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-15-12, Nuclear Waste Partnership LLC/Central Characterization Program Quality Assurance Program

Dear Mr. Cannon:

The Carlsbad Field Office (CBFO) performed Audit A-15-12 of the Nuclear Waste Partnership LLC (NWP)/Central Characterization Program (CCP) Quality Assurance Program (QAP), April 7 – 9, 2015. The audit team concluded that the NWP/CCP QAP continues to adequately address the upper-tier requirements of the CBFO Quality Assurance Program Document. 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 four conditions adverse to quality resulting in four Corrective Action Reports (CARs). Two additional conditions adverse to quality, requiring only remedial action, were corrected during the audit. The team identified two Observations, and four Recommendations were offered to Management.

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

Sincerely,

[Signature]

Dennis S. Miehls
Senior Quality Assurance Specialist

Enclosure
cc:w/enclosure
M. Brown, CBFO
M. Navarrete, CBFO
J. R. Stroble, CBFO
N. Castaneda, CBFO
S. L. Ross, DOE/EM-43
P. Breidenbach, NWP
R. McQuinn, NWP
J. Harris, NWP
F. Sharif, NWP
M. Sensibaugh, NWP
V. Cannon, NWP
A. J. Fisher, NWP
J. Carter, NWP
B. Allen, NWP
W. Ledford, NWP
S. Punchios, NWP
S. Escareno-Soto, NWP
T. Peake, EPA
L. Bender, EPA
S. Holmes, NMED
R. Maestas, NMED
C. Smith, NMED
V. Daub, CTAC
R. Allen, CTAC
P. Martinez, CTAC
B. Pace, CTAC
T. Ackman, CTAC
P. Hinojos, CTAC
D. Sellmer, CTAC
G. White, CTAC
Site Documents
CBFO QA File
CBFO M&RC
*ED denotes electronic distribution
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-15-12

NWP/CCP QUALITY ASSURANCE PROGRAM

April 7 – 9, 2015

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

Approved by: Michael R. Brown, Director
CBFO Quality Assurance Division

Date: 04/29/15
Date: 5-1-15
1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-15-12 was conducted at the Nuclear Waste Partnership LLC (NWP) Central Characterization Program (CCP) offices in Carlsbad, NM, April 7 – 9, 2015. 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 12 concerns. Four of the 12 concerns were determined to be conditions adverse to quality resulting in the issuance of four Corrective Action Reports (CARs) (see section 6.1). Two additional conditions adverse to quality required only remedial action and were corrected during the audit (CDA) (see section 6.2). Two concerns were classified as Observations (see section 6.3), and the remaining four concerns were offered for management consideration as Recommendations (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
- Control of Measuring & Test Equipment
- 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)
Paul Gomez  Auditor, CTAC
Cindi Castillo  Auditor, CTAC
Prissy Martinez  Auditor, CTAC
Bob Prentiss  Auditor, CTAC
Harley Kirschenmann  Auditor, CTAC
Jack Walsh  Auditor, CTAC
Charlie Riggs  Auditor, CTAC
Judith Stewart  Auditor, CTAC
Gayla White  Auditor-in-Training, CTAC
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 April 7, 2015. 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 April 9, 2015.
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.

Twelve 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 14-030 through 14-036 identified during CBFO Audit A-14-10, NWP/CCP QA Program (All Sites), conducted March 25 – 27, 2014. 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 CCP-PO-001, Rev. 21, CCP Transuranic Waste Characterization Quality Assurance Project Plan, CCP-QP-014, Rev. 6, CCP Quality Assurance Trend Analysis and Reporting, CCP-QP-019, Rev. 8, CCP Quality Assurance Reporting to Management, WP 13-1, Rev. 35, NWP Quality Assurance Program Description, and QA implementing procedures established for documenting the CCP QAP to ensure that they adequately address the applicable requirements of DOE/CBFO-94-1012, Rev. 11, CBFO Quality Assurance Program Document (QAPD). The audit team interviewed CCP 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, 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.

It was concluded that the QA organization has the required authority, independence, access to work areas, and organizational freedom necessary to perform assigned responsibilities.
The audit team interviewed the CCP QA Engineer and QA Specialist, and reviewed documentation to verify the implementation and effectiveness of the QAP.

