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Department of Energy
Carlsbad Field Office
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APR 2 0 2016

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Mr. Val Cannon, Manager
Quality Assurance
Nuclear Waste Partnership LLC
P.O. Box 2078
Carlsbad, NM 88221-2078

Subject: Carlsbad Field Office Report for Audit A-16-12, Nuclear Waste Partnership LLC/ Central Characterization Program Quality Assurance Program

Dear Mr. Cannon:

The Carlsbad Field Office (CBFO) performed Audit A-16-12 of the Nuclear Waste Partnership LLC (NWP)/Central Characterization Program (CCP) Quality Assurance Program (QAP), March 29 – 31, 2016. The audit team concluded that the NWP/CCP QAP continues to adequately address the upper-tier requirements of the CBFO Quality Assurance Program Document (QAPD). Further, the audit team concluded that the NWP/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) resulting in two Corrective Action Reports (CARs). One additional CAQ, requiring only remedial action, was corrected during the audit. The team identified no Observations, and one Recommendation was offered to management.

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

Sincerely,

Dennis S. Miehls
Senior Quality Assurance Specialist

Enclosure

cc: w/enclosure

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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-16-12
NWP/CCP QUALITY ASSURANCE PROGRAM

March 29 – 31, 2016

Prepared by: Tamara D. Ackman
Tamara D. Ackman, CTAC
Audit Team Leader

Date: 04/15/16

Approved by: D. J. Mills FOR
Michael R. Brown, Director
CBFO Office of Quality Assurance

Date: 4-20-16

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-16-12 was conducted at the Nuclear Waste Partnership LLC (NWP) Central Characterization Program (CCP) offices in Carlsbad, NM, March 29 – 31, 2016. 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. Two of the four concerns were determined to be conditions adverse to quality resulting in the issuance of two Corrective Action Reports (CARs) (see section 6.1). One additional condition adverse to quality required only remedial action and was corrected during the audit (CDA) (see section 6.2). There were no Observations (see section 6.3) identified. The remaining concern was offered for management consideration as a Recommendation (see section 6.4).

The conditions resulting in CARs were individually and collectively evaluated and determined not to negatively affect the overall adequacy and implementation of the NWP/CCP QAP. As a result, the audit team concluded that the NWP/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 NWP/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 Quality Assurance Program (including Trend Analysis & Quality Assurance Reports to Management)
- Personnel Qualification and Training
- Quality Improvement (WIPP Forms & Nonconformance Reports [NCRs])
- Document Control
- Records
- Work Processes
- Procurement and Graded Approach
- Inspection and Testing
- Assessments
- Sample Control
- Software Quality Assurance

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

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

2.2 Purpose

The audit was conducted to determine the degree to which the NWP/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

AUDITORS

Dennis Miehls	Management Representative, CBFO
Tamara D. Ackman	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC)
Roger Vawter	Auditor, CTAC
Prissy Martinez	Auditor, CTAC
Jack Walsh	Auditor, CTAC
Cindi Castillo	Auditor, CTAC
Paul Gomez	Auditor, CTAC
Bob Prentiss	Auditor, CTAC
Gene Safley	Auditor-in-Training, Sandia National Laboratories
Katie Martin	Auditor/Technical Specialist, CTAC
Jim Schuetz	Auditor/Technical Specialist, CTAC

4.0 AUDIT PARTICIPANTS

NWP/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 29, 2016. Daily audit briefings were held with NWP/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 31, 2016.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The following sections identify each of the NWP/CCP 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 NWP/CCP QAP is effectively implemented.

Four concerns were noted during the audit and are further described in respective areas outlined in this report. Concerns may pertain to areas other than the area in which they were identified.

The audit team also evaluated the implementation and effectiveness of sustained corrective actions for CARs 15-034, 15-035, and 15-038 identified during CBFO Audit A-15-12, NWP/CCP QA Program (All Sites), conducted April 7–9, 2015. The audit team determined that the corrective actions were successful in precluding recurrence of those issues.

Attachment 1 identifies the 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 following documents and QAP implementing procedures to ensure that they adequately address the applicable requirements of DOE/CBFO-94-1012, Rev. 12, *CBFO Quality Assurance Program Document* (QAPD), for CCP-related activities:

- WP 13-1, Rev. 36, *NWP Quality Assurance Program Description*
- CCP-PO-001, Rev. 22, *CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAPjP)*
- CCP-PO-002, Rev. 27, *CCP Transuranic Waste Certification Plan*

The overall NWP QA Program Description is contained in WP 13-1. QAP requirements specifically applicable to CCP-related activities are contained in CCP-PO-001, Section C5 and Attachment 1, and in CCP-PO-002, Section 5.0, with the exception of both the corrective action program and the surveillance program, which are implemented under WP 13-1 program requirements. Standing Orders CCP-SO-107 and CCP-SO-116 have been issued to address the current corrective action program and surveillance program to be followed.

