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Department of Energy
Carlsbad Field Office
P. O. Box 3090
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MAY 3 1 2013

MAY 2013

Mr. D.E. Gulbransen, Manager
National TRU Certification Program
Nuclear Waste Partnership, LLC
P.O. Box 2078
Carlsbad, New Mexico 88221-2078

Subject: Transmittal of Audit Report for CBFO Audit A-13-11 of the CCP QAP

Dear Mr. Gulbransen:

The Carlsbad Field Office (CBFO) performed Audit A-13-11 of the Central Characterization Program (CCP) Quality Assurance Program (QAP), April 16-18, 2013. 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 three conditions adverse to quality. The team offered one Recommendation for consideration.

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

Sincerely,

D. S. Miehls

Dennis S. Miehls
Acting Director, Office of Quality Assurance

Enclosure

cc: w/enclosure

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*ED denotes electronic distribution

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U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE

AUDIT REPORT

OF THE

NUCLEAR WASTE PARTNERSHIP LLC (NWP)

CENTRAL CHARACTERIZATION PROGRAM (CCP)

CARLSBAD, NEW MEXICO

AUDIT NUMBER A-13-11

CCP QUALITY ASSURANCE PROGRAM

April 16 – 18, 2013

Prepared by: _____ **Date:** 5/31/13
Rick L. Castillo, CTAC
Audit Team Leader

Approved by: _____ **Date:** 5-31-13
Dennis Miehls, CBFO
Acting Director, Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-13-11 was conducted at the Nuclear Waste Partnership LLC (NWP) Central Characterization Program (CCP) offices in Carlsbad, NM, April 16 – 18, 2013. The purpose of the audit was to evaluate the sustained adequacy, implementation, and effectiveness of the NWP 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 four concerns in the areas of personnel qualification and training and work processes. Two concerns were identified that necessitated the generation of three corrective action reports (CARs) (see section 6.1). The audit team identified no Observations during the evaluations (see section 6.3). One Recommendation was identified in the area of work processes (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 QAP
- 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 M&TE
- Assessments
- Software Quality Assurance (QA)

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

- DOE/CBFO-94-1012, *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 QA 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

Dennis Miehls	Management Representative, CBFO
Rick L. Castillo	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC)
Tamara Bowden	Auditor, CTAC
Paul Gomez	Auditor, CTAC
Greg Knox	Auditor, CTAC
Katie Martin	Auditor, CTAC
Earl Bradford	Auditor, CTAC
B.J. Verret	Auditor, CTAC
Jim Schuetz	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 April 16, 2013. 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 April 18, 2013.

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.

Four concerns were noted during the audit and are further described in respective areas outlined in this report. 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.

The audit team evaluated the implementation and effectiveness of sustained corrective actions for CARs 12-010 (Training) and 12-011 (Records) identified during the previous audit A-12-09. The audit team determined that the corrective actions were successful in precluding recurrence of those issues.

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. QA management personnel confirmed 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.

The audit team concluded that the CCP QA organization has the authority, independence, access to work areas, and organizational freedom necessary to perform assigned responsibilities. The audit team verified no stop-work orders had been implemented over the past year. The performance of independent assessments was verified, which were determined to have been adequately performed for compliance with the QAPD, suggesting that the QA organization has the authority and overall responsibility to independently assess quality affecting organizations.

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 regarding 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. This is reflected in CCP-QP-014, *CCP Quality Assurance Trend Analysis and Reporting*. The audit team verified the completion of two trend reports, CP:12:01451 (*Semiannual Report on the Central Characterization Project Quality Assurance Program: First Half of Calendar Year 2012*) and CP:13:01034 (*Semiannual Report on the National Waste Partnership Quality Assurance Program: Second Half of Calendar Year 2012)*. The reports trend the conditions adverse to quality per procedures CCP-QP-005 for NCRs and CCP-QP-029 for CARs. The audit team determined that trending is performed, documented, and reported as required.

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

5.2.2 Personnel Training and Qualification

The audit team conducted interviews with responsible personnel and reviewed documentation to verify that CCP complies with the requirements of the CBFO QAPD and CCP-QP-002, Revision 34, *CCP Training and Qualification Plan*.

