that necessitated the generation of two corrective action reports (CARs) (see section 6.1). The audit team identified four Observations during the evaluation in the areas of personnel qualification and training, documents, and SQA (see section 6.3), and three Recommendations were identified in the areas of personnel qualification and training and documents (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)
- Document Control
- Records
- Work Processes
- Procurement and Graded Approach
- Inspection and Testing
- Control of Measuring and Test Equipment
- Assessments
- Software QA

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

- DOE/CBFO-94-1012, Carlsbad Field Office (CBFO) *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

Courtland G. Fesmire	Management Representative, CBFO
Tamara D. Bowden	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC)
Charlie Riggs	Auditor, CTAC
Jack Walsh	Auditor, CTAC
Katie Martin	Auditor, CTAC
Greg Knox	Auditor, CTAC
Cindi Castillo	Auditor, CTAC
Earl Bradford	Auditor, CTAC
Rick Castillo	Auditor, CTAC
Norman Frank	Auditor, CTAC

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 6, 2012. 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 8, 2012.

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. Although concerns may have been identified during evaluation of those areas, the concerns may pertain to areas other than those 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

5.2.1 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 requirements of the CBFO QAPD. The audit team interviewed management and QA management personnel and reviewed documentation, including organizational 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 CCP 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 CCP QAP. Established adequacy was verified for the technical and QA training for personnel performing activities subject to the CBFO 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 determined that sufficient trending is performed, documented, and reported. This is reflected 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.

5.2.2 Personnel Training and Qualification

The audit team conducted interviews with responsible personnel and reviewed documentation to verify that CCP met the requirements of DOE/CBFO-94-1012, Revision 11, *CBFO Quality Assurance Program Document* (QAPD), and CCP-QP-002, Revision 31, *CCP Training and Qualification Plan.*

The objective evidence reviewed pertains to CCP characterization and certification operations performed at each applicable host site. The evidence included training and qualification records for the following positions or disciplines: acceptable knowledge experts (AKEs), nondestructive assay (NDA), headspace gas (HSG), and visual examination (VE). Helium leak testing and nondestructive examination (NDE) qualification requirements were also verified according to the guidance of the American Society for Nondestructive Testing (ASNT) Recommended Practice Number SNT-TC-1A, implementing procedure CCP-QP-002, and implementing procedure CCP-QP-030, Revision 8, *CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel.*

The audit team reviewed Lists of Qualified Individuals (LOQIs); Table-Top Job Analyses; appointment letters for subject matter experts (SMEs); remote-handled (RH) waste technical staff and visual examination experts (VEEs); and verification of approvals where required. Reviews were also 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 by personnel, where required.

During the course of the interviews and reviews of documentation, the audit team identified three concerns. The first concern pertained to the lack of documentation to show evidence that two CCP positions (RH Waste Radiological Characterization Technical Staff and Nondestructive Assay Expert Analyst) were analyzed to determine task responsibilities, as required by CCP-QP-002, section 3.3.2 and CBFO QAPD section 1.2.1 (see section 6.1, CAR 12-010).

The second concern was identified during the adequacy review of CCP-QP-002. The following bulleted recommendations were made:

- **Section 4.1.2 [E.4]**: *All approved training materials shall be maintained, secured, and controlled in the CCP Training area.*

  The audit team found that approved Table-Top Job Analyses and other training materials are stored in places other than the Training area. Because of the lack of space in the CCP Training area, this section should be updated to allow for storage of training materials outside of the CCP Training area.

- **Section 4.1.2 [H]**: *Unsatisfactory performance will result in disqualification by the CCP Manager responsible for Training.*

  The audit team recommends adding verbiage after the first sentence to clarify that once disqualified, the operator is removed from the applicable LOQIs and the must successfully complete the initial CCP Qualification Card to re-establish qualification. If this instruction is not added to the procedure, there is a high probability or potential for an unqualified individual to remain on applicable LOQIs and continue to operate after disqualification by the CCP Training Manager.

- Attachment 4 – *CCP Test Drum Data Sheet for Contact-Handled Waste (Continued)*:

  The second page of the Data Sheet is missing a form field #7.

- Attachment 5 – *Training Container Instructions*:

  Section 2.0 instructs completion of Blocks 1-5 of Attachment 6, Training Container Evaluation Data Sheet. The instruction should be to complete Blocks 1-4.

