



**Department of Energy**  
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 MAY 13 2016

ENTERED



Mr. Val Cannon, Manager  
 Quality Assurance  
 Nuclear Waste Partnership LLC  
 P.O. Box 2078  
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Subject: Carlsbad Field Office Audit Report A-16-16

Dear Mr. Cannon:

Carlsbad Field Office (CBFO) Audit A-16-16 was performed April 26 – 28, 2016, to evaluate Nuclear Waste Partnership LLC (NWP) Radiological Control Program. The details of the audit and conclusions from the audit team are contained in the enclosed audit report. Five concerns were identified during the audit, as described in the report.

Three Corrective Action Reports (CARs) addressing conditions adverse to quality identified during the audit have been transmitted under separate cover.

The audit team concluded that overall, the activities evaluated are adequate, satisfactorily implemented, and effective in all areas except as documented in the audit report.

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

Sincerely,

Dennis S. Miehl  
 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

WIPP RADIOLOGICAL CONTROL PROGRAM

CARLSBAD, NEW MEXICO

AUDIT NUMBER A-16-16

APRIL 26 – 28, 2016



Prepared by: Robert J. Verret FOR Date: 13 MAY 16  
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Audit Team Leader

Approved by: Michael R. Brown FOR Date: 5-13-16  
Michael R. Brown, Director  
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## **1.0 EXECUTIVE SUMMARY**

U.S. Department of Energy (DOE) Carlsbad Field Office (CBFO) Audit A-16-16 was conducted April 26 – 28, 2016, to evaluate the adequacy, implementation, and effectiveness of the Nuclear Waste Partnership LLC (NWP) Radiological Control (RADCON) Program. The evaluation included Waste Isolation Pilot Plant (WIPP) site radiological control instruments and calibration; WIPP External Emergency Response instrumentation and calibration; and WIPP Laboratories sample receipt, instrument calibration, and reporting.

Based on the results of the evaluation, the audit team determined that the elements of the NWP RADCON Program reviewed adequately address upper-tier requirements, are satisfactorily implemented, and are effective in achieving the desired results. Four conditions adverse to quality (CAQs) were identified during the audit necessitating the initiation of Corrective Action Reports (CARs) 16-036, 16-037, and 16-038. No Observations were reported, and one Recommendation was offered for management consideration.

## **2.0 SCOPE**

The scope of the audit included evaluations of NWP dosimetry and RADCON instruments, implementing procedures, training, and records; External Emergency Response instrumentation and calibration; and WIPP Laboratories sample receipt, instrument calibration, training, analysis, and reporting. Responsible personnel were interviewed to assess their understanding of requirements and to confirm that requirements were being fulfilled. The following areas were evaluated:

- Radiological Control Instrumentation and Calibration
- Source Control
- Radiological Control and Analysis
- Training
- WIPP Laboratories RADCON Sample Instrumental Analysis and Reporting
- Software Quality Assurance
- Quality Assurance Program

## **3.0 AUDIT TEAM AND OBSERVERS**

Dennis Miehl	Management Representative, CBFO Office of Quality Assurance
B.J. Verret	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC)
Robert Boyko	Technical Specialist, CTAC
Cindi Castillo	QA Auditor, CTAC
Paul Gomez	QA Auditor, CTAC
Michel Hall	Technical Specialist, CTAC
Kathy Hood	QA Auditor in Training, CTAC
Jim Oliver	Technical Specialist, CTAC
Charlie Riggs	QA Auditor, CTAC
Jim Schuetz	Technical Specialist, CTAC
Jason Flora	DOE, Observer
Brandon Madrid	DOE, Observer

## **4.0 AUDIT PARTICIPANTS**

Individuals contacted during the audit are identified in Attachment 1. A pre-audit conference was held in the WIPP Support Building large conference room and the WIPP Laboratories conference room on April 26, 2016. The audit was concluded with post-audit conferences at the WIPP Laboratories facility in Carlsbad and at the WIPP site on April 28, 2016.

## **5.0 SUMMARY OF AUDIT RESULTS**

### **5.1 Program Adequacy, Implementation, and Effectiveness**

The audit team concluded that the NWP RADCON Program instruments, the External Emergency Response instrumentation and calibration, the WIPP Laboratories activities, and the associated documents identified in Attachment 2 are adequately established and effectively implemented for compliance with requirements.

### **5.2 Audit Activities**

The following sections describe audit activities and the methods used to conduct evaluations for each of the areas and organizations included in the audit. Requirements are cited as applicable to the program areas evaluated.

NWP RADCON, External Emergency Response, and the WIPP Laboratories participate in the collection of samples and data, analysis of samples, modeling of data and, ultimately, the delivery of data to decision-makers and response elements both at NWP and at external organizations. The audit team evaluated sample media collection and distribution and found these activities to be technically sound and compliant with procedural requirements.

#### **5.2.1 NWP Dosimetry and RADCON**

The audit team reviewed NWP Dosimetry and RADCON instrument and quality assurance procedures and governing documents prior to the audit and prepared checklists based on the documents. Activities generally described as Dosimetry and RADCON are handled by a number of organizations within NWP and by outside facilities such as the WIPP Laboratories. Numerous personnel interviews were conducted to track the collection of sample media, sample storage and analysis, data collection, verification, and validation of results.