The audit team interviewed CCP and QA management personnel and reviewed documentation, including organizational charts. Interviews with QA management were conducted to ensure the independence of the QA organization, to verify the organization has direct access to responsible management at a level where appropriate action could be effected, and to confirm its independence from cost and schedule considerations. The audit team 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 reviewed the methods for tracking and performing trend analysis of problem areas. This included review of CCP trend reports prepared by the CCP Site QA Engineers and CCP semiannual reports required by the following implementing procedures:

- CCP-QP-014, Rev. 7, *CCP Quality Assurance Trend Analysis and Reporting*
- CCP-QP-019, Rev. 8, *CCP Quality Assurance Reporting to Management*

During last year's audit, CAR 15-038 was issued and concerned the preparation of trend reports for sites without an assigned QA Engineer. As part of the CAR corrective action, CCP-QP-014 was revised to require trend report input only from sites with an assigned QA Engineer and trend report data for all sites would be contained in the CCP semiannual reports prepared under CCP-QP-019. Review of this area determined the corrective action for CAR 15-038 was effectively implemented.

The audit team concluded that the upper-tier requirements in CBFO QAPD, Section 1.1, *Organization and Quality Assurance Program*, are adequately addressed, satisfactorily implemented, and effective.

5.2.2 Personnel Qualification and Training

The audit team conducted interviews with responsible personnel and reviewed documentation to verify that CCP met the requirements of the CBFO QAPD and implementing procedure CCP-QP-002, Rev. 39, *CCP Training and Qualification Plan.*

The objective evidence reviewed pertains to qualification of personnel who are involved with characterization and certification operations performed at each CCP contract host site. The evidence included training and qualification records for multiple disciplines, including real-time radiography (RTR), acceptable knowledge (AK), nondestructive assay (NDA), visual examination (VE), dose-to-curie (DTC), and project level.

RTR, helium leak detection (HLD), and pressure change leak testing (PCLT) qualification requirements were 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, Rev. 9, *CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel*, and CCP-QP-032, Rev. 2, *CCP Written Practice for the Qualification of CCP Pressure Change Leak Testing Personnel.*

The audit team reviewed qualification packages for applicable CCP personnel (including RTR operators, NDA operators, VE operators, independent technical reviewers, AK experts, HLD & PCLT Level II (L) and Level III (L) personnel, and project management staff. Other objective evidence reviewed included Lists of Qualified Individuals and appointment letters for subject matter experts, NDA expert analysts, remote-handled (RH) waste technical staff, and VE experts for each applicable CCP contract host site.

The process for required reading/lessons learned is established as required by CCP-PO-005, Rev. 27, *CCP Conduct of Operations*, and training is assigned by cognizant managers. Documented evidence of required reading receipt acknowledgments are kept on file in the CCP Training department.

During the evaluation of the records process, one concern relative to personnel qualification and training was identified. The audit team recommends that a re-evaluation be performed of the table-top job analysis (TTJA) for CCP Records Center records custodians (RCs) and facility records custodians (FRCs) at the host sites. Initially a TTJA was performed and subsequently required a qualification card for the positions, but the most current TTJA no longer requires issuance of the qualification cards.

There is no qualification required for RCs or FRCs; therefore, the audit team recommends that the word "qualified" be removed from the verbiage in section 2.2.1 of CCP-QP-008, *CCP Records Management*, Rev. 25 (see section 6.4, Recommendation 1). This concern is also discussed in section 5.2.5 of this report.

The audit team concluded that the CCP Training and Qualification Program is adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

5.2.3 Quality Improvement (NCRs and WIPP Forms)

Nonconformance Reporting

The audit team reviewed implementing procedure CCP-QP-005, Rev. 25, *CCP TRU Nonconforming Item Reporting and Control,* to determine the degree to which the procedure adequately addresses upper-tier requirements. The audit team interviewed the CCP Project Office QA Engineer and reviewed the following randomly selected contact-handled (CH) and RH waste nonconformance reports (NCRs) issued from various sites:

NCR-ORNL-0063-15
NCR-ORNL-0117-15
NCR-ORNL-0122-15
NCR-ORNL-0126-15
NCR-RHANL-0164-16
NCR-RHORNL-0271-16
NCR-LANL-0029-15
NCR-INL-0015-15
NCR-RHSNL-0344-15
NCR-RHANL-0413-15
NCR-RHINL-0224-15
NCR-RHANL-0214-15