Established adequacy was verified for the technical and QA training for personnel performing activities subject to the CBFO QAPD. This is documented in CCP-QP-002, Rev. 38, 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 problem areas. A condition adverse to quality (CAQ), relative to the generation and issuance of Semiannual Trend Reports, was identified. CCP-QP-014, Rev. 6, CCP QA Trend Analysis and Reporting, requires each Host site to create and submit a Semiannual Trend Report. The audit team determined that only the Host sites that have a QA Engineer are submitting Semiannual Trend Reports, as required. No trend reports for January through June 2014 or July through December 2014 have been generated and/or submitted for the following sites: Savannah River Site (SRS), Hanford Site, Sandia National Laboratory (SNL), and Argonne National Laboratory (ANL) (see section 6.1, CAR 15-038).

Semiannual reports were provided to the Site Project Manager (SPM) and the CBFO during the periods of January through June and July through December of calendar year 2014. Verification and review of the reports showed all relevant information on QA/quality control activities during these periods was covered.

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 NWP/CCP met the requirements of the CBFO QAPD, and implementing procedure CCP-QP-002, Rev. 38, 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.

Real-time radiography (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, Rev. 38, CCP Training and Qualification Plan, 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 (AKEs), HLD and PCLT Level II [L] and Level III [L] personnel, and project management staff. Other objective evidence reviewed included lists of qualified individuals, appointment letters for VE experts, and qualifications of NDA expert analysts and remote-handled (RH) waste technical staff for each applicable CCP contract Host site.

The process for required reading/lessons learned is established as required by CCP-PO-005, Rev. 26, CCP Conduct of Operations, and training is assigned by cognizant managers. Documented evidence of required reading receipt acknowledgments are kept on file in CCP Training.

The audit team also evaluated the implementation and effectiveness of sustained corrective actions for training-related CARs 14-030 and 14-035, identified during the previous CBFO Audit A-14-10. The audit team determined that the corrective actions were successful in preventing recurrence of those issues by establishing procedure modifications, including adding attachments to the procedures.

The audit team concluded that the CCP Qualification and Training 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. 24, 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 remote-handled (RH) waste nonconformance reports (NCRs) issued from all sites:

- NCR-CCP-0496-14, R0
- NCR-CCP-0498-14, R0
- NCR-INL-0004-14, R0
- NCR-INL-0009-14, R0
- NCR-INL-0031-14, R0 & R1
- NCR-INL-0309-14, R0
- NCR-LANL-0535-14, R0
- NCR-LANL-0540-14, R0 & R1
- NCR-ORNL-0044-15, R0 & R1
- NCR-ORNL-0052-15, R0
- NCR-ORNL-0100-15, R0

- NCR-CCP-0496-14, R0
- NCR-CCP-0498-14, R0
- NCR-INL-0004-14, R0
- NCR-INL-0009-14, R0
- NCR-INL-0031-14, R0 & R1
- NCR-INL-0309-14, R0
- NCR-LANL-0535-14, R0
- NCR-LANL-0540-14, R0 & R1
- NCR-ORNL-0044-15, R0 & R1
- NCR-ORNL-0052-15, R0
- NCR-ORNL-0100-15, R0

- NCR-CCP-0496-14, R0
- NCR-CCP-0498-14, R0
- NCR-INL-0004-14, R0
- NCR-INL-0009-14, R0
- NCR-INL-0031-14, R0 & R1
- NCR-INL-0309-14, R0
- NCR-LANL-0535-14, R0
- NCR-LANL-0540-14, R0 & R1
- NCR-ORNL-0044-15, R0 & R1
- NCR-ORNL-0052-15, R0
- NCR-ORNL-0100-15, R0

- NCR-ORNL-0113-15, R0
- NCR-ORNL-0005-15, R0
- NCR-SRS-0183-14, R0
- NCR-SRS-0376-14, R0
- NCR-SRS-0377-14, R0
- NCR-SRS-0382-14, R0
- NCR-RHANL-0317-14, R0-R2
- NCR-RHINL-0225-15, R0
- NCR-RHINL-0241-15, R0
- NCR-RHINL-0242-15, R0
- NCR-RHINL-0358-14, R0
- NCR-RHORNL-0330-15, R0
The team concluded that deficiencies are being appropriately documented and tracked through resolution as required. One of the NCRs selected (NCR-SRS-0376-14, RO) documented a non-administrative deficiency first identified at the SPM level. This NCR was verified as having been reported to the Permittee within seven days, as required by the Permit.