The audit team conducted interviews to verify that the NWP Dosimetry and RADCON programs meet upper-tier requirements, and activities are conducted in accordance with implementing procedures. Personnel interviews were conducted with the radiological engineer to address checklist questions and verify the adequacy of training, surface and underground radiological controls, and configuration control measurement and testing equipment (M&TE) on radiological survey equipment.

### Statements of Work

The audit team verified the following current statements of work (SOWs) for the WIPP Laboratories:

- Radiological Control Waste Isolation Pilot Plant (WIPP) Sample Analysis Requirements and Data Quality Objectives, Rev. 9, June 19, 2014
- Statement of Work, Environmental Radiochemistry Analyses at the WIPP Site for WIPP Laboratories, Rev. 4, October 2014
- Statement of Work for Environmental Compliance (Radio Bioassay)

The SOWs reviewed reflect the types of work performed at the WIPP Laboratories and were found to be complete and representative of the type of quality reports and protocols expected by the WIPP Programs and WP 13-1, Rev. 36, *NWP Quality Assurance Program Description*.

### Sample and Standard Tracking

The audit team interviewed NWP RADCON personnel responsible for sample collection and custody, standard maintenance, and review of documentation provided by the WIPP Laboratories in reporting data per the requirements of WP 12-RL1001, Rev. 12, *Sample Tracking and Custody*; WP 12-RL1550, Rev. 13, *Control of Radioactive Standards*; and WP 13-1, Rev. 36, *NWP Quality Assurance Program Description*.

The audit team verified that the Environmental Monitoring (EM) group collects samples, which are sent to the WIPP Laboratories for analysis. These samples are monitored for emissions as required by National Emissions Standards Hazardous Air Pollutants (NESHAP) regulations. The NESHAP samples are couriered to the WIPP Laboratories for analysis, and are tracked by chain of custody (COC). The EM group monitors the progress of the samples through the labs. The EM group receives updates on laboratory analysis and is provided with batch data reports (BDRs) documenting results.

The audit team verified that sample tracking at the laboratory is a two-fold process when samples are received in the dock area of the WIPP Laboratories. Receipt of the samples is recorded in a logbook, as well as the Laboratory Information Management System (LIMS). The sample custodian verifies sample tampering indication devices (TIDs) are intact and that the volume of sample is adequate. Samples are swiped and tested for radiation at the Carlsbad Environmental Monitoring and Research Center (CEMRC) using a Ludlum alpha-beta scanner. All samples received at the labs are considered radioactive until proven otherwise.

The audit team verified that the samples are logged into the sample tracking logbook, and custody is relinquished by signature indicating sample receipt. The samples are logged into LIMS for analysis tracking utilizing the Internal Chain of Custody Form and unique sample identification. The samples are logged into storage and are refrigerated to prevent a biological hazard. No samples are opened. Weekly meetings are conducted to discuss

the work to be completed and any incoming samples to the facility. Nonconformance issues for samples are handled before the samples are logged.

During the walk-through of the laboratory, the audit team verified the calibration of the analytical balance and the calibration weights. The class "S" weights used are M&TE and are annually calibrated. The calibration is monitored by all personnel who use the balances. The balance calibration date and the due date are documented in the BDRs. Tracking of the certified weights was not as readily available to show the calibration dates. Therefore, the audit team recommended that the labs employ a recall system (i.e., LIMS) to provide an automated process for tracking system calibrations and thereby preventing the use of out-of-tolerance equipment (see Recommendation 1, section 7.3).

The WIPP Laboratories maintain their own calibrated radioactive source standards. The standards are appropriately maintained and their pedigrees, traced to the National Institute of Standards and Technology (NIST), are maintained in logbooks by the standards custodian. The following laboratory logbooks were examined for completeness:

- Sample Preparation Logbook 16-04-02 under SDG 2016-086 started 3/18/2016
- Sample Preparation Logbook 16-05-02 under SDG 2016-098S106 started 4/25/2016
- Deionized Water Resistivity Logbook 2015-1 and 2016-1

The audit team verified that the laboratory program for in-vivo radio bioassay is listed on the site's qualified suppliers list (QSL), with an expiration date of 5/31/2016. The vendor that provides lab equipment repair and calibration, TEKTRONIX, Inc., was included on the QSL with an expiration date of 2/28/2017.

The audit team verified final data packages are validated by the laboratory, and the EM group verifies the correctness, precision, and accuracy of the data as the end user.

The audit team determined that overall, sample and standard tracking for the WIPP Laboratories meets program adequacy requirements, and WIPP Laboratories procedures meet requirements and are adequately implemented and effective.

#### WIPP Laboratories RADCON Sample Instrumental Analysis and Reporting

At the WIPP Laboratories, the audit team verified acceptable operation of the alpha spectroscopy and gross alpha-beta systems. Prior to the audit, the team reviewed the following WIPP Laboratories procedures:

- WP 12-RL1002, *Alpha Spectroscopy System*
- WP 12-RL1008, *Alpha/Beta and Sr Absorption Curves*
- WP 12-RL1009, *Gross Alpha/Beta Activity*
- WP 12-RL1010, *Sample Preparation*
- WP 12-RL3002, *Radiochemistry Laboratory Validation and Verification*
- WP 12-RL3003, *Data Reduction and Reporting*

The audit team noted that procedures WP 12-RL1054, WP 12-RL1056, WP 12-RL1057, WP 12-RL1314, and WP 12-RL2001 have not been used for NWP RADCON-associated work. All other procedures evaluated were determined to contain the necessary flow-down of requirements related to analyses and documentation from the current revision of the CBFO *Quality Assurance Program Document (QAPD)*.