NCR-SRS-0303-16	NCR-CCP-0349-15
NCR-CCP-0348-15	NCR-INL-0091-15
NCR-CCP-0351-15	NCR-RHINL-0229-15
NCR-SRS-0329-15	NCR-LANL-0024-15
NCR-RHSRS-0252-15	NCR-ORNL-0050-15
NCR-RHORNL-0333-15	NCR-RHSNL-0344-15
NCR-ORNL-0563-15	NCR-RHSRS-0238-15
NCR-ORNL-0052-15	NCR-RHSRS-0251-15

The team concluded that nonconformances are being appropriately documented and tracked through resolution, as required.

The NCRs examined were verified to have been entered, managed, and tracked in the CCP Integrated Data Center/Nonconformance Report Modules, and through the required reconciliation reporting mechanism. Maintenance and control of quality records generated by CCP-QP-005 was also verified in the CCP Records Center.

The audit team verified corrective actions for CAR 15-035 were implemented and no evidence of incorrect process choice in block two (2) of the NCR form has since occurred.

During the evaluation of the procurement process, one concern was identified relative to the NCR process. Requisition package 505170 identified two NCRs. Upon further investigation, NCR-LANL-0574-15 identified an actual condition as: "Three (3) of the containers were noted as showing signs of rust (004, 016, 024)." The NCR package did not provide sufficient documentation to support disposition for the rust identified. The NCR was closed before the information was documented supporting final disposition of the amount of rust identified in the containers (see section 6.1, CAR 16-031). This concern is also discussed in section 5.2.7 of this report.

The procedures reviewed and objective evidence assembled provided evidence to confirm that the applicable requirements for nonconformance reporting are adequately established for compliance with upper-tier requirements, effectively implemented, and satisfactory in achieving the desired results.

WIPP Forms

The audit team reviewed implementing procedure WP 15-GM1002, Rev. 4, *Issues Management Processing of WIPP Forms,* to determine the degree to which the procedure adequately addresses upper-tier requirements. The WIPP Form system is used to track issues from the initiation stage through completion of assigned actions and submittal of relevant objective evidence. The audit team interviewed the WIPP Forms Coordinator and verified that the issue screening process is performed according to the procedure and that it involves multiple individuals with varied expertise providing input to the screening.

The following randomly selected CCP-related WIPP Forms were reviewed and verified within the Issues Management Processing System (IMPS):

WF15-346	WF15-540
WF15-697	WF15-535
WF15-696	WF15-295
WF15-659	WF15-214
WF15-194	WF15-199
WF15-184	WF15-193

All of the reviewed WIPP Forms were determined to have been properly categorized and processed in accordance with the procedure. Conditions adverse to quality (CAQs) that had been categorized as significant were reviewed to verify that causal analysis had been performed. The audit team also verified that causal analysis training (QAP-104) had been given to CCP personnel who were responsible for preparing corrective action plans to correct Action Level (AL) 1 and AL 2 issues.

The audit team verified the process for electronic notifications of WIPP Form closure to the Lessons Learned Coordinator. The notifications are automated within the WIPP Form system in IMPS and are tracked accordingly.

The audit team concluded that the WIPP Form process is adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

5.2.4 Document Control

The audit team verified that NWP/CCP complies with the requirements of CBFO QAPD Section 1.4, *Documents*. The audit team evaluated procedure CCP-QP-010, Rev. 25, *CCP Document Preparation, Approval, and Control*, to determine the degree to which the procedure adequately addresses upper-tier requirements. The results of the review confirmed that the procedure adequately addresses upper-tier requirements.

The audit team conducted interviews with the CCP Document Control Manager. The audit team reviewed randomly selected CCP procedures/documents and resulting records packages to verify appropriate preparation, review, approval, issuance, distribution, control, and changes. For the review, the audit team selected CCP technical procedures, configuration management procedures, and quality and project office procedures. Acceptable Knowledge Summary Reports were also evaluated. Reviews included verifications that procedures used were current and that, where appropriate, obsolete procedures are managed so as to preclude their use.

The audit team verified that the current revision of the following CCP procedures contained the required approvals on their respective coversheets: CCP-PO-001, CCP-PO-002, CCP-PO-003, CCP-PO-006, CCP-PO-016, CCP-PO-401, CCP-PO-505, and CCP-QP-001. The audit team also verified sustained corrective actions for CAR 15-034

identified during the previous CBFO Audit A-15-12, and found no similar instances during this audit.