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.

A condition adverse to quality was identified regarding the NCR process. During issuance of NCR-RHANL-0317-14, R0, the NCR originator entered "RH-DG" to answer Block #2 of the NCR. "RH-DG" is not a process choice listed in the instructions for completing an NCR (Attachment 2 of CCP-QP-005). CCP-QP-005, Rev. 24, Section 4.1.3[A] states: "NCR Originator complete Blocks 1 through 7, as applicable, of the NCR (see Attachment 2, Instructions for Completing Attachment 1, Nonconformance Report [NCR] ...)." Also, CCP-QP-005, Attachment 2 – Instructions for Completing Attachment 1, Nonconformance Report (NCR), Block 2, states: "NCR Originator enter kind of process. Choose one or a combination from the following: AK, CRMU Project, DA, Exterior Surface Radiological Survey, FGA, GGTP, HE-RTR, Lot Evaluation, MOVER, NDA, NDE, OSRP, Radiochemistry, Receipt Inspection, RH-DTC, RH-NDE, RH-RTR, RH-Sampling, RH-VE, Solids Analysis, Surface Finish, Testing, Transportation, VE, WCO, WWIS/WDS, Other. If not applicable, enter 'N/A'." (See section 6.1, CAR 15-035.)

Although one concern was identified, 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. 3, *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):
All of the above WIPP Forms were determined to have been properly categorized and processed in accordance with the procedure. Conditions adverse to quality 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 identified an individual who had not completed the suspect counterfeit item (SCI) refresher training. During discussions with responsible personnel, it was discovered that this condition had been previously identified and documented on WIPP Form WF14-154. Corrective actions were developed to address the concern, but have not yet been fulfilled as of the date of this audit. For these reasons, this concern was classified as an Observation (see section 6.3, Observation #2).

The audit team concluded that the WIPP Form system 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 conducted interviews with responsible personnel and reviewed randomly selected CCP procedures/documents and resulting records to verify 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.

The audit team identified one condition adverse to quality with regard to review and approval of procedures. CCP-QP-010, Rev. 25, CCP Document Preparation, Approval, and Control, Section 3.10.4.[A], requires that the DOE/CBFO Manager sign the cover sheet of CCP-PO-006 and there is no evidence that the DOE/CBFO Manager has signed the cover sheet (see section 6.1, CAR 15-034).

With the exception of the above mentioned concern, the audit team concluded that the upper-tier requirements in CBFO QAPD, Section 1.4, Documents, 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, Records Inventory and Disposition Schedules (RIDS), records inventory worksheets, and operational 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.

The audit team confirmed that corrective actions resulting from CAR 14-036 from the previous CBFO Audit A-14-10 are continuing to be implemented. The audit team reviewed random samples from container inspection/weight reports and RTR quarterly repeat results and no discrepancies were noted.

The audit team identified two concerns in the area of logbooks. The first concern required the Vendor Project Manager (VPM) to review, sign, and date the operational logbook each operational week, at a minimum. There was no indication that operational logbook CCP-SN-RH-DTC-002 was reviewed, signed, and dated by the VPM for the week of 06/22/14 through 06/26/14. Objective evidence was provided to the auditor showing the CAQ had been corrected during the audit (see section 6.2, CDA #2).

The second concern related to the requirement that operational logbooks be submitted to CCP Records for reconciliation of assigned operational logbook numbers. There was no objective evidence that logbook CCP-ORNL-NDA-IQ3-002 had met this requirement. CCP took the necessary steps to revise the operational logbook annual reconciliation report to include CCP-ORNL-NDA-IQ3-002. Since this was an isolated condition, it was determined corrected during the audit (see section 6.2, CDA #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, Rev. 26, Conduct of Operations, was verified by the audit team to flow-down the requirements of CBFO QAPD, Rev. 11, 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 approximately 99 percent of the time to manage the required reading process. Several documents sent to selected personnel via the IDC process for required reading were reviewed to demonstrate
compliance with the requirements. Individual standing orders and operator aids were reviewed which demonstrated compliance with the procedural requirements.

**Handling, Storage and Shipping**

Flow-down of the requirements of the CBFO QAPD, Rev. 11, 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.