WIPP Laboratories sample preparation activities were being performed during the audit. The audit team observed the digestion and preparation of samples for counting, interviewed the laboratory technician, and verified that activities were being performed according to procedures. The audit team interviewed other project participants, inspected the laboratory, and reviewed relevant data packages, laboratory logbooks, and NIST standards for the heat sources. The team observed sample tracking and custody for urine samples and confirmed COC forms were completed properly and samples were stored under refrigeration in accordance with procedure WP 12-RL1001.

The WIPP Laboratories Level IV batch data packages for the following sample delivery groups (SDGs) were examined:

- SDG: 2016-071; Client: Environmental Monitoring; Matrix: Water
- SDG: 2016-066; Client: Environmental Monitoring; Matrix: Soil
- SDG: 2016-044; Client: Dosimetry; Matrix: Urine
- SDG: 2016-065; Client: NESHAPS; Matrix: Filter
- SDG: 2016-023; Client: Dosimetry; Matrix: Urine

The sample preparations for different environmental matrices were found to be adequate and the associated data packages were compiled in accordance with procedures. The COCs, M&TE certifications for the NIST source standards and laboratory scales, control charts of instrument background and response to sources of known activities, instrument pulser checks and calibrations, sample logbooks, and equipment logbooks were reviewed and found to be acceptable.

The audit team found that analytical variance reporting was documented in accordance with the approved procedure. Radiochemistry analysis data verification and validation were evaluated and found to be adequate.

The audit team assessed WIPP Laboratories performance evaluation processes. Results for both the CEMRC Management Self-Assessment (MSA-SO-2015-001) and Internal Quality Assurance Assessment Report (URS-PS-1A-15-001) were reviewed and determined to be adequate.

The audit team determined that for fecal and biota sampling, the entire sample is used and nothing remains. Excess urine samples are placed in a barrel. When the barrel is full, it is transferred to the CEMRC for storage. Other waste and completed samples are also transferred to CEMRC. Periodically, CEMRC transfers all the accumulated wastes to a disposal facility.

The audit team evaluated WIPP Laboratories facilities both at the WIPP site and in Carlsbad. The team reviewed and prepared audit checklists from the following WIPP Laboratories procedures to assess compliance with CBFO requirements documents:

- 12-HP3500, *Airborne Radioactivity*, Rev. 21
- 12-RE3004, *Periodic Confirmatory Analysis, Reporting, and Compliance Activities*, Rev. 6
- 12-RL1010, *Sample Preparation*, Rev. 14
- 12-RL1011, *Elemental Separation - Sr-90*, Rev. 15
- 12-RL1012, *Elemental Separation - TRU Products*, Rev. 9
- 12-RL1015, *Canberra Alpha Analyst System Operation*, Rev. 18
- 12-RL1016, *Oxford Series 5 Gas Proportional Counter*, Rev. 15
- 12-RL1017, *Vacuum-Assisted Rapid Sequential Separation of Actinides and Strontium in Various Matrices*, Rev. 6
- 12-RL1030, *Canberra Apex Alpha System Operation*, Rev. 0
- 12-RL1332, *Genie 2000 Gamma Spectrometry System Operations*, Rev. 11

At the WIPP site, the audit team observed the collection and preparation of air filter samples from Station B downstream from the high-efficiency particulate air (HEPA) filters. The Radiological Control Technician (RCT) and RADCON Manager were interviewed to verify that procedures were adequately implemented and that RADCON practices were technically correct.

At the WIPP Laboratories facility in Carlsbad, the audit team inspected the sample preparation area and interviewed and observed a sample preparation technician as he demonstrated various sample preparation techniques and described work in progress. No concerns were identified.

The audit team inspected all of the RADCON analysis systems currently in use at the WIPP Laboratories. These systems included a large array of alpha and gamma spectrometers and a gas proportional counter. The audit team interviewed operations personnel and examined hardware and software to ensure that procedural requirements were followed and analyses were technically adequate. The audit team reviewed batch data packages SDG: 2016-023, SDG: 2016-044, SDG: 2016-065, SDG: 2016-066, and SDG: 2016-071. No concerns in the analysis of samples were identified.

The audit team reviewed documentation to verify that, from sample collection to disposal, all preparation, measurement, analysis, and comparison with trends or regulatory requirements met procedural requirements and demonstrated technical adequacy.

The audit team determined that WIPP Laboratories RADCON Sample Instrumental Analysis and Reporting activities are adequately established for compliance with upper-tier

requirements, satisfactory in the implementation of these requirements, and effective in achieving the desired results.