No document control concerns were identified during the audit. The procedures reviewed and objective evidence assembled and evaluated during the audit provided evidence that the applicable requirements for document control are adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

5.2.5 Records

The audit team verified that the NWP/CCP complies with the requirements of CBFO QAPD Section 1.5, *Records*. The audit team evaluated the adequacy of procedures CCP-QP-008, Rev. 25, *CCP Records Management*, and CCP-QP-028, Rev. 16, *CCP Records Filing, Inventorying, Scheduling, and Dispositioning*, with respect to the requirements of the CBFO QAPD, and determined that the procedures contain adequate flow-down of upper-tier requirements. The audit team also reviewed CCP-PO-005, Rev. 27, *CCP Conduct of Operations*, to verify requirements for CCP operational logbooks are being met.

The audit team conducted interviews with the CCP Records Manager and CCP records clerks in the Records Center. The following randomly selected records were examined: records submittals (including batch data reports from various host sites and NCRs), transmittal/receiving forms, and operational logbooks.

The audit team also reviewed three CCP Records Inventory and Disposition Schedules (RIDS), including the general RIDS dated 3/14/16; the CH RIDS dated 7/30/15; and the RH RIDS dated 7/16/15. The team verified that inventory worksheets (EA15RM3002-1-0 forms) were created for each record and non-record series using the instructions contained in WP 15-RM3002, *Records Filing, Inventorying, Scheduling, and Dispositioning*. The team also verified that the CCP RIDS were developed in accordance with requirements in WP 15-RM3002.

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 concerns were identified during the audit. The first concern was in regard to the requirement of a designation (of a person or organization responsible for receiving records at host sites) that is documented through an email generated by the CCP Records Manager. This documented designation was not identified as a record in implementing procedure CCP-QP-008, *CCP Records Management*, Rev. 25. Objective evidence (Standing Order CCP-SO-118, Rev. 0) was provided to the audit team showing the CAQ had been corrected during the audit (see section 6.2, CDA 1).

The second concern resulted in a recommendation offered to CCP management for consideration. The audit team recommended that a re-evaluation be performed of the TTJA for CCP Records Center RCs and FRCs at the host sites. Initially a TTJA was performed and subsequently required a qualification card for the positions, but the most current TTJA no longer requires issuance of the qualification cards.

There is no qualification required for RCs or FRCs; therefore, the audit team recommended that the word "qualified" be removed from the verbiage in section 2.2.1 of CCP-QP-008, *CCP Records Management*, Rev. 25 (see section 6.4, Recommendation 1).

With the exception of the identified concerns, the audit team concluded that the upper-tier requirements in CBFO QAPD Section 1.5, *Records*, are adequately addressed, satisfactorily implemented, and effective.

5.2.6 Work Processes

The adequacy of CCP implementing procedure CCP-PO-005, *Conduct of Operations,* Rev. 27, was verified by the audit team to flow down the requirements of CBFO QAPD, Rev. 12, Section 2.1.1, *Work Processes.* The audit team conducted interviews with CCP personnel and reviewed documentation to determine compliance with CCP-PO-005, Section 16, *Required Reading*, Section 17, *Timely Instructions/Orders*, and Section 19, *Operator Aids*.

The Integrated Data Center (IDC) software system is used to manage the required reading process. All documents processed since the last audit via the IDC process for required reading were reviewed and verified to be compliant with requirements. Individual standing orders and operator aids, including indices for each, were also reviewed and verified to be compliant with procedural requirements.

Handling, Storage and Shipping

Flow-down of the requirements of the CBFO QAPD, Rev. 12, Section 2.1.5, *Handling, Storage and Shipping*, were verified by the audit team to be adequately addressed in CCP-QP-023, *Handling, Storage and Shipping,* Rev. 4. This procedure has not been implemented within the last year.

Identification and Control of Items

The audit team verified the adequacy of CCP-QP-017, *CCP Identification and Control of Items,* Rev. 4, by assuring the flow-down of the requirements of CBFO QAPD, Rev. 12, Section 2.1.3, *Item Identification and Control.* This procedure has not been implemented in the last year.

No concerns were identified. The audit team concluded that the upper-tier requirements in CBFO QAPD, Rev. 12, are adequately addressed, satisfactorily implemented, and effective.