  Section 3.0 instructs documentation of discrepancies on Block 6 of Attachment 6; this should be done on Block 5.

  Section 4.0 instructs recording of "pass" or "fail" on Block 7 of Attachment 6; this should be recorded on Block 6.

- Attachment 6 – *Training Container Evaluation Data Sheet:*

  This attachment is missing a form field #8.

Although this second concern was identified during the evaluation of Personnel Qualification and Training, it ultimately pertains to document control. It has been offered to CCP management as a Recommendation (see section 6.4, Recommendation 1).

The third concern pertains to the current CCP Training system. The current system used for maintaining training qualification or requalification status for CCP operational personnel is a manual system. Currently, the LOQI, which is only a tool, is being utilized to maintain personnel qualification and requalification status and it is the determining factor for when to issue requalification cards or re-qualify personnel. There is no automated system in place. After interviews with CCP Training personnel, it was determined that the current manual system is cumbersome and poses a potential risk for human error.

The audit team recommends that a more modern, automated system of maintaining personnel status should be developed and utilized to enhance the program for qualification and requalification tracking (see section 6.4, Recommendation 3).

During the previous CCP QA All-Sites Audit (A-11-06), the following Observation was identified:

"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 to be re-qualified at a periodic basis. Records show that there are three approved HLT level III (L) individuals, but only one of these is identified on the current LOQI."

The audit team re-evaluated this Observation. CCP Training is currently tracking all qualified HLT Level III (L) personnel on the applicable LOQI.

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.

5.2.3 Quality Improvement (CARs, NCRs, and Trend Analysis)

The audit team conducted interviews with responsible personnel and reviewed procedures established for nonconformance reports and corrective action management. Reviews of randomly selected CARs, NCRs, and trend analysis reports were performed to verify that deficiencies are being 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). These modules 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 in accordance with CBFO QAPD requirements.

One Recommendation was identified and provided for CCP management consideration. CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*, Revision 21, became effective on March 5, 2012, which was one day prior to the beginning of the audit. The audit team identified two NCRs generated on March 5, 2012, using CCP-QP-005, Revision 20. The justification given was that the two NCRs (NCR-SRS-0256-

12 and NCR-SRS-0257-12), which were generated at Savannah River Site, were issued when Revision 20 was still in effect.

The audit team recommends that CCP does not revise procedures during the middle of a work shift. Although this Recommendation was identified during the evaluation of Quality Improvement, it actually pertains to Document Control (see section 6.4, Recommendation 2).

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.

5.2.4 Document Control

The audit team conducted interviews with responsible personnel and reviewed randomly selected CCP procedures/documents and resulting records to verify the 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 so as to preclude their use.

Two concerns were identified regarding records developed during the document preparation/revision process. The first concern pertained to QA records created during the document creation/revision process. The QA records in document review records packages have significantly changed since the last audit. Some of the information formerly contained in the packages is no longer part of the records package. Therefore, the QA records requirements for such packages may not have been completely identified. The second concern pertained to a requirement in the CBFO QAPD, which requires evidence of review document resolution to be listed on the organization's Records Inventory and Disposition Schedule (RIDS). This verbiage is not listed on the RIDS; therefore, the documentation is not being maintained as part of the document review records packages. The two concerns were combined, documented as CAR 12-011, and issued under a separate cover letter (see section 6.1, CAR 12-011).

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

5.2.5 Records

The audit team conducted interviews and reviewed procedures for the control of records. Randomly selected records were examined, including records submittals, transmittal/receiving forms, 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, completeness, legibility, and appropriate annotations for corrections when necessary.

Two Observations were identified pertaining to CCP records packages. The first Observation pertained to a missing notation on a transmittal for an Unclassified Controlled Nuclear Information (UCNI) document. The document contained an "UCNI" number so no security risk occurred (see section 6.3, Observation 1).

During the review of CCP records packages and transmittal/receiving forms, it was identified that one CCP batch data report (BDR) page contained highlighter markings. Also, the audit team identified that additional information was added to the CCP Radiography Independent Technical Reviewer Checklist of Batch Data Report INRTR5120001. The additional information was dated, but was not initialed (see section 6.3, Observation 2).

Overall, the audit team concluded that the upper-tier requirements in the CBFO QAPD section 1.5 governing Records are adequately addressed, satisfactorily implemented, and effective.