#### Radiological Assistance Program

The audit team verified the source control and dosimeter control maintained by the Radiological Assistance Program (RAP). The source control log was provided to the team for review. The source log is maintained according to NWP procedure WP 12-HP3201, Rev. 2, *Radioactive Source Accountability and Control*. EM provided the inventory list and all sources were accounted for in the RAP vehicle. The alpha and beta (Ludlum) instruments and the hand-held gamma (neutron ball) detector were verified to be calibrated. Calibrations and repairs are contracted to F&J Specialty Products, Inc., and are on the NWP QSL. Operations of the RAP facility are conducted per DOE Order 412.1, National Nuclear Security Agency, and work authorization is granted under the Nuclear Counterterrorism Incident Response Project last updated February 2016.

Overall, the Radiological Assistance Program was determined to be satisfactory, and the program procedures were determined to be adequately implemented and effective.

#### RADCON and Dosimetry WIPP Laboratories Quality Assurance Program

The audit team verified that WIPP Laboratories maintains service contracts for the instruments and vendors are on the NWP QSL. The items that do not meet established requirements are identified, documented in lab logbooks, controlled and placed out-of-service. The team verified a tagged-out centrifuge that was placed in a Conex outside the lab. All other serviceable pieces are maintained in the lab and are calibrated internally or corrected by service contract from the manufacturer.

Documents are maintained in Fire King two-hour fire-rated cabinets at the WIPP site as well as at WIPP Laboratories. The procedures are stored in appropriate places in the laboratory and are readily available online from the Q&MIS electronic document storage system. Maintenance and control of procedures is performed by Document Services at the WIPP site.

Laboratory records were verified by the audit team for sample delivery groups 2015-319 with preparation batch 15-14-17. The BDR consisted of Station C samples from the WIPP for the third quarter of 2015. BDR 2015-319 was also verified to be complete. The BDR consisted of Station C sample results for filter samples collected using COC 15-0009. Laboratory logbook STLC-09 was verified for the uranium-238 standard, plutonium-242 standard, and primary standards. All logbooks were complete, legible, and accurate for the work sent to records. The final reports are dispositioned correctly per the Regulatory and Environmental Services (RES)/Effluent Monitoring Program Records Inventory and Disposition Schedule (RIDS) dated 5/27/2015.

The audit team found that all standards were controlled administratively and maintained according to procedures. All instruments were calibrated correctly and tracked in each BDR. No violations of uncalibrated equipment were found by the audit team as long as it

was listed in the BDR. Thus, the audit team made a recommendation (see section 7.3) to the labs to document tracking for calibrated equipment in an automated system such as LIMS, even though each piece of calibrated equipment had an appropriately labeled and legible sticker or certificate of calibration.

The audit team verified an internal audit and a management assessment reported late last year. The team verified Internal Quality Assurance Assessment Report URS-PS-IA-15-001 completed December 2015. The team also verified self-assessment report, Science and Development/WIPP Laboratories Annual Management Self-Assessment Calendar Year 2015 number MSA-SD-2015-001 dated 11/9/2012 and 2/1/2015, and signed 12/21/2015 by the WIPP Laboratories Manager.

Overall, the RADCON and Dosimetry WIPP Laboratories Quality Assurance Program were determined to be satisfactory. Applicable program procedures were determined to be satisfactorily implemented and effective.

At the time of the audit, the WIPP Laboratories were not using the inductively-coupled plasma (ICP) mass spectrometer (MS). Therefore, activities associated with procedure WP 12-RL2001, Rev. 1, *Analysis of Actinides in Bioassay Samples by Agilent 770x ICP/MS*, were not evaluated.

The audit team found that analytical variance reporting was documented in accordance with the approved procedure. Radiochemistry analysis data verification and validation were evaluated, and no recurrence was found of the previously identified condition adverse to quality in which the required second review was either not performed or was performed after final approval by the QA Officer (CAR 15-040 from CBFO Audit A-15-15).

The audit team verified that a management assessment and an assessment by NWP had been performed, as appropriate.

#### Operational Performance Assessment

The audit team observed the performance of daily operational checks by the RCTs for the following instruments.

##### Portable Contamination Counter, Model 2360, Ser. #1231

Operational checks were satisfactorily performed in accordance with implementing procedure WP 12-HP1307, Rev. 16. The instrument met all initial Precautions and Limitations set forth in the procedure, including calibration. The appropriate NIST-traceable sources were utilized, were observed to be in good condition, and were handled and stored appropriately. The RCTs demonstrated technical knowledge of the procedure and instrument. Records and documents associated with the operational checks contained inaccuracies, as noted below.

One concern was identified and corrected during the audit in the area of performance of operability checks. Three instances of inaccurate  $\pm 20\%$  operational range checks were

recorded on Attachment 2 of the procedure. Further investigation revealed that the inaccuracies were all due to transcription errors from the previous in-use Attachment 2 forms or the associated Attachment 1 calculation sheets. The inaccuracies did not affect instrument use and no survey results were compromised due to the errors. RADCON management corrected the issue during the audit (see CDA-1, section 7.2).

**Tennelec Counting System, Model 5 XLB, Ser. #1032**

The audit team found that operational checks were satisfactorily performed in accordance with implementing procedure WP 12-HP1245, Rev. 9. The instrument met all initial Precautions and Limitations set forth in the procedure, including calibration. The appropriate NIST-traceable sources were utilized, observed to be in good condition, and were handled and stored in an appropriate manner. The RCTs demonstrated technical knowledge of the procedure and instrument. Records and documents associated with the operational checks were found to be legible, accurate, and complete.