The audit team verified, by review of fiscal year (FY) 2014 assessments and the FY 2015 assessment schedule, that CCP QA provides oversight of the handling, storage and shipping processes identified in CCP-QP-023. CCP QA scheduled a surveillance of procedure CCP-QP-023 for March 2015. The surveillance has not been completed as of this audit. The previous CCP QA audit of handling, storage, and shipping was performed in February 2013. The Idaho National Laboratory (INL), Los Alamos National Laboratory (LANL), and Oak Ridge National Laboratory (ORNL) have scheduled assessments for packaging and shipping at the respective sites during the last quarter of calendar year 2015.

CCP develops manuals that provide general guidance for handling, loading, and storage of items, including storage requirements for standard waste boxes, ten-drum overpacks, and criticality control overpacks. Methods for handling, storage, and shipping of spare parts, and functions such as maintenance of marking and identification tags, protection of markings and tags, and management of shelf-life items (e.g., rubber gaskets) are controlled by the NWP Warehouse organization with oversight of these functions provided by NWP QA.

The audit team identified one concern regarding CCP-QP-023, *Handling, Storage and Shipping*, Rev. 4. The procedure addresses requirements that are not implemented by CCP, but rather by the WIPP site and Host site contractors at remote sites. As such, the audit team recommends that CCP-QP-023 be clarified to identify the specific activities within CCP scope, or perhaps delete the procedure if adequate control for handling, storage, and shipping is provided by the WIPP site and other Host site organizations at the remote sites (see section 6.4, Recommendation #1).

Results from the audit of this area, with the exception of the recommendation described above, identify the flow-down of requirements in CBFO QAPD, Rev. 11, and indicate that the requirements are adequately addressed, satisfactorily implemented, and effective.

**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. 11, Section 2.1.3, *Item Identification and Control*. 
The audit team verified that equipment labeling, tags, and physical segregation were used and applied in a manner that provides a clear, legible identification for measuring and test equipment (M&TE). Test and inspection reports were used for status of items undergoing testing and inspection. The audit team verified that status indicators for M&TE items are initiated and removed by the M&TE Custodian or the calibration service organizations that perform the verification of status.

Status indicator activities, such as for application and maintenance of status tags and indicators for items other than M&TE, are typically performed by NWP organizations at the WIPP site, including receiving, receipt inspection, and operations.

The audit team identified one concern and recommended that the CCP Item Identification and Control procedure be clarified to identify the specific activities that are within CCP scope to perform versus WIPP site organizations. Alternatively, CCP may decide to delete the CCP Item Identification and Control procedure if adequate control is provided by the WIPP site and other Host site organizations at the remote sites (see section 6.4, Recommendation #1).

Results from the audit of this area, with the exception of the recommendation described above, identify the flow-down of requirements in CBFO QAPD, Rev. 11, and indicate that the requirements 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 for graded approach. Review of the procurement process included graded approach as described in CCP-QP-001, Rev. 8, CCP Graded Approach, and procurement processes identified in CCP-QP-015, Rev. 12, CCP Procurement, WP 15-PC3044, Rev. 10, Quality Credit Card Purchases, and WP 15-PC3609, Rev. 28, Preparation of Purchase Requisitions. Specific documents reviewed included CCP Quality Level Determination Checklists (Attachment 1 to CCP-QP-001), purchase requisitions, 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, Approving Officials, Q-Cardholders, and Receipt Inspectors.

Graded Approach

The audit team witnessed a demonstration of the IDC CCP Graded Approach Module. The audit team randomly selected completed procurement requisitions and verified that the CCP grading process had been completed in accordance with CCP-QP-001, and included the signed and approved Quality Level Determination Checklists.
Procurement

The audit team randomly selected task order transactions that had been processed after the last audit conducted March 25 – 27, 2014, and verified that all assigned reviewers for the requisitions completed their approvals and that the requisitioner’s manager, NWP QA, technical reviewers, and the CCP Equipment Engineer were included as reviewers.

Q-Card Purchases

The audit team randomly selected Q-Card transactions that had been processed after the last audit conducted March 25 – 27, 2014. The audit team witnessed a demonstration of the on-line Master Inspection Plan (MIP) and verified the MIP was prepared, approved, and entered into the MIP database by NWP QA, and verified that the cardholder created the Individual Inspection Plan prior to placing the order for each of the transactions selected for review.

The audit team verified that NWP QA oversees the MIP database and approves all transactions prior to the Q-Card holder being allowed to place each order. The audit team reviewed two Q-Card transactions for calibration gases and verified the CCP Receipt Inspector completed all required documents including the Receipt Inspection Verification Sheet (RIVS).