5.2.6 Work Processes

The adequacy of CCP-PO-005, *CCP Conduct of Operations*, Revision 22, as related to work processes, was evaluated during this audit. The CCP Standing Order Index and Operator Aids Index for the project and generator sites (Los Alamos National Laboratory, Sandia National Laboratories, and Idaho National Laboratory), required reading documentation, and CCP Surveillance Program were reviewed and personnel were interviewed.

CCP Conduct of Operations related to work processes were determined to be adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results. No concerns were identified.

The audit team evaluated the adequacy of the CCP-QP-023, *CCP Handling, Storage, and Shipping*, Revision 3, against the QAPD, section 2.1.5. It was determined that the CCP procedure captures all flow-down requirements of upper-tier documents. The audit team reviewed the CCP Assessment Schedule documentation and interviewed CCP QA management and personnel. The team determined the need for assessment of CCP's use of special equipment, special protective environments, special tools, tags, and similar items was not required, since these activities are performed by WTS.

Overall, CCP Work Processes activities were determined to be adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results. No concerns were identified.

5.2.7 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, emails, internal memos, and 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, Measuring and Test Equipment (M&TE) calibration requirements, and appropriate quality clauses, such as 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. No concerns were identified.

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

5.2.8 Inspection and Testing

CCP procedure CCP-QP-026, *Inspection Control*, Revision 12, was verified to contain the requirements of the CBFO QAPD, section 2.4. Inspection documentation for

supplies received was examined and qualified Receipt Inspectors were verified to be adequately trained. Documentation was examined and CCP inspection personnel were interviewed.

CCP Inspection Control activities were determined to be adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results. No concerns were identified.

Test control activities, as detailed in CCP-QP-027, *Test Control,* Revision 5, were audited. The adequacy of the procedure was determined to be satisfactory when compared to the CBFO QAPD, Section 2.4. Test plans, and procedure review and approval, were verified to be compliant. Configuration management and CCP QA review and concurrence of Test Control Plans were audited and were found to be adequately implemented. Test procedures and test plans were reviewed and found to contain all required information, including signatures and dates.

CCP Inspection and Testing activities were determined to be adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results. No concerns were identified.

5.2.9 Control of Measuring and Test Equipment

The audit team interviewed personnel and reviewed documentation to verify that CCP meets the requirements of the CBFO QAPD section 2.4.6, Use and Control of Measuring and Test Equipment. The team verified the adequacy of CCP-QP-016, CCP *Control of Measuring, Testing and Data Collection Equipment*, Revision 16. 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 were verified to be compliant.

CCP Control of Measuring and Test Equipment activities were determined to be adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desire results. No concerns were identified.

5.2.10 Assessments

The audit team interviewed the CCP QA Manager and the CCP Surveillance Coordinator and evaluated objective evidence to verify implementation of the assessment processes conducted by CCP, including internal management assessments and surveillances.

The audit team verified that the assessment procedures for management assessments and surveillances were adequate, satisfactorily implemented, and effective.

In addition, the audit team interviewed the CCP QA Manager and the WTS QA Administrative Staff/QSL Coordinator and verified that WTS QA conducts annual independent assessments of the CCP program, as well as independent assessments of suppliers that provide consumable products in support of the CCP program.

The audit team verified that the WTS assessment schedule included the annual audits of the CCP QA program and verified the adequacy of the last two independent assessments. The audit team verified that independent assessments are conducted by WTS qualified auditors. The audit team selected CCP suppliers of consumable products and evaluated audit reports and records associated with placement and maintenance of the suppliers of the WTS QSL.

Overall, the audit team concluded that WTS independent assessments of the CCP QA Program were conducted in accordance with the appropriate WTS QA Independent Assessment Program and that the WTS procedure was adequate, satisfactorily implemented, and effective for performing Independent Assessments of both the CCP overall QA Program and suppliers of CCP consumable products. No concerns were identified.

5.2.11 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 samples 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 Categories: 1) Commercial-off-the-shelf [COTS] Software; 2) Applications within COTS or System Software; 5) CCP Developed Software; and 6) Exempt software were evaluated. Excluded were Category 3, Qualified Supplier Software; and Category 4, Non-Qualified Supplier Software because no examples of this software were included on the Software Inventory Listing (SIL) for the Project Office.

Fifteen software items 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. The following table gives a breakdown of the sampled software items presented in order of the software categories and unique Software Change Order (SCO) number, as defined in CCP-QP-022.