Laboratory analysis of the Station B air sample filter was also observed. The RCT utilized the current revision (21) of WP 12-HP3500. The instrument met all initial Precautions and Limitations set forth in the procedure, including calibration and background limitations. Sample preparation, data recording, and filter handling were performed in accordance with the governing document and standard industry radiological practices. No activities associated with gravimetric measurements were observed. Records and documents associated with the operational checks were found to be legible, accurate, and complete.

One concern was identified during the performance of the operability checks. The Tennelec utilized Eclipse software version 3.3, which is not yet approved for use due to incomplete installation documentation. This concern is further discussed in the Software QA section of this report.

**Station B iCam Air Monitor, Ser. #365-CAM-018-001**

Operational checks were satisfactorily performed in accordance with implementing procedure WP 12-HP1325, Rev. 5. The instrument met all initial Precautions and Limitations set forth in the procedure, including calibration. The RCTs demonstrated technical knowledge of the procedure and instrument. Records and documents associated with the operational checks were found to be legible, accurate, and complete.

**iSolo Counting System, Model Solo 300 G, Ser. #240-RI-000-1311**

Operational checks were satisfactorily performed in accordance with implementing procedure WP 12-HP1317, Rev. 1. The instrument met initial Precautions and Limitations set forth in the procedure, including calibration. The appropriate NIST-traceable sources were utilized, observed to be in good condition, and were handled and stored appropriately. Review of the iSolo source registry indicated the proper check sources were included. The RCTs demonstrated technical knowledge of the procedure and instrument. Records and documents associated with the operational checks were found to be legible, accurate, and complete.

### Canberra Alpha Sentry Continuous Air Monitor, Ser. #411-RIC-007-152A

Operational checks were determined to be satisfactorily performed in accordance with governing document WP 12-HP1306, Rev. 9. The instrument met initial Precautions and Limitations set forth in the procedure, including calibration. The appropriate NIST-traceable sources were utilized, observed to be in good condition, and were handled and stored in an appropriate manner. The RCTs demonstrated technical knowledge of the procedure and instrument. Records and documents associated with the operational checks were found to be legible, accurate, and complete.

### Sentinel Instrument Calibrator, Model 773

The audit team observed that the unit was properly secured in a locked (combination) safe and properly posted "Caution Radiation Area," with a maximum dose rate of 1.55 mrad/hour measured at the boundary. Established boundaries were appropriate, and documentation associated with the calibrator was found to be legible, accurate, and complete.

### Emergency Response Instrumentation

The audit team reviewed external emergency response equipment and the radioactive source list associated with the Radiological Assistance Plan (RAP) response vehicle. Calibration information for the instrumentation was found to be current and satisfactory. Review of the associated source check list indicated the appropriate sources were available for the instrument inventory. The source inventory sheet was found to be complete and contained all necessary and pertinent information.

### Air Monitoring System Maintenance

The audit team reviewed documentation associated with inspections and maintenance of the Station B and Station C air monitoring system, specifically the Station C sampler rake (PM411050, Rev. 0) and vacuum pumping systems (PM534006, Rev. 5, TRN 2), and the Station B sample probe (PM365001, Rev. 5, TRN 1). Recall and maintenance is tracked and scheduled in the Computerized History and Maintenance Planning System (CHAMPS). Air monitoring system maintenance was found to be performed at the intervals specified by the governing documents. Work packages associated with these system maintenance activities for the past three years were complete, legible, and accurate. No concerns were identified with air monitoring system maintenance.

### Radioactive Source Storage and Inventory

The audit team evaluated activities associated with radioactive source storage, retrieval, inventory, and handling at the WIPP site and the CEMRC lab. The team examined equipment source calibration and maintenance of the source log, and verified storage of the sources in the limited access safe and storage room. The team verified the contents of the storage areas and matched the sources to the source log maintained in the area. The sources matched a list of sources that was provided by RADCON management,

including Pu-239, Cs-137, Am-241, Sr-90, and Tc-99. No concerns were identified with the radioactive source inventory and storage program.

### Document Control

The audit team verified that the NWP RADCON Program complies with the requirements of CBFO QAPD, section 1.4, Documents. The audit team evaluated the current version of the following air flow monitoring procedures to determine their adequacy in addressing upper-tier requirements:

- IC041072 – *Effluent Monitoring Skids A-1, A-2, A-3 and B2 Flow Instrumentation Calibration*
- IC041096 – *Calibration of Station C Mass Flow*
- IC041097 – *Effluent Monitoring Station C FAS Flow Annual Calibration*
- IC413000 – *Station B Mass Flow Measurement System Loop 41A001W2001*
- PM365001 – *Inspection And Maintenance Of Station B Radiological Sample Probes 365-S-100 & 365-S-102*
- PM411050 – *Inspection and Maintenance of Station C Radiological Sampler Rake*
- PM534006 – *Effluent Monitoring Fixed Air Sampler (FAS) Vacuum Pumping System*
- WP 12-HP1245 – *Tennelec Series 5XLB Low Background Alpha/Beta Counting System Operation*
- WP 12-HP1307 – *Portable Instrument Operability Checks*
- WP 12-HP1306 – *Canberra Alpha Sentry Continuous Air Monitor*
- WP 12-HP1317 – *Canberra iSolo Alpha/Beta Counting System*
- WP 12-HP1304 – *Canberra iCAM Alpha/Beta Continuous Air Monitor*
- WP 12-HP1325 – *Station B Canberra iCAM Alpha Continuous Air Monitor*