The audit team confirmed that corrective actions resulting from CARs 14-032 and 14-033 from the previous CBFO Audit A-14-10 continue to be implemented. The audit team reviewed the scope of work and verified it to be adequate for the task order transactions selected for review. Also, the audit team verified that all Q-Card holders, approving officials, and receipt inspectors were current on all training requirements.

The audit team concluded that the requirements for the use of a graded approach and the requisition and procurement of goods and services are adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

5.2.8 Inspection and Testing

The audit team verified the adequacy of implementing procedures CCP-QP-026, Rev. 14, CCP Inspection Control, and CCP-QP-027, Rev. 6, CCP Test Control, against the requirements of CBFO QAPD, Rev. 11, 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 performance for procurements by Q-Card and purchase order. The audit team observed that 100 percent inspections are typically used for small quantities procured, such as gas cylinders, while sample sizes for larger quantities procured are determined per CCP-QP-026, Attachment 2, CCP Random Sampling Plan for Receipt Inspection. It was verified by the audit team's review of completed RIVS.
forms that CCP QA checks the secure file transfer protocol (SFTP) site prior to utilizing the RIVS form to ensure that the current revision of the form is being used, and that the form is completed and signed. It was also verified that the RIVS forms are maintained as records, through the review of completed CCP-QP-008, Attachment 2, CCP Records Transmittal/Receiving Forms, for several procurements.

The audit team reviewed documentation and interviewed personnel to verify adequate implementation of CCP-QP-027, Rev. 6, CCP Test Control. Review of test plan CCP-CM-035, Rev. 0, CCP Test Plan for Qualification of Test Weight for TWPC Hot Cell, verified that test plans and procedures have been reviewed and approved by CCP Configuration Management, CCP team leader, manager or lead operator, and QA, and conform to CCP-QP-010 requirements. 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 have any test hold points or witness points.

It was also verified by the audit team that CCP Configuration Management and CCP QA have evaluated the test data and reviewed the test results and the acceptance criteria to ensure all test requirements have been satisfied. Each has accepted the test by printing name, signing, and dating the test results.

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

Flow-down of the requirements of the CBFO QAPD, Rev. 11, Sections 2.4.6, Use and Control of M&TE, and 2.4.7, Calibration, was verified by the audit team to be adequately addressed in CCP-QP-016, Rev. 20, CCP Control of Measuring and Testing Equipment.

Implementation of CCP-QP-016 was determined by the audit team's review of documentation and interview of personnel. The audit team selected several files from the IDC and verified that a database has been established for documenting M&TE calibration schedules and history; user notifications for 60 day recall; and traceability of M&TE equipment to nationally recognized standards. It was also verified that the IDC included controls for managing out-of-tolerance (OOT) M&TE and methods for extending calibration due dates. The audit team verified by review of several M&TE items that damaged, suspect, OOT and out-of-calibration M&TE is identified in the IDC and tagged, segregated, or otherwise controlled to prevent use. The audit team also verified that the VPM initiates evaluations for OOT/defective or lost M&TE. The evaluations are documented on Attachment 3, OOT/Defective or Lost Evaluation, from CCP-QP-016, and submitted to CCP Records by the M&TE Custodian. The audit team verified that calibration services are performed by approved calibration suppliers and that each procurement included the requirement for a certificate of calibration identifying...
the required information. CCP M&TE has a standard listing of requirements which is included by the M&TE Custodian in each procurement for calibration services.

One condition adverse to quality resulted from review of CCP control of M&TE. Recall notification to M&TE users is automatically generated by the IDC. The IDC generates a weekly report identifying a 1-week, 1-month, and 60-day look-ahead for recall. The audit team reviewed the weekly reports but could not verify that the recall notifications were sent to CCP at ORNL. It was confirmed by the CCP software developer that CCP ORNL was not in the database for these notifications (see section 6.1, CAR 15-036).

The audit team concluded that the requirements for control of M&TE, with the exception of the concern described above, are adequately established for compliance with upper-tier requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

5.2.10 Assessments

The audit team interviewed the CCP Assessments Manager and CCP Surveillance Coordinator and evaluated objective evidence to verify implementation of the assessment processes.