Category No.	Category Name	SCP #	Software Name
1	COTS	1101 1152	GENIE 2000 MCNP5
2	Application within COTS or System Software	1065 1075 1083 1092 1099 1154	WDS Master Template.xls SQS WDS Master Template.xls File Conversion.xls Summary_Statistics.xls Cert Tracker.xls RPD
3	Qualified Supplier Software	N/A – no examples available	N/A – no examples available
4	Non-Qualified Supplier Software	N/A – no examples available	N/A – no examples available
5	CCP Software	822 1022 1029	CCP DataCenter Module for the QA – SQA CCP SQS Integrated Data Center (IDC)
6	Exempt	N/A – SCO not assigned to Exempt	Statistica %RSD Template.xls DoubleTake

Two concerns were identified during the audit. The first concern identified that the more recent records for software do not include the printout of the code or cells and the cell formulas for Excel spreadsheets. Examples include:

- SCO 822, CCP DataCenter Module for the QA – SQA, Version 1.
- SCO 1022, CCP SQS, Version 1
- SCO 1065, WDS Master Template.xls, Version 6
- SCO 1075, SQS WDS Master Template.xls, Version 3
- SCO 1092, Summary_Statistics.xls, Version 1
- SCO 1099, Cert Tracker.xls, Version 0

The audit team suggests that training for the SQA positions should clarify and/or identify what records should be sent to CCP Records so that problems do not arise in the future (see section 6.3, Observation 3).

The second concern pertains to changes/corrections that are being identified and filed into a "Freeze File." Examination of the Freeze File showed that process changes had been identified, but had not been incorporated, even though the actual process was different from that described in procedure CCP-QP-022, Revision 12.

The audit team suggests that when CCP revises CCP-QP-022, the "actual" processes be incorporated into the revision to avoid future issues (see section 6.3, Observation 4).

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD section 6 concerning Software QA 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 CAQs necessitating the generation of CARs were identified as a result of this audit, as described below.

CAR 12-010

Documentation was not provided to show evidence that the following CCP positions were analyzed to determine task responsibilities: RH Waste Radiological Characterization Technical Staff and NDA Expert Analyst.

CCP-QP-002, section 3.3.2 states, *CCP Training supports the CCP Lead SPM in evaluating training and qualification requirements of each position. This may be done by, but is not limited to, evaluating training requirements using a training analysis.* Also, the CBFO QAPD, section 1.2.1 instructs:

> *The responsible organization shall:*
>
> *A. Analyze each job position to determine the task responsibilities of the position subject to the QAPD. The analysis shall identify minimum education, experience, and training prerequisites for each position involved in the planning, performance, or verification of activities subject to the QAPD, commensurate with the scope, complexity, and nature of the work.*

CAR 12-011

Two concerns were identified regarding records developed during the document preparation/revision process. The first concern pertained to QA Records created during the document creation/revision process. The QA Records in document review records

packages have significantly changed since the last audit. Some of the information formerly contained in the packages is no longer part of the records package. Therefore, the QA Records requirements for such packages may not have been completely identified. The second concern pertained to the CBFO QAPD requirement that evidence of review document resolution be listed on the organization's RIDS. This verbiage is not listed on the RIDS; therefore, the documentation is not being maintained as part of the document review records packages. The two concerns were combined, documented as CAR 12-011, and issued under a separate cover letter.

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.

No deficiencies, determined to be minor and isolated in nature, were identified and corrected during the audit.

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

The transmittal for M110_UCNI Electronic File of Historical PDF Source Documents for LANL-4 contains an UCNI Document, dated 11/21/2011, that does not contain an UCNI

statement in the comment section. The document contained an "UCNI" number, so no security risk occurred.

Observation 2

During the review of CCP records packages and transmittal/receiving forms, one CCP BDR page was found to contain highlighter markings. The audit team also found that additional information was added to the CCP Radiography Independent Technical Reviewer Checklist of BDR INRTR5120001. The additional information was dated, but was not initialed.

Observation 3

The more recent records for software do not include the printout of the code or cells and the cell formulas for Excel spreadsheets. Examples include:

- SCO 822, CCP DataCenter Module for the QA – SQA, Version 1
- SCO 1022, CCP SQS, Version 1
- SCO 1065, WDS Master Template.xls, Version 6
- SCO 1075, SQS WDS Master Template.xls, Version 3
- SCO 1092, Summary_Statistics.xls, Version 1
- SCO 1099, Cert Tracker.xls, Version 0

The audit team suggests that training for the SQA positions clarify and/or identify what records should be sent to CCP Records.