The following procedures have been designated obsolete since the previous audit:

- WP 12-HP1308 – *Portable Alpha-6 Continuous Air Monitors*
- WP 12-HP1315 – *Ludlum Model 2350-1 Data Logger*
- WP 12-HP1318 – *RADOS Continuous Air Monitor*
- WP 12-HP1319 – *RADOS RAM 31 Functional Check*

The audit team conducted interviews with the WIPP Document Control Manager and personnel. The team reviewed randomly selected RADCON-related procedures/documents and resulting records packages to verify that appropriate

preparation, review, approval, issuance, distribution, control, and changes are performed in accordance with upper-tier requirements.

The team identified one concern regarding document control was identified (see CAR 16-037, Section 7.1). The following documents could not be accessed from the Electronic Document Management System (EDMS) for verification of use of the current revisions because required periodic reviews had not been performed:

- WP 12-HP1305, Rev. 12, *Fixed Air Monitoring Equipment*
- WP 12-HP1313, Rev. 0, *Operation of the Sentinel Model 773 Instrument Calibration*
- IC534000, Rev. 1, *RAM 31 Continuous Air Monitor for Alpha and Beta*
- IC041098, Rev. 6, *Quarterly Underground Exhaust Mass Flow Measurement System Calibration for Fans 700A, 700B, and 700C*

WP 15-PS3002, Rev. 36, *Controlled Document Processing*, section 9.0 requires that periodic reviews occur at 24-month intervals unless a shorter time period is specified by the Cognizant Individual/Cognizant Manager (CI/CM). The CI/CM is notified 30 days prior to the review date by the EDMS. It is the responsibility of the CI/CM to ensure that periodic reviews are performed and documented. Also, WP 04-AD3034, Rev. 1, *Technical Procedure Compliance*, section 1.1 states, "Obtain a copy of procedure, round sheet and/or associated data sheets from one of following sources:

- Electronic Document Management System (EDMS)
- A Controlled Copy binder"

Section 1.3 states, "Identify procedure as 'Issued/Working Copy,' and perform Working Copy verification of procedure against EDMS to ensure it is latest revision prior to use."

With the exception of the concern identified above, the audit team concluded that the upper-tier requirements in CBFO QAPD, section 1.4, Documents, are adequately addressed, satisfactorily implemented, and effective.

### Records

The audit team verified that the NWP RADCON Program complies with the requirements of CBFO QAPD, section 1.5, Records. The audit team evaluated the adequacy of procedure WP 15-RM, Rev. 8, *WIPP Records Management Program*, with respect to the requirements of the CBFO QAPD, and determined that the procedure contains adequate flow-down of upper-tier requirements. The audit team also reviewed WP 04-CO.01-11, Rev. 4, *Conduct of Operations Program Logkeeping*, to verify requirements for radiological logbooks are being met.

The audit team conducted interviews with the WIPP Radiological Control and Dosimetry Deputy Manager and reviewed the current NWP/Environmental, Safety, and Health

Radiological Control RIDS dated January 25, 2016. The team verified that the RIDS were developed in accordance with the requirements of WP 15-RM3002, *Records Filing, Inventorying, Scheduling, and Dispositioning*. The audit team also verified that the appointed RADCON records coordinators are appropriately trained and qualified.

The following randomly selected records were examined for accuracy, completeness, and legibility: radiological logbooks, operability check sheets and check labels for related-radiological equipment, associated radiological work permits (RWPs), pre-job and post-job briefing records, management assessment/observation forms, and training records (including required job performance measures documentation) for radiological personnel.

Records storage arrangements were evaluated to verify compliance with requirements for the preservation of in-process and completed RADCON records.

No concerns were identified in this area. The audit team concluded that the upper-tier requirements in CBFO QAPD, section 1.5, Records, are adequately addressed, satisfactorily implemented, and effective.

#### Personnel Qualification and Training

The audit team verified that the NWP RADCON Program complies with the requirements of CBFO QAPD, section 1.2, Personnel Qualification and Training. The audit team evaluated RADCON personnel training records and verified qualification requirements were established per WP 12-RC.02, *WIPP Radiological Control and Dosimetry Department Training Program Plan*.

The audit team conducted interviews with WIPP Technical Training management and training records file room personnel. The team reviewed training records packages for qualified RCTs, radiological engineers (REs), and the current RADCON supervisor. Objective evidence included table-top job analysis for applicable radiological control positions, and qualification and requalification cards (including applicable job performance measures). Documentation of quarterly continuing training for RCTs was also evaluated during the audit.

The audit team evaluated training records for qualified source custodians, and identified one concern in this area. No objective evidence was provided during the audit to demonstrate that source custodians had received training (or a required reading assignment) documenting knowledge of WP 12-HP3201, *Radioactive Source Accountability and Control*, an essential procedure for source custodians (see CAR 16-036, section 7.1).