5.2.7 Procurement and Graded Approach

The audit team verified the completeness and adequacy of the CCP and NWP procedures for procurement of items to the requirements of the CBFO QAPD. Procedures verified included:

- CCP-QP-001, Rev. 8, *CCP Graded Approach*
- CCP-QP-015, Rev. 12, *CCP Procurement*
- WP 15-PC3609, Rev. 29, *Preparation of Purchase Requisitions*
- WP 15-PC3044, Rev. 10, *Quality Credit Card Purchases*

The audit team verified the training of procurement requisition and reviewer personnel to the procedures and verified their qualifications as provided within the procedures, using the NWP site "Technical Training Report for Purchaser's, Site Technical Representatives, and Reviewer's," dated 03-30-2016. Training produced a list of personnel who are qualified as Purchaser, Site Technical Representative (STR), and Reviewer utilizing self-paced module training: CON-004, -006, -008, and -011.

The audit team interviewed CCP purchase requisition personnel to obtain information regarding items purchased since the previous audit. The following requisition packages were reviewed:

- 504846 – Nucfil-19DS filters for CCP - Idaho National Laboratory
- 505170 – 110-gallon drums for CCP – Los Alamos National Laboratory
- 506250 – Gases for CCP Oak Ridge National Laboratory Flammable Gas Analysis Internal Standard
- 506268 - Gases for CCP Oak Ridge National Laboratory Flammable Gas Analysis Initial Calibration gas

Each package was complete with a copy of a requisition, a screen shot of the requisition approvers, list of items within the purchase (including size, amount, material safety data sheet as applicable, quality of product, quality level required, purchase number), signed quality level determination checklist, specifications paperwork, certificate of conformance, and NCR documents as applicable.

One concern was identified. Requisition package 505170 identified two NCRs. Upon further investigation, NCR-LANL-0574-15 identified an actual condition as: "Three (3) of the containers were noted as showing signs of rust (004, 016, 024)." The NCR package did not provide sufficient documentation to support disposition for the rust identified. The NCR was closed before the information was documented supporting final disposition of the amount of rust identified in the containers (see section 6.1, CAR 16-031).

The audit team verified that the appropriate reviews of the data packages were completed, including the STR review as required.

The audit team verified that the appropriate receipt inspection verification sheets (RIVSs) were included in the reviews completed at the various sites. The RIVSs indicated appropriate levels of review.

The audit team verified the Quality Credit Card Master Inspection Plan and four Q-Credit Card Inspection Plans for torque wrenches and a pressure gauge. The purchases were for service calibrations per ISO 17000 requirements and American National Standards Institute standard recalibrations.

With the exception of the identified concern, the audit team concluded that the upper-tier requirements in the CBFO QAPD are adequately addressed, satisfactorily implemented, and effective.

5.2.8 Inspection and Testing

Inspection Control

The audit team verified the adequacy of implementing procedures CCP-QP-026, *CCP Inspection Control,* Rev. 14, and CCP-QP-027, *CCP Test Control,* Rev. 6, against the requirements of CBFO QAPD, Rev. 12, Section 2.4, *Inspection and Testing.*

Documentation was reviewed demonstrating that inspection personnel were qualified in accordance with the requirements of WP-13-QA.04. Use of the RIVS was verified for inspection planning and for procurements made by Q-Card and purchase order. The audit team observed that 100 percent inspections are typically used for small quantity procurements, such as gas cylinders, while sample sizes for larger quantity procurements are determined per Attachment 2 of procedure CCP-QP-026, *CCP Inspection Control.* The audit team reviewed completed RIVSs and verified that QA checks the secure file transfer protocol (SFTP) site prior to utilizing the RIVS to ensure that the current revision of the form is being used and that the form is completed and signed. Audit team review of completed CCP-QP-008, Attachment 2, CCP Records Transmittal/Receiving forms for several procurements also verified that RIVSs are maintained as records in accordance with requirements.

Test Control

The audit team reviewed documentation and interviewed personnel to verify adequate implementation of CCP-QP-027, Rev. 6, *CCP Test Control.* Review of CCP-CM-035, Rev. 0, *CCP Test Plan for Qualification of Test Weight for TWPC Hot Cell,* verified that test plans and procedures conform to CCP-QP-010 requirements and have been reviewed and approved by CCP Configuration Management; CCP Team Leader, Manager, or Lead Operator; and QA. CCP Configuration Management initiated the plan which contains, among other requirements, test prerequisites, test requirements, method of test, procedural requirements, and test results. The test plan did not include any test hold points or witness points.

The audit team verified that CCP Configuration Management and QA have evaluated the test data and reviewed the test results and the acceptance criteria to ensure all test requirements have been satisfied. Acceptance of test results was indicated by the reviewer's printed name, signature, and date. Test documentation was submitted to CCP Records on March 26, 2014. Test Plan CCP-CM-035 was verified to be stored in CCP Records in the Skeen-Whitlock Building.