Observation 4

Changes and/or corrections to CCP-QP-022 are being identified and filed into a "Freeze File." Examination of the Freeze File showed that process changes had been identified, but had not been incorporated, even though the actual process was different from that described in procedure CCP-QP-022, Revision 12.

The audit team suggests that when CCP revises CCP-QP-022, the actual processes be incorporated into the procedure revision to ensure the correct processes are in use.

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.

The following three Recommendations were provided for CCP management consideration.

Recommendation 1

The following bulleted items were identified during the adequacy review of CCP-QP-002, *CCP Training and Qualification Plan*, and are provided for CCP management consideration:

- **Section 4.1.2 [E.4]**: *All approved training materials shall be maintained, secured, and controlled in the CCP Training area.*

  Approved Table-Top Job Analyses and other training materials are stored in places other than the Training area. Because of the lack of space in the CCP Training area, this section should be updated to allow for storage of training materials outside of the CCP Training area.

- **Section 4.1.2 [H]**: *Unsatisfactory performance will result in disqualification by the CCP Manager responsible for Training.*

  The audit team recommends adding verbiage after the first sentence to clarify that once disqualified, the operator is removed from the applicable LOQIs and the must successfully complete the initial CCP Qualification Card to re-establish qualification. If this instruction is not added to the procedure, there is a high probability or potential for an unqualified individual to remain on applicable LOQIs and continue to operate after disqualification by the CCP Training Manager.

- Attachment 4 – *CCP Test Drum Data Sheet for Contact-Handled Waste (Continued)*:

  The second page of the Data Sheet is missing a form field #7.

- Attachment 5 – *Training Container Instructions*:

  Section 2.0 instructs completion of Blocks 1-5 of Attachment 6, Training Container Evaluation Data Sheet. The instruction should be to complete Blocks 1-4.

  Section 3.0 instructs documentation of discrepancies on Block 6 of Attachment 6; this should be done on Block 5.

  Section 4.0 instructs recording of "pass" or "fail" on Block 7 of Attachment 6; this should be recorded on Block 6.

- Attachment 6- *Training Container Evaluation Data Sheet:*

  This attachment is missing a form field #8.

Recommendation 2

CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*, Revision 21, became effective on March 5, 2012, which was one day prior to the beginning of the audit. The audit team identified two NCRs generated on March 5, 2012, using CCP-QP-005, Revision 20. The justification given was that the two NCRs (NCR-SRS-0256-12 and NCR-SRS-0257-12), which were generated at Savannah River Site, were issued when Revision 20 was still in effect.

The audit team recommends that CCP does not revise procedures during the middle of a work shift.

Recommendation 3

The current system used for maintaining training qualification or requalification status for CCP operational personnel is a manual system. Currently, the LOQI, which is only a tool, is being utilized to maintain personnel qualification and requalification status, and is the determining factor for when to issue requalification cards or re-qualify personnel. There is no automated system in place. After interviews with CCP Training personnel, it was determined that the current manual system is cumbersome and poses a potential risk for human error.

The audit team recommends that a more modern, automated system of maintaining personnel status be developed and utilized to enhance the program for qualification and requalification tracking.