With the exception of the identified concern, the audit team concluded that the RADCON 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.

## Software Quality Assurance

The audit team conducted interviews with personnel responsible for controlling and managing software applications used at the NWP RADCON program at the WIPP site and at the WIPP Laboratories. The audit team randomly selected and reviewed software records packages documenting the application of software quality assurance for individual software applications. Both NWP and WIPP Laboratories personnel implement WP 16-2, Rev. 14, *Software Screening and Control*. NWP quality assurance personnel perform oversight of implementation of software quality assurance by NWP and WIPP Laboratories and review software documentation in accordance with procedure WP 16-2, as appropriate. The audit team reviewed a sample of software quality assurance documentation packages generated by NWP and WIPP Laboratories personnel. The team reviewed packages generated by NWP for the Air Sample Report & Air Sample Report with direct DPM Entry, Ver. 5; Eclipse LB Control & Analysis, Ver. LB 3.3; and the Sentinel Software Suite, Ver. 1.11 software applications.

The audit team reviewed packages generated by WIPP Laboratories for the Automated QC Template, Ver. 1; Autoscribe Matrix Gemini LIMS (AlphaSpec Test), Ver. 5.3.12; Environmental Monitoring GAB, Ver. 2.0; and the Relative Error Ratio, Ver. 2.0 software applications. Software applications related to RADCON at the WIPP site are controlled by either the RADCON/Dosimetry or Engineering departments, as noted on the Controlled Software Log (CSL). The sample of software packages reviewed included applications that were written with commercial off-the-shelf software (COTS) acquired from vendors, and applications developed by NWP personnel. The acquired software applications were procured more than 12 months prior to this audit. No software applications have been procured at NWP or by the WIPP Laboratories within the last 12 months.

Packages for applications that were built with COTS contain completed screening forms, QA checklists, a list of the software formulae, hand calculations used to test the spreadsheet, and installation documentation. The audit team determined that the scope of documentation in the COTS software quality assurance documentation packages provided adequate detail to describe and manage this type of software application.

Acquired software applications at NWP include software that is embedded within analytical equipment (e.g., Tennelec/Canberra radiation count measurement equipment). Acquired software items at the WIPP Laboratories include software that is embedded within analytical equipment and LIMS, which is customizable for use in laboratory environments. The software embedded in analytical equipment is older and runs on older versions of system software (e.g., Microsoft Office Excel 2003 and Windows NT and XP operating system versions). Although the operating system software is older, the computer workstation hardware is capable of running the software and interfacing with operating equipment hardware and sensors. The audit team verified a sample of operating environments and COTS software versions and determined that the older computer hardware was running the versions noted on the CSL. The LIMS software is a management type application that will be implemented throughout the WIPP Laboratories to control and manage operations and data, including approval and storage of data generated during a specific analysis. Calculations and data manipulation are performed

within equipment software applications or by use of developed and tested spreadsheets. COTS applications are typically installed and run on individual computers workstations, while the LIMS is a server-based application to allow access by personnel who are granted server roles and permissions. The audit team determined that control and management of the different types of software is adequate and that life-cycle documentation and software records packages are adequate for the classification of individual software applications.

The audit team determined that new versions of currently controlled software applications are screened and a place holder is entered on the CSL marked "Pending." When all software quality assurance documentation is complete, the CSL is updated (removing the "Pending" annotation) and the software quality assurance documentation package is completed and submitted to records. Previous version line items are removed when all installations of a version are removed from operating hardware computers, and the CSL is updated to show all installed versions of an individual software application.

Two concerns related to deficiencies in the application of software quality assurance at NWP and the WIPP Laboratories were identified during the audit. These concerns were combined into CAR 16-038 (see section 7.1).

The first part of the concern is related to discrepancies between the CSL and the version information noted on installation and checkout (I&C) forms for six individual software applications (Automated Alpha Input Template, Automated QC Template, Eclipse -- LB Alpha/Beta Proportional Counters (Multi-systems), Environmental Monitoring, Genie 2000, and OSUM). All of the details regarding the operating environment and COTS version identification on the I&C forms had not been transferred to the CSL or were transferred incorrectly.

The second part of the concern is related to completion of the software quality assurance documentation package for Eclipse LB Control & Analysis Ver. LB 3.3. All computers associated with the Tennelec/Canberra analytical equipment installations have been upgraded to ver. LB 3.3 of the operating and measurement software, which is marked as "Pending" on the current CSL. The audit team determined that the Tennelec/Canberra equipment is being used to perform RADCON-related measurement counts. Software quality assurance packages that included testing documentation and I&C forms were not complete and were not available at the time of the audit.

Other than the two concerns identified during the audit, the audit team determined that Software Quality Assurance is adequately established with respect to flow-down of upper-tier requirements and that procedures are satisfactorily implemented, resulting in an effective program.

## **6.0 CONCLUSION**

Based upon the examination of the verified and collected evidence and interviews with responsible personnel, the audit team determined that the NWP Dosimetry and RADCON Instrumentation Programs are adequately established for compliance with the CBFO

QAPD, satisfactory in the implementation of requirements, and effective in achieving the desired results.