The objective evidence reviewed pertains to CCP TRU waste 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, nondestructive assay (NDA), headspace gas, and visual examination. Helium leak detection and real-time radiography (RTR) qualification requirements were also verified according to the guidance of the American Society for Nondestructive Testing (ASNT) Recommended Practice Number SNT-TC-1A standard, and implementing procedures CCP-QP-002, CCP-QP-030, Revision 8, *CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel*, and CCP-QP-032, Rev. 1, *CCP Written Practice for the Qualification of CCP Pressure Change Leak Testing Personnel*.

The audit team reviewed the Lists of Qualified Individuals; Table-Top Job Analyses; appointment letters for subject matter experts (SMEs); remote-handled waste technical staff, and visual examination experts; and verification of approvals where required. Additionally, it was determined that reviews performed were based on documented evidence to confirm processes were conducted in accordance with approved procedures, and 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 two concerns. The two elements in the first concern were separated into two CARS. The first concern included the following two issues specific to the requirements in CCP-QP-002 (see section 6.1, CARs 13-024 and 13-025):

1. CCP Training Module, CCP-113, CCP Subject Matter Expert/On-the-Job Training Instructor, has a document number, revision number, and effective date. However, changes were made to the electronic version of this module without formal revision. The version of the document used by new Subject Matter Expert/On-the-Job Training (SME/OJT) trainees is the electronic version. It also contains information that is inaccurate (see CAR 13-024).

2. Per CCP-QP-002, Rev. 34, the SPM is required to submit acceptable knowledge (AK)/waste stream training briefing materials, along with the completed briefing sheet(s) to training. During the auditor's review of AK briefings that were submitted to Training by the SPM, six of the 15 did not contain briefing materials. However, the auditee has provided briefing materials for all but one briefing prior to closeout of the audit (see CAR 13-025).

The second concern, identified during the review of CCP Pressure Change Leak Testing Personnel Qualification files and CCP Helium Leak Detection Personnel Qualification files, identified that an ASNT LT-III or ANST LT-III (L) is not signing all exams after grading them (see section 6.1, CAR 13-026).

With the exception of the two concerns described, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.2, 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 identification and control of non-conforming items and corrective action management processes. Review of the Continuous Improvement process included nonconforming item reporting and control as described in CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control,* and corrective action management processes identified in CCP-QP-029, *CCP 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 random sample of NCRs and CARs evaluated were from both generation-level and project-level activities supporting active CCP sites and included examples of voided NCRs, voided CARs, and CBFO reportable NCRs.

The audit team observed and reviewed the Nonconformance Reporting Module and the Corrective Action Report Module. These modules are used in support of tracking and trending conditions adverse to quality. Procedural requirements were verified and the records supporting and providing objective evidence of completion of procedural requirements are maintained as QA records. Successful performance of two real-time demonstrations confirmed that the two systems adequately support the tracking and resolution of 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 NCRs (NCR-LANL-0083-12, NCR-LANL-0187-13, NCR-LANL-0194-13, NCR-LANL-1385-12, NCR-SRS-0164-13, NCR-SRS-0169-13, NCR-SRS-1212-12) and CARs (CAR-ALD-0001-13 and CAR-CCP-0002-13) are managed in accordance with procedural requirements. A random sample of a CBFO reportable NCR (NCR-SRS-0105-12) was reviewed and verified to have been processed in accordance with CBFO QAPD requirements. During the review of NCRs and CARs, the audit also verified that trend codes were being identified on the appropriate forms.

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

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.

With the exception of the first concern related to document control identified in section 5.2.2, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.4, Documents, are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

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.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.5, Records, are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

5.2.6 Work Processes

The adequacy of CCP-PO-005, *CCP Conduct of Operations*, Revision 23, as related to work processes, was evaluated during this audit. The audit team interviewed personnel and reviewed the CCP Standing Order Index, Operator Aids Index for the project and generator sites (Los Alamos National Laboratory (LANL), Sandia National Laboratories, and Idaho National Laboratory (INL)), required reading documentation, and CCP Surveillance Program. Audit team evaluations confirmed compliance with procedural requirements.