A review of management assessment, audit, and surveillance schedules and logs was conducted to verify compliance with CCP procedures. Evaluations of randomly selected audits, surveillances, and management assessments confirmed that CCP personnel are performing assessment activities according to procedural requirements. Management assessments reviewed and evaluated included MA-CCP-0002-14, MA-CCP-0011-14, MA-CCP-0012-14, MA-CCP-0015-14, and MA-CCP-0019-14. Surveillances reviewed and evaluated included SUR-CCP-04-14, SUR-CCP-08-14, SUR-CCP-09-14, SUR-LANL-02-14, SUR-ORNL-07-14, and SUR-RHNIL-02-14. Additionally, assessment procedures for audits, 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, I15-01, verified the audit was performed in three segments and compliance to CCP procedures was confirmed. The audit team verified that independent assessments are conducted by NWP qualified lead auditors and 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.

During the course of the interviews and reviews of documentation, the audit team identified two concerns. The first concern was identified during review of Surveillance
Reports SUR-CCP-09-14 and SUR-RHINL-02-14. There were several deviations within the reports that should have been noted and corrected during the review process (see section 6.3, Observation #1).

The second concern was identified during the review of procedure CCP-QP-021, CCP Surveillance Program. The procedure presently requires anyone who will perform a surveillance to complete a Surveillance Personnel Qualification Card. The audit team recommends that NWP-qualified lead auditors forego this requirement based on the education and training needed to become a lead auditor (see section 6.4, Recommendation #2).

The audit team verified that the corrective actions for CBFO CAR 14-034 and CAR 14-035, identified during the previous CBFO Audit A-14-10, have been implemented and appear to be effective.

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 evaluated sample control as a function of QA, starting from the records generated from the CCP Host sites. Sample control involves the radiochemistry laboratory analysis at the INL, the SRS, and the ORNL, who are contracted by NWP to provide radioanalytical services on samples collected in support of the DTC processes. Each facility has been evaluated appropriately and placed on the NWP Qualified Suppliers List. The batch data reports from the sites are evaluated during recertification audits. The audit team evaluated the sample control documentation from the sample disposition that occurs after the reporting of the data.

The audit team reviewed the RH RIDS dated June 14, 2014, and selected the file containing chain of custody (COC) records from as early as 2007. The team chose to evaluate only those records completed in calendar year 2014. These records included three COC sets of data providing final disposition information on each COC record with exception to ORNL. The final record of the disposition is verified by CCP Records for completeness via CCP-QP-008, CCP Records Management. The record included the Records Transmittal Form that provided a description of the item and where it originated. This completed the process for sample control regarding the request for analysis and the final disposition of the samples from the reports provided by each lab facility.

The audit team concluded that the requirements for sample control are adequate, satisfactorily implemented, and effective. No concerns were identified.
5.2.12 Software QA

The audit team conducted interviews of CCP personnel responsible for software and records control, witnessed a demonstration of the IDC, 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 software items. The SFTP site was viewed to verify that the site is adequately managed and adequately communicates software control data to users.

The audit team evaluated CCP Software Inventory Lists (SILs) and compared a sample of items on the active spreadsheet of the SIL with the content of the SFTP site for the appropriate Host site. These packages were reviewed for evidence of implementation of procedure steps for Software Change Order (SCO), SCO Addendums, Software Problem Report and Change Request (SPRCP), and review and modification of life-cycle documents (test plans, test reports, design documents, requirements documents, user manuals, and code listings) that were generated as appropriate for the category of the individual software applications.