No concerns were identified. The audit team concluded that the requirements for inspection and testing are adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

5.2.9 Control of Measuring and Test Equipment

Measuring and Test Equipment was evaluated during Audit A-16-06 of NWP Calibration Programs.

5.2.10 Assessments

The audit team verified the adequacy of implementing procedures CCP-QP-018, *CCP Management Assessment*, Rev. 11, and WP 13-QA.03, *Quality Assurance Independent Assessment Program*, Rev. 25, against the requirements of CBFO QAPD, Rev. 12, Section 3, *Assessments*.

The audit team interviewed the CCP Manager, the CCP Support Services Manager, the CCP Records Manager, and the Acting NWP Project Integration Manager, and evaluated objective evidence to verify implementation of the CCP assessment processes.

A review of CCP management assessment and audit schedules and logs was conducted to verify compliance with CCP procedures. Evaluations of randomly selected audits and management assessments confirmed that CCP personnel are performing assessment activities according to procedural requirements. Management assessments reviewed and evaluated included MA-CCP-0003-15, MA-CCP-005-15, MA-CCP-0007-15, MA-CCP-0009-15, MA-CCP-0011-15, MA-CCP-0002-16, and MA-CCP-0004-16. Audits reviewed and evaluated included I15-14. Additionally, assessment procedures for audits and management assessments were verified to be adequate, satisfactorily implemented, and effective.

The audit team verified that management assessments are scheduled, planned, and conducted by all levels of CCP management. The audit team verified that assessment reports discussed the scope, identified elements assessed, classified any issues or problems, were reviewed and approved, and were distributed to appropriate levels of management. The audit team interviewed the CCP Records Manager to verify that original assessment reports are submitted, authenticated, and stored in CCP Records. The CCP Support Services Manager and the CCP Manager were interviewed to verify

that the management assessments were effective for coordination of resources, identification and resolution of issues, and tracking of improvement opportunities.

The audit team interviewed the Acting NWP Project Integration Manager and verified that NWP QA conducts annual audits of the CCP. Evaluation of the latest CCP QAP audit, I15-14, verified the audit was performed and compliance to CCP procedures was confirmed. Audit I15-14 resulted in one finding and two observations. The finding was tracked on a WIPP Form, the corrective actions performed, and the objective evidence verified as completed.

During the course of the management interviews and reviews of documentation, the audit team identified no concerns. The audit team concluded that the upper-tier requirements in the CBFO QAPD, Section 3, *Assessments*, are adequately addressed, satisfactorily implemented, and effective.

5.2.11 Sample Control

The audit team verified through CCP Records that no sampling events have occurred since the last audit; therefore, see the results for CBFO Audit A-15-12 for evaluation of CCP Sample Control.

5.2.12 Software QA

The audit team conducted interviews of CCP personnel responsible for software and records control and reviewed samples of software documentation packages. Evaluations of the samples verified implementation of CCP procedure CCP-QP-022, Rev. 16, *CCP Software Quality Assurance Plan*, with respect to application of software QA to project office and host site location software items. The NWP SFTP website was viewed to verify that the website adequately manages availability of controlled software to users.

The audit team evaluated CCP Software Inventory Lists (SILs) for project level and host site location software applications and compared a sample of the items on active spreadsheet tabs of the SILs with applications posted on the SFTP website. These packages were reviewed for evidence of implementation of procedure steps for Software Change Order (SCO), SCO Addendums, Software Problem Report and Change Request (SPRCR), SCO test planning, and SCO test reporting. Packages were also reviewed for documentation of impact of changes on life-cycle documents (test plans, test reports, design documents, requirements documents, user manuals, and code listings) that were generated or revised per the scope of an SCO and as appropriate for the category of the individual software application.

The following table shows the items sampled along with their status:

Category Name	Site	SCO #	SCO Addendum #	SCO Addendum Description	Software Name
Applications within COTS Software	FGA	1014	2	Verification that the ICAL spreadsheet works with Excel 2010 and 2013 using Windows 7.	ICAL Spreadsheet.xls
Applications within COTS Software	ORNL	1046	2	Revised to add background correction	Pre-SETF DTC.xlsx
Applications within COTS Software	ORNL	1132	2	Test spreadsheet for Windows 7 and Microsoft Excel 2007 and 2010	ORNL DTC-HFIR-HFIR 30 gal.xlsx
Applications within COTS Software	ORNL	1133	2	The spreadsheet needs testing for Windows 7 and Microsoft Excel 2007 and 2010.	ORNL DTC-HFIR-HFIR 15gal.xlsx
Applications within COTS Software	ORNL	1134	2	The spreadsheet needs testing for Windows 7 and Microsoft Excel 2007 and 2010	ORNL DTC-Mark-HFIR 30gal.xlsx
Qualified Supplier Software	LANL	1163	14	This will be for additional installations for a new EA in training.	LANLU234.wsc
Qualified Supplier Software	Project Level (PL)	1191	32	Additional installation of software on computer listed on Attachment A. Removal of software from computers listed on Attachment A.	Flat File Generator
Applications within COTS Software	SNL	1213	4	Need to add drums and updated uncertainties for drums to include mass distribution uncertainty.	DTC for SNL Lot 2.xlsx
Qualified Supplier Software	ORNL	1221	3	Additional Installation	ISTPPU240.wsc
Applications within COTS Software	ORNL	1224	2	New Development	ORNL DTC-3525 Debris.xlsx
Applications within COTS Software	INL	1225	0	Initial Development	DTC for INL Lot 6.xlsx
Applications within COTS Software	ORNL	1231	0	New Development	ORNL DTC-3525 Debris.xlsx
Applications within COTS Software	INL	1232	0	New Development	DTC for INL Lot 6-Second Batch of Liners.xlsx

CCP manages no software applications classified as *Non-Qualified Supplier Software,* or classified as *Safety Software.*

One concern was identified as a result of evaluation of software QA packages. Testing of Excel spreadsheets used in calculations was not adequately documented for all operating configurations where spreadsheets are tested for operation on more than one operating configuration. Testing documentation did not include details of system software and COTS software applications that comprise the operating configurations used for testing individual software application versions (see SCOs 1046, 1134, 1134, 1134, 1213, and 1231) (see section 6.1, CAR 16-030).

With the exception of the above-mentioned concern, the audit team concluded that the CCP Software QA Program is adequately established with respect to compliance with upper-tier requirements, that implementation of these requirements is satisfactory, and that the program is effective in achieving application of software QA and management of CCP software applications.

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 descriptions 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.

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

CAR 16-030

CCP-QP-022, Rev. 16, Section 1.15 requires that Test Reports/Results identify or address the following, as applicable: operating system(s) and version(s) used during test performance. Further, Section 1.9 requires that applications developed within COTS that are posted to the SFTP site contain the following information: operating environment(s) in which the application was tested (e.g., operating system and platform). The software testing for Excel spreadsheets that perform calculations was not performed on all applicable software application versions (operating environment and platform). The software testing documentation did not identify which software application versions were tested. (For an example see SCOs 1231 and 1232.)

CAR 16-031

Requisition package 505170 identified two NCRs. Upon further investigation NCR-LANL-0574-15 identified an actual condition as: "Three (3) of the containers were noted as showing signs of rust (004, 016, 024)." The NCR package did not provide sufficient documentation to support disposition for the rust identified. The NCR was closed before the information was documented supporting final disposition of the amount of rust identified in the containers.

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.

CDA 1

This concern was in regards to the requirement of a designation (of a person or organization responsible for receiving records at host sites) that is documented through an email generated by the CCP Records Manager. This documented designation was not identified as a record in the implementing procedure, CCP-QP-008, *CCP Records Management*, Rev. 25. Objective evidence (Standing Order CCP-SO-118, Rev. 0) was provided to the audit team showing the CAQ had been 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.

One Recommendation was provided for CCP management consideration.

Recommendation 1

The audit team recommended that a re-evaluation be performed of the table-top job analysis (TTJA) for CCP Records Center records custodians (RCs) and Facility Records Custodians (FRCs) at the host sites. Initially a table-top job analysis was performed and subsequently required a qualification card for the positions, but the most current TTJA no longer requires issuance of the qualification cards.

There is no qualification required for RCs or FRCs; therefore, the audit team recommended that the word "qualified" be removed from the verbiage in section 2.2.1 of CCP-QP-008, *CCP Records Management*, Rev. 25. See procedure section verbiage below:

> Section 2.2 Training Requirements
>
> (2.2.1) Personnel performing this procedure will be trained and **qualified** in accordance with CCP-QP-002, *CCP Training and Qualification Plan*, prior to performing this procedure.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During Audit A-16-12
Attachment 2: Summary of Audit A-16-12 Results
Attachment 3: Documents Reviewed During Audit A-16-12