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-12-09				
NAME	**ORG/Title**	**PREAUDIT MEETING**	**CONTACTED DURING AUDIT**	**POST AUDIT MEETING**
Allen, Randall	CTAC/Audits & Assessments Manager	X	X	X
Armijo, Cheryl	CCP/Records Clerk III		X	
Billett, Michele	CCP/Training Coordinator		X	
Burns, Scott	WTS/CCP/Engineering	X		
Cannon, Val	WTS/CCP QAM	X	X	X
Chester, Curtis	WTS/RCT/Eng & Program Support Manager		X	
Fesmire, Court	CBFO/QA Engineer	X	X	X
Fisher, A.J.	WTS/CCP/Senior Technical Advisor	X	X	X
Golden, Jerry	WTS/RCT Engineer		X	
Gomez, C.M.	CCP/QA/NCR Coordinator		X	
Gonzales, Marty	WTS/Procurement Manager		X	
Harvill, Joe	CTAC/Senior Manager		X	
Hayes, Jack	WTS/CCP/Procurement		X	
Holmes, Steve	NMED Observer	X	X	X
Jones, Laura R.	CCP/Quality Assurance Engineer		X	
Keathley, Susan	CCP/Records Analyst		X	
Keller, Jeff	CCP/Document Services/ Technical Editor		X	
Littlefield, Miles	CTAC/Observer		X	X
Martin, Ryan	CCP/Stoller/Training/Records Analyst		X	
McGinnis, E. Ray	URS/Database Administrator/ Software Developer		X	
Mireles, Jessica	WTS/QA Analyst		X	
Morgan, Tom	CBFO/CCP PM		X	
Morrison, Jim	URS/Database Administrator/ Software Developer		X	
Mullins, Mary Ann	WTS/QA Admin		X	
Nesser, Cathy	WTS/Sr. QA Specialist	X	X	
Parker, Tami	CCP/Records Custodian		X	
Payanes, Jose	CCP/Document Services Manager		X	X
Pearcy, Sheila	CCP/Stoller/Records Manager	X	X	X

PERSONNEL CONTACTED DURING AUDIT A-12-09				
NAME	**ORG/Title**	**PREAUDIT MEETING**	**CONTACTED DURING AUDIT**	**POST AUDIT MEETING**
Preciado, Erin	CBFO/Quality Assurance		X	
Punchios, Sheri	CCP/Records Custodian		X	
Reeves, Ron	WTS/CCP/Projects	X	X	
Roberts, Nicholas	WTS/CCP/Software Configuration Management Coordinator/Software Configuration Management Engineer (SCMS/SCME)	X	X	
Sensibaugh, Michael	WTS/CCP/Manager		X	X
Walker, Mak	WTS/CCP/QA/CAR Coordinator		X	

Summary of Audit Results

Documents	Concern Classification				QA Evaluation		Technical
	CARs	CDAs	Obs	Rec	Adequacy	Implementation	Effectiveness
Audit Activity					A	S	E
Organization & QA Program					A	S	E
Personnel Qualification & Training	1			1	A	S	E
Quality Improvement					A	S	E
Documents			1	2	A	S	E
Records	1		2		A	S	E
Work Processes					A	S	E
Procurement & Graded Approach					A	S	E
Inspection & Testing					A	S	E
Assessments					A	S	E
Software QA			1		A	S	E
TOTALS	2	0	4	3	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-12-09

	Procedure Number	Procedure Title	Rev
1	CCP-PO-001	CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAPjP)	20
2	CCP-PO-005	CCP Conduct of Operations	22
3	CCP-PO-008	CCP Quality Assurance Interface with the WTS Quality Assurance Program	9
4	CCP-QP-001	CCP Graded Approach	6
5	CCP-QP-002	CCP Training and Qualification Plan	31
6	CCP-QP-004	CCP Corrective Action Management	10
7	CCP-QP-005	CCP TRU Nonconforming Item Reporting and Control	21
8	CCP-QP-006	CCP Corrective Action Reporting and Control	9
9	CCP-QP-008	CCP Records Management	19
10	CCP-QP-010	CCP Document Preparation, Approval and Control	22
11	CCP-QP-011	CCP Laboratory Logbooks	10
12	CCP-QP-014	CCP Quality Assurance Trend Analysis and Reporting	5
13	CCP-QP-015	CCP Procurement	11
14	CCP-QP-016	CCP Control of Measuring and Testing Equipment	16
15	CCP-QP-017	CCP Identification and Control of Items	3
16	CCP-QP-018	CCP Management Assessment	9
17	CCP-QP-019	CCP Quality Assurance Reporting to Management	6
18	CCP-QP-021	CCP Surveillance Program	7
19	CCP-QP-022	CCP Software Quality Assurance Plan	12
20	CCP-QP-023	CCP Handling, Storage and Shipping	3
21	CCP-QP-026	CCP Inspection Control	12
22	CCP-QP-027	CCP Test Control	5
23	CCP-QP-028	CCP Records Filing, Inventorying, Scheduling, and Dispositioning	14
24	CCP-QP-030	CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel	8
25	WP 13-QA.03	Quality Assurance Independent Assessment Program	19
26	WP 15-PC3044	Quality Credit Card Purchases	8
27	WP 15-PC3609	Preparation of Purchase Requisitions	23