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

<table>
<thead>
<tr>
<th>Category Name</th>
<th>Site</th>
<th>SCO No.</th>
<th>Software Name</th>
<th>Status</th>
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<tr>
<td>Qualified Supplier Software</td>
<td>LANL</td>
<td>455</td>
<td>Genie 2000</td>
<td>Active</td>
</tr>
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<td>Qualified Supplier Software</td>
<td>LANL</td>
<td>456</td>
<td>NDA 2000</td>
<td>Active</td>
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<td>984</td>
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<tr>
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<td>ORNL DTC-HFIR-HFIR.xls</td>
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<tr>
<td>COTS Software</td>
<td>ALL</td>
<td>1016</td>
<td>MSD Productivity Chemstation</td>
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<tr>
<td>Applications within COTS</td>
<td>LANL</td>
<td>1023</td>
<td>ORNL RH Template.xls</td>
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<td>CCP Software</td>
<td>CCP</td>
<td>1029</td>
<td>Integrated Data Center</td>
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<tr>
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<td>1036</td>
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</tr>
<tr>
<td>Category Name</td>
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<td>SCO No.</td>
<td>Software Name</td>
<td>Status</td>
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<td>1190</td>
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<td>NucDecay.exe</td>
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<td>Applications within COTS</td>
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<td>SNM Limit Evaluation Software</td>
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<td>1216</td>
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<td>Active</td>
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<tr>
<td>Applications within COTS</td>
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<td>DTC for SRS H-Canyon Berl saddle Waste.xls</td>
<td>Active</td>
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<td>Exempt</td>
<td>ALL</td>
<td>N/A</td>
<td>Container Management</td>
<td>Exempt</td>
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<tr>
<td>Exempt</td>
<td>LANL</td>
<td>N/A</td>
<td>Weighted Average Isotopic Spreadsheet</td>
<td>Exempt</td>
</tr>
</tbody>
</table>

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

Two concerns were identified as a result of the review of software QA. The first concern is related to verbiage and flow of steps in procedure CCP-QP-022, Rev. 16. The audit team recommends that CCP-QP-022, CCP Software Quality Assurance Plan, be clarified by adding a corresponding step number when performing the steps of Section 4.2.3[A] if the software modification is not considered minor. The step numbers will point to the appropriate steps for the two alternatives. Adding the step numbers will make this section similar to verbiage in other sections of the procedure (see section 6.4, Recommendation #3).

The second concern is related to information included on CCP SILs. The audit team identified that the SIL "Retired" tab does not include the date that the software was retired. This information is captured in the IDC, but is not shown on the SIL. The audit team recommended that a "retired date" column be added to CCP SIL documents to provide clarification of retired items. Information is currently documented using the SPRCR form and is entered in the IDC, but some site representatives do not have access to the IDC and utilize the SFTP-posted SIL documents as reference regarding details for retired software applications. SIL documents are currently posted on the
SFTP site, providing notification to users of retired software status (see section 6.4, Recommendation #4).

With the exceptions of the above-mentioned concerns, 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 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.

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

**CAR 15-034**

CCP-QP-010, Rev. 25, Section 3.10.4[A], requires that the SPM, QA, CCP Manager, and DOE/CBFO Manager review and approve CCP-PO-006. It also requires the DOE/CBFO Manager to sign the cover sheet. There is no evidence that the DOE/CBFO Manager signed the cover sheet of procedure CCP-PO-006, Rev. 4, CCP Conduct of Operations Matrix.

**CAR 15-035**

During issuance of NCR-RHANL-0317-14, R0, the NCR originator entered "RH-DG" to answer Block # 2 of the NCR. "RH-DG" is not a process choice listed in the instructions for completing an NCR (Attachment 2 of CCP-QP-005). CCP-QP-005, Rev. 24, CCP TRU Nonconforming Item Reporting and Control, Section 4.1.3[A] states: "NCR Originator complete Blocks 1 through 7, as applicable, of the NCR (see Attachment 2, Instructions for Completing Attachment 1, Nonconformance Report [NCR] ...)." Also, CCP-QP-005, Attachment 2 - Instructions for Completing Attachment 1, Nonconformance Report (NCR), Block 2, states: "NCR Originator enter kind of process. Choose one or a combination from the following: AK, CRMU Project, DA, Exterior..."

CAR 15-036

CCP-QP-016, Rev. 20, Section 4.2.4[B], requires that the IDC M&TE Module notify the VPM or designee and QA within 60 days of the expiration of M&TE calibration for recall using the recall notification e-mails. The audit team was unable to obtain objective evidence indicating that the VPM or designee and CCP QA at the ORNL are on distribution of the IDC M&TE Module-generated e-mails for the 60-day M&TE recall notifications.

CAR 15-038

CCP-QP-014, Rev. 6, Sections 4.3 and 4.3.3 require the Semiannual Trend Reports for various Host sites to be generated and reviewed by the Assurance Programs Manager. It was determined that only the Host sites that have a QA Engineer are submitting trend reports semiannually. For January through June 2014 and July through December 2014, no trend reports were submitted from the following Host Sites: SRS, Hanford, SNL, and ANL.

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.

Two deficiencies, determined to be minor and isolated in nature, were identified and corrected during the audit.