PERSONNEL CONTACTED DURING AUDIT A-16-12				
NAME	**ORG/Title**	**PREAUDIT MEETING**	**CONTACTED DURING AUDIT**	**POST AUDIT MEETING**
Armijo, Cheryl	TFE/CCP Training Records Analyst		X	
Billett, Bob	NWP/Issues Management & Performance Monitoring Manager		X	
Billett, Michele	TFE/CCP/Training Coordinator	X	X	X
Chavarria, Antonio	NWP/QAE/LANL (per telecom)		X	
Davis-Schilling, Penny	NWP/NTP Project Support Manager		X	
Edwards, Mark	NWP/Procurement Services Manager		X	
Fisher, A.J.	NWP/CCP/Support Services	X	X	X
Gulbransen, Ed	NWP/CCP Manager		X	X
Jones, Laura R.	NWP/QA	X	X	X
Kirkes, Creta	NWP/CCP/WCO	X		
Lee, Ronnie	NWP/CCP Waste Characterization Manager		X	
Martinez, Porf	CTAC/Reg. Assur. Mgr			X
Miehls, Dennis	CBFO/Sr. QA Specialist	X		X
Morrison, Jim	NWP/NTP Software Developer		X	
Navarrete, Leon	NWP/CCP Records Clerk		X	
Nesser, Cathy	NWP/Sr. QA Specialist		X	X
Oberbeck, Leslie	NWP/NTP/SCME	X	X	X
Pace, Berry	CTAC/QA Pgms Mgr.	X		X
Payanes, Jose	NWP/CCP Document Services		X	X
Pearcy, Sheila	TFE/CCP/Records Manager	X	X	X
Ramirez, Mike	NWP/CCP/Manager		X	X

PERSONNEL CONTACTED DURING AUDIT A-16-12				
NAME	**ORG/Title**	**PREAUDIT MEETING**	**CONTACTED DURING AUDIT**	**POST AUDIT MEETING**
Reeves, Ron	NWP/CCP Operations Manager		X	
Wade, Daniel	NWP/NTP/CCP SPM		X	
Waldram, Veronica	NWP/Acting Project Integration Manager		X	

Summary of Audit A-16-12 Results

Documents	Concern Classification				QA Evaluation		Technical
	CARs	CDAs	Obs	Rec	Adequacy	Implementation	Effectiveness
Audit Activity							
Organization & Quality Assurance Program					A	S	E
Personnel Qualification & Training	16-031			1	A	S	E
Quality Improvement					A	S	E
Document Control					A	S	E
Records		1			A	S	E
Work Processes					A	S	E
Procurement & Graded Approach					A	S	E
Inspection & Testing					A	S	E
Control of Measuring & Test Equipment					A	S	E
Assessments					A	S	E
Sample Control					A	S	E
Software Quality Assurance	16-030				A	S	E
TOTALS	2	1		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 Reviewed During Audit A-16-12

	Document Number	Document Title	Rev
1	CCP-PO-001	CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAPjP)	22
2	CCP-PO-002	CCP Transuranic Waste Certification Plan	27
3	CCP-PO-005	CCP Conduct of Operations	27
4	CCP-QP-001	CCP Graded Approach	8
5	CCP-QP-002	CCP Training and Qualification Plan	39
6	CCP-QP-005	CCP TRU Nonconforming Item Reporting and Control	25
7	CCP-QP-008	CCP Records Management	25
8	CCP-QP-010	CCP Document Preparation, Approval and Control	25
9	CCP-QP-014	CCP Quality Assurance Trend Analysis and Reporting	7
10	CCP-QP-015	CCP Procurement	12
11	CCP-QP-017	CCP Identification and Control of Items	4
12	CCP-QP-018	CCP Management Assessment	11
13	CCP-QP-019	CCP Quality Assurance Reporting to Management	8
14	CCP-QP-022	CCP Software Quality Assurance Plan	16
15	CCP-QP-023	CCP Handling, Storage and Shipping	4
16	CCP-QP-026	CCP Inspection Control	14
17	CCP-QP-027	CCP Test Control	6
18	CCP-QP-028	CCP Records Filing, Inventorying, Scheduling, and Dispositioning	16
19	CCP-QP-030	CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel	9
20	CCP-QP-032	CCP Written Practice for the Qualification of CCP Pressure Change Leak Testing Personnel	2
21	WP 13-1	NWP Quality Assurance Program Description	36
22	WP 13-QA.03	Quality Assurance Independent Assessment Program	25
23	WP 13-QA.04	Quality Assurance Department Administrative Program	21
24	WP 15-GM1002	Issues Management Processing of WIPP Forms	4
25	WP 15-PC3044	Quality Credit Card Purchases	10
26	WP 15-PC3609	Preparation of Purchase Requisitions	29