The audit team evaluated the adequacy of CCP-QP-023, *CCP Handling, Storage, and Shipping*, Revision 3, in relation to 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 verified procedural compliance through reviews of the CCP Assessment Schedule documentation and interviews with CCP QA management and personnel. The audit team reviewed CCP report SUR-CCP-0001-13 for a surveillance performed on February 26, 2013. The surveillance determined that "CCP does not control any items or materials that require 'special equipment ' or 'special protective environments' ... for storage or shipping as described in CCP-QP-023." Therefore, the audit team has made a recommendation that CCP-QP-023 be canceled (see section 6.4, Recommendation 1).

The audit team evaluated the adequacy of CCP-QP-017, *CCP Identification and Control of Items*, Revision 3, in relation to the QAPD, Section 2.1.3. It was determined that the CCP procedure captures all flow-down requirements of upper-tier documents and is adequately established. The team was unable to verify the implementation and effectiveness of CCP-QP-017 as these activities are exclusively performed at the generator sites and not at the Skeen-Whitlock facility in Carlsbad, NM. Implementation and effectiveness are routinely addressed during annual site recertification audits.

With the exception of the one concern described, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.1, Work Processes, are adequately addressed, satisfactorily implemented, and effective.

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*. The audit team verified that the CCP Graded Approach procedure had been approved by CBFO QA Management as required. Specific documents reviewed included CCP QA grading level checklists (Attachment 1 to CCP-QP-001), Purchase Requisitions (PRs), Purchase Orders, CCP Receipt Inspection Verification Sheets (Attachment 1 to CCP-QP-026), Quality Credit

Card Purchase Logs and forms, and Training Status Reports for Requisitioners and Q-Cardholders.

Additionally, the audit team witnessed a demonstration of the Integrated Financial Management System (IFMS) and the system's ability to demonstrate traceability for procurement package information. The audit team randomly selected both active and completed procurement requisitions and verified that the purchases were identified in the IFMS and that all records were traceable and the completed records had been sent to the CCP Records Management facility.

The audit team verified that the CCP Graded QA Database is established, maintained current, 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 in appropriate records storage areas as required.

The audit team verified that procurement requisitioners and Q-cardholders 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, such as Certificates of Conformance (C of C). The audit team verified the prohibition of mixing different QL requirements on the same PR. The identification of appropriate personnel reviewing and approving each PR was verified through access to the IFMS database. CCP QA initiates inspection planning and Receipt Inspection Verification Sheets when required. Inspection results and receipt of C of C's when National Institute of Science and Technology (NIST) traceability is a requirement are recorded on the CCP Receipt Inspection Verification Sheets when applicable.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.3, Procurement, are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

5.2.8 Inspection and Testing

Procedure CCP-QP-026, *Inspection Control*, Revision 14, was verified to meet the requirements of CBFO QAPD Section 2.4, *Inspection and Testing*. Inspection documentation for supplies received was examined and qualified receipt inspectors were verified to be adequately trained. Examinations of documentation and interviews with CCP inspection personnel verified compliance with procedural requirements.

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.

Test control activities were evaluated per CCP-QP-027, *Test Control*, Revision 6, requirements. Procedure review and approval processes were verified to be compliant.

The audit team determined configuration management and CCP QA review and concurrence of test control plans to be adequately implemented. Additionally, interviews with CCP personnel indicated that no test plans have been developed to the requirements of CP-QP-027 since 2010.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.4, Inspection and Testing, are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

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 CBFO QAPD Section 2.4.6, *Use and Control of Measuring and Test Equipment*. The audit team verified the adequacy of CCP-QP-016, *CCP Control of Measuring, Testing and Data Collection Equipment*, Revision 17. Evaluations of 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 verified compliance to procedural requirements.

One concern was identified when CCP was unable to provide documentation supporting the statement of traceability to a national standard of the calibration standards used by the INL and LANL calibration groups to calibrate several pieces of M&TE. However, new objective evidence was given to the audit team at the end of the audit. The audit team was able to evaluate the new evidence during the audit, and it was determined that it satisfied and adequately addressed the issue. Therefore, the concern was considered to be resolved.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 2.4.6, Use and Control of M&TE, are adequately addressed, satisfactorily implemented, and effective.

5.2.10 Assessments

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

A review of audit and surveillance schedules and logs verified compliance with CCP procedures. Evaluations of randomly selected surveillances and management assessments confirmed CCP personnel are performing assessment activities according to procedural requirements. Additionally, assessment procedures for management assessments and surveillances were verified to be adequate, satisfactorily implemented, and effective.