CDA 1

There was no indication that operational logbook CCP-ORNL-NDA-IQ3-002 had been submitted to CCP Records for reconciliation. CCP took the necessary steps to revise
the operational logbook annual reconciliation report to include CCP-ORNL-NDS-IQ3-002.

CDA 2

There was no indication that operational logbook CCP-SN-RH-DTC-002 was reviewed, signed, and dated by the VPM for the week of 06/22/14 through 06/26/14. Objective evidence was provided to the auditor 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.

Two Observations were identified during the audit.

Observation 1

During review of Surveillance Reports SUR-CCP-09-14 and SR-RHINL-02-14, it was noted that there were several deviations within the reports that should have been corrected during the review process. The deviations did not constitute a CAQ, but if not captured in the future, could potentially result in a CAQ.

Observation 2

The audit team identified an individual who had not completed the SCI refresher training. During discussions with responsible personnel, it was discovered that this condition had been previously identified and documented on WIPP Form WF14-154. Corrective actions were developed to address the concern, but have not yet been fulfilled as of the date of this 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.

Four Recommendations were provided for CCP management consideration.

**Recommendation 1**

Work process procedures CCP-QP-023, Rev. 4, *Handling, Storage and Shipping*, and CCP-QP-017, Rev. 4, *CCP Identification and Control of Items*, address requirements that are not implemented by CCP, but rather by the WIPP site and Host site contractors at remote sites. As such, it is recommended that the procedures be clarified to identify the specific activities within the CCP scope, or perhaps deleted if adequate control for handling, storage, and shipping and identification and control of items is provided by the WIPP site and other Host site organizations at the remote sites.

**Recommendation 2**

CCP-QP-021, *CCP Surveillance Program*, requires anyone who will perform a surveillance to complete a Surveillance Personnel Qualification Card. The audit team recommends that NWP-qualified lead auditors forego this requirement based on the education and training needed to become a lead auditor.

**Recommendation 3**

The audit team recommends that CCP-QP-022, Rev. 16, *CCP Software Quality Assurance Plan*, be clarified by adding a corresponding step number when performing the steps of Section 4.2.3[A] if the software modification is not considered minor. The step numbers will point to the appropriate steps for the two alternatives. Adding the step numbers will make this section similar to verbiage in other sections of the procedure.

**Recommendation 4**

The audit team identified that the SIL "Retired" tab does not include the date that the software was retired. This information is captured in the IDC, but is not shown on the SIL. The audit team recommends that a "retired date" column be added to CCP SIL documents to provide clarification of retired items. Information is currently documented using the SPRCR form and is entered in the IDC, but some site representatives do not have access to the IDC and utilize the SFTP-posted SIL documents as reference regarding details for retired software applications. SIL documents are currently posted on the SFTP site providing notification to users of retired software status.
7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During Audit A-15-12
Attachment 2: Summary of Audit A-15-12 Results
Attachment 3: Documents Audited During Audit A-15-12
<table>
<thead>
<tr>
<th>NAME</th>
<th>ORG/Title</th>
<th>PREAUDIT MEETING</th>
<th>CONTACTED DURING AUDIT</th>
<th>POST AUDIT MEETING</th>
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</thead>
<tbody>
<tr>
<td>Armijo, Cheryl</td>
<td>NWP/CCP/Training Record Analyst</td>
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<td>Billett, Michele</td>
<td>NWP/CCP/Training Coordinator</td>
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<td>Billett, Robert (Bob)</td>
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<td>Donner, Tony</td>
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<td>Fisher, A.J.</td>
<td>NWP/CCP/Support Services Manager</td>
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<td>Jones, Laura R.</td>
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<td>Kantrowitz, Rich</td>
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## PERSONNEL CONTACTED DURING AUDIT A-15-12

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<th>POST AUDIT MEETING</th>
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<td>Wise, Charles G.</td>
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### Summary of Audit A-15-12 Results

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**Definitions**

- **E** = Effective
- **S** = Satisfactory
- **I** = Indeterminate
- **M** = Marginal
- **CAR** = Corrective Action Report
- **CDA** = Corrected During Audit
- **Rec** = Recommendation
- **A** = Adequate
- **NE** = Not Effective
- **NA** = Not Adequate
- **Obs** = Observation
## Documents Audited During Audit A-15-12

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<tr>
<th>Document Number</th>
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<td>CCP-PO-001 CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAP)</td>
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