The audit team interviewed the Assessments Manager and QA administrative staff and verified that NWP 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. Evaluations of the latest CCP QAP independent assessment, I12-12, and audit report, E12-02, for supplier Ranier Rubber, verified compliance to CCP procedures. The audit team verified that independent assessments are conducted by NWP qualified auditors and personnel performing management assessments, audits, and surveillances have training documentation compliant with procedural requirements. The audit team determined that the NWP assessment program for Management Assessments, Audits, and Surveillances of the CCP QAP were conducted in accordance with the appropriate NWP QA Independent Assessment Program procedures.

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 3, Assessments, are adequately addressed, satisfactorily implemented, and effective. No concerns were identified during this portion of the audit.

5.2.11 Software QA

The audit team conducted interviews of CCP personnel responsible for software control, witnessed a demonstration of the Integrated Data Center (IDC), and reviewed samples of software documentation packages. Evaluations of the samples verified implementation of CCP procedures with respect to application of software quality assurance to project office and host location software items. Additionally, an electronic demonstration of the structure of the CCP secure file transfer protocol (sftp) site determined the sftp site is adequately managed and adequately communicates software control data to users.

The audit team evaluated CCP Software Inventory Lists (SILs) and selected a sample of software applications for evaluation. Software document records packages provided evidence of implementation of procedure steps for Software Change Order (SCO), SCO addendum, Software Problem Report and Change Request (SPRCR), and life-cycle documents (Test Plans, Test Reports, Design Documents, Requirements Documents, USER MANUALS, and code listings) that were generated as appropriate for the classification of the individual software applications. The software items evaluated during this assessment activity, covering CCP-QP-022, *CCP Software Quality Assurance Plan*, included software categories: *Applications within COTS or System Software* (Category 2), *Qualified Supplier Software* (Category 3), and *CCP Developed Software* (Category 5). Categories not evaluated included *Commercial-off-the-shelf [COTS] Software* (Category 1), *Non-Qualified Supplier* (Category 4), *Exempt Software* (Category 6), and *Safety Software* (Category 7), as there was no implementation of procedure steps for these categories during the past year.

The following table shows a breakdown of the sampled software items presented in order of the software categories and unique SCO number, as defined in CCP-QP-022.

Category No.	Category Name	SCO #	Software Name
3	Qualified Supplier Software	1158	CCPNDADATA.wsc (this item was reviewed as evidence of new development, modification of the software, and retirement; all of which was performed in a short time frame of approximately one year)
2	Applications within COTS Software	1065	WDS Master Template.xls
2	Applications within COTS Software	1081	WDS FGA TEMPLATE.xlsm
2	Applications within COTS Software	1189	RTR_Data_Sheet.xls
5	CCP Software	1190	IDC Electronic Data Transfer Ver. 1.2 utility application
3	Qualified Supplier Software	1191	Flat File Generator Ver. 1.0 utility application
NOTE: The software documentation packages containing SCO numbers listed above were reviewed and were found to include examples of life-cycle documents (test plans, test reports, design documents, requirements documents, and user manuals) and procedure forms (SIL, SCO, SPRCR, SEC, Software Review Action Item).			
3	Qualified Supplier Software	799	PC-FRAM (example of removal of a software application)
5	CCP Software	1029 Addendum 25	IDC Electronic Data Transfer Ver. 1.8 utility application (example of minor change to a CCP developed software application)
3	Qualified Supplier Software	1158 Addendum 1	CCPNDAData.wsc (install the software on computer HDB5QC1 at the LANL host location)
3	Qualified Supplier Software	1158	CCPNDAData.wsc (new development of the software application)
3	Qualified Supplier Software	1159	NDA 2000 (additional installation of software application on hardware at the LANL host location)
NOTE: The SCO numbers listed above were reviewed to evidence implementation of specific procedure sections as described in parentheses next to the software name.			

Overall, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 6.3, Software Quality Assurance, adequately flow down into the CCP software QA procedure, that procedure steps are satisfactorily implemented, and that the program is effective in application of software QA to project level and host location software items. No concerns were identified during this portion of the audit.

6.0 CORRECTIVE ACTIONS, OBSERVATIONS, AND RECOMMENDATIONS

6.1 Corrective Action Reports

During the audit, the audit team may identify conditions adverse to quality (CAQs), according to the description below, and document such conditions on 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.

Three CAQs necessitating the generation of CARs were identified as a result of this audit, as described below.

CAR 13-024

CCP Training Module CCP-113, *CCP Subject Matter Expert/On-the-Job Training Instructor*, has a document number, revision number, and effective date; yet, changes were made to the electronic version of this module without a formal revision. The version of the document used by new SME/OJT trainees is the electronic version, which contained information that was inaccurate. The auditee provided a revised briefing prior to close-out of the audit. However, the method used to revise and control training materials is not specified.

CCP-QP-002, Rev. 34, *CCP Training and Qualification Plan*, Section 4.1.2 [G.4] states, "Other required formal training materials, such as the Waste Analysis Plan (WAP)/Quality Assurance Project Plan (QAPjP) Briefing or training determined by a training evaluation (i.e., classroom, OJT, or self-paced instruction) shall be approved for format, technical content, and use by a SPM and the Manager Responsible for Training. (a) As initial and continuing qualification and training requirements change, these approved training materials shall be revised by Training. (b) All approved training materials shall be maintained, secured, and controlled by Training."

CAR 13-025

Per CCP-QP-002, Rev. 34, the SPM is required to submit AK/Waste Stream Training briefing materials, along with the completed briefing sheet(s), to Training. During the auditor's review of AK briefings that were submitted to Training by the SPM, six of approximately 15 did not contain briefing materials. However, the auditee provided briefing materials for all briefings prior to close-out of the audit. It was noted that during the audit interviews, Training personnel were not familiar with the requirements to retain the AK briefing materials, as specified per procedural requirements. Training personnel did indicate that they retained the briefing materials with the briefing attendance sheets when they were submitted to Training. CCP-QP-002, Rev. 34, Section 3.2.10 requires both the briefing materials and briefing attendance sheets to be submitted to Training.

CCP-QP-002, Rev. 34, *CCP Training and Qualification Plan*, Step 3.2.10 states, "SPM, submit the briefing materials and the completed briefing sheet(s) (or personnel can send individual email acknowledgements) to Training." Also, Step 5.1.1 states, "Records generated during the performance of this plan are maintained as quality assurance (QA) records in accordance with CCP-QP-008. The records are the following: [F] Training materials (e.g., course presentation, exam) and [G] Completed attendance/briefing forms."

CAR 13-026

During the review of CCP Pressure Change Leak Testing Personnel Qualification files and CCP Helium Leak Detection Personnel Qualification files, it was identified that ASNT LT-III or ANST LT-III (L) personnel are not signing all exams after grading them. CCP-QP-030, Rev. 8, *CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel,* and CCP-QP-032, Rev. 1, *CCP Written Practice for the Qualification of CCP Pressure Change Leak Testing Personnel*, state in Section 4.7 of each procedure, "After the candidate has completed all required examinations in the allotted time, the ASNT LT-III or LT-III (L) shall grade and sign the examinations and/or checklists."

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.

No Observations were identified during the audit.

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 Recommendation was provided for CCP management consideration.

Recommendation 1

The audit team could not find any objective evidence of performance of work to CCP-QP-023, Rev. 4, *CCP Handling, Storage and Shipping*. Additionally, CCP Surveillance Report, SUR-CCP-0001-13, performed February 26, 2013, verified no work had been performed using this procedure. For example, the surveillance report stated, "The surveillance team determined that CCP does not control any items or material that require 'special equipment' or 'special protective environments' ... for storage or shipping as described in CCP-QP-023. Therefore, it is recommended that NWP/CCP determine whether this procedure is needed or should be canceled.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During Audit A-13-11
Attachment 2: Summary of Audit A-13-11 Results
Attachment 3: Documents Audited During Audit A-13-11

PERSONNEL CONTACTED DURING AUDIT A-13-11				
NAME	ORG/Title	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Allen, Randall	CTAC/Audits & Assessments Manager			X
Armijo, Cheryl	CCP/Records Analyst		X	
Billett, Michele	CCP/Training Coordinator		X	
Bowden, Tammy	CTAC/Auditor	X		
Bradford, Earl	CTAC/Auditor	X		
Cannon, Val	NWP/Quality Assurance Program Manager	X	X	
Fisher, A.J.	NWP-CCP/Support Services Manager	X	X	X
Gomez, Paul	CTAC/Auditor	X		
Gulbransen, Ed	CCP/NTPC Manager	X	X	
Harvill, Joe	CTAC/Senior Manager			X
Hoff, Jon E.	NWP/QA Manager	X		
Holmes, Steve	NMED Observer	X	X	X
Jones, Laura R.	CCP/Quality Assurance Engineer		X	
Ledford, Wayne	NWP/QA Specialist	X	X	X
Martin, Katie	CTAC/Auditor	X		
Miehls, Dennis S.	DOE-CBFO/Sr. Quality Assurance Specialist	X		X
Mireles, Jessica	NWP/QA Analyst		X	X
Mueller, Terry	NWP/QA Specialist		X	
Nesser, Cathy	NWP/Sr. QA Specialist	X	X	X
Payanes, Jose	CCP/Document Services Manager		X	
Pearcy, Mark	NWP-CCP/SPM	X	X	X
Pearcy, Sheila	CCP-Stoller/Records Manager	X	X	X
Reeves, Ron	NWP-CCP/Tech. Team Lead Ops		X	
Roberts, Nicholas	NWP-CCP/Software Configuration Management Engineer (SCME)	X	X	
Schuetz, Jim	CTAC/Technical Specialist	X		
Sexton, Chris	NWP/Engineer		X	
Verret, B.J.	CTAC/Auditor	X		
Walker, Mak	NWP-CCP/QA Specialist/CAR Coordinator		X	

Summary of Audit A-13-11Results

Documents	Concern Classification				QA Evaluation		Technical
	CARs	CDAs	Obs	Rec	Adequacy	Implementation	Effectiveness
Audit Activity					A	S	E
QA Program & Organization					A	S	E
Personnel Qualification & Training	3				A	S	E
Quality Improvement					A	S	E
Document Control					A	S	E
Records					A	S	E
Procurement & Graded Approach					A	S	E
Work Processes				1	A	S	E
Inspection & Testing					A	S	E
Assessments					A	S	E
Software QA					A	S	E
TOTALS	3	0	0	1	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-13-11

	Document Number	Document Title	Rev
1	CCP-PO-001	CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAPjP)	20
2	CCP-PO-002	CCP Transuranic Waste Certification Plan	26
3	CCP-PO-005	CCP Conduct of Operations	23
4	CCP-PO-008	CCP Quality Assurance Interface with the WTS Quality Assurance Program	9
5	CCP-QP-001	CCP Graded Approach	7
6	CCP-QP-002	CCP Training and Qualification Plan	34
7	CCP-QP-005	CCP TRU Nonconforming Item Reporting and Control	22
8	CCP-QP-008	CCP Records Management	21
9	CCP-QP-010	CCP Document Preparation, Approval and Control	23
10	CCP-QP-011	CCP Laboratory Logbooks	10
11	CCP-QP-014	CCP Quality Assurance Trend Analysis and Reporting	5
12	CCP-QP-015	CCP Procurement	12
13	CCP-QP-016	CCP Control of Measuring and Testing Equipment	17
14	CCP-QP-017	CCP Identification and Control of Items	3
15	CCP-QP-018	CCP Management Assessment	10
16	CCP-QP-019	CCP Quality Assurance Reporting to Management	7
17	CCP-QP-021	CCP Surveillance Program	8
18	CCP-QP-022	CCP Software Quality Assurance Plan	13
19	CCP-QP-023	CCP Handling, Storage and Shipping	4
20	CCP-QP-026	CCP Inspection Control	14
21	CCP-QP-027	CCP Test Control	6
22	CCP-QP-028	CCP Records Filing, Inventorying, Scheduling, and Dispositioning	15
23	CCP-QP-029	CCP Corrective Action Management	0
24	CCP-QP-030	CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel	8
25	CCP-QP-032	CCP Written Practice for the Qualification of CCP Pressure Change Leak Testing Personnel	1
26	WP 13-QA.03	Quality Assurance Independent Assessment Program	21
27	WP 15-PC3044	Quality Credit Card Purchases	8
28	WP 15-PC3609	Preparation of Purchase Requisitions	25