Three concerns were identified during the audit, necessitating the initiation of three CARs. One concern was corrected during the audit and the audit team offered one Recommendation to management, as described in the following sections.

## **7.0 SUMMARY OF DEFICIENCIES**

### **7.1 Corrective Action Reports**

During the audit, the audit team may identify CAQs, as defined 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.

Three CAQs were identified during Audit A-16-16, necessitating the initiation of three CARs, as described below.

#### **CAR 16-036**

No objective evidence was provided during the audit to document that source custodians had received training or required reading assignments to demonstrate knowledge of WP 12-HP3201, *Radioactive Source Accountability and Control*, an essential procedure for source custodians.

#### **CAR 16-037**

The following documents could not be accessed from EDMS for verification and use of the current revision because required periodic reviews had not been performed:

- WP 12-HP1305, Rev. 12, *Fixed Air Monitoring Equipment*
- WP 12-HP1313, Rev. 0, *Operation of the Sentinel Model 773 Instrument Calibration*
- IC534000, Rev. 1, *RAM 31 Continuous Air Monitor for Alpha and Beta*
- IC041098, Rev. 6, *Quarterly Underground Exhaust Mass Flow Measurement System Calibration for Fans 700A, 700B, and 700C*

#### **CAR 16-038**

The NWP CSL does not reflect exact information from WIPP Laboratories I&C forms. The audit team identified the following items containing discrepancies between the I&C forms and the CSL.

- PG. 3, Automated Alpha Input Template (Operating Environment cell)
- PG. 3, Automated QA Template (Operating Environment cell)
- PG. 8, Eclipse LB Alpha/Beta Proportional Counters (Multi-Systems) (Operating Environment cell)
- PG. 9, Environmental Monitoring GAB (Operating Environment cell)
- PG. 11, Genie 2000 (Operating Environment cell)
- PG. 19, OSUM (Oxford systems Unit Manager) (Operating Environment cell)
- PG. 18, Nexxis Lab Labtronics LIMSLINK (Operating Environment cell)
- PG. 20, the word Reagent is misspelled

The completed and signed I&C form and the software quality assurance documentation for the Eclipse LB Control & Analysis Ver. LB 3.3 software was not available at the time of the audit. Tennelec/Canberra equipment is being used to perform measurements using this version of the software, but the CSL shows the software items as "Pending."

## **7.2 Deficiencies Corrected During the Audit (CDAs)**

Isolated deficiencies that do not require a root cause determination or actions to preclude recurrence, and where correction of the deficiency can be verified prior to the end of the audit may be corrected during the audit (CDA).

The audit team identified one concern which was corrected during the performance of the operability checks. Three instances were found of inaccurate  $\pm 20\%$  operational range checks, as recorded on Attachment 2 of the procedure. Further investigation revealed that the inaccuracies were all due to transcription errors from the previous in-use Attachment 2 forms or the associated Attachment 1 calculation sheets. The inaccuracies did not affect instrument use and no survey results were compromised due to the errors. RADCON management corrected the issue during the audit.

## **7.3 Observations and Recommendations**

**Observation** – A condition that is determined not to be a violation of procedure or requirement at the time but, if not controlled or addressed, may result in a CAQ during future activities.

**Recommendation** – A suggestion that is directed toward identifying opportunities for improvement and enhancing methods of implementing requirements.

### **Observations**

No Observations were identified during this audit.

### **Recommendations**

During the walk-through of the laboratory, the audit team verified the analytical balance and the calibration weights. The class "S" weights used are M&TE and are annually calibrated. The calibration is observed by all personnel who use the balances. The balance calibration date and the due date for its calibration are documented in the BDRs. The tracking of the certified weights was not as readily available to show the calibration dates. Therefore, the audit team recommends that the labs employ an automated recall system (i.e., LIMS) to track the calibration of these systems so that calibration dates are not overlooked.

## **8.0 LIST OF ATTACHMENTS**

- Attachment 1: Personnel Contacted During the Audit
- Attachment 2: List of Audited Documents

<b>PERSONNEL CONTACTED DURING THE AUDIT</b>				
<b>NAME</b>	<b>ORGANIZATION/ DEPARTMENT</b>	<b>PRE- AUDIT MEETING</b>	<b>CONTACTED DURING AUDIT</b>	<b>POST- AUDIT MEETING</b>
Akbarzadeh, Mansour	NWP, WIPP Laboratories	X	X	X
Allen, B.	NWP, Quality Assurance	X		X
Beekman, Marsha	NWP, External Emergency		X	
Boyea, Amy	NWP, QA Admin.	X		X
Britian, Beau	NWP / RC&D		X	
Cannon, V.	NWP, Quality Assurance			X
Carnathan, Matt	NWP, Deputy RADCON Mgr.		X	
Celletti, Michael A.	NWP Training		X	
Fell, Clifford	NWP, Engineering & Technical Services		X	
Galindo, Marissa	NWP, Rad. Tech.		X	
Galloway, Glen	NWP, RC&P		X	
Gomez, Christine	URS, WIPP Laboratories	X	X	X
Gonzalez, Ariana	NWP, Technical Training		X	
Guavara, Donna	URS, Engineering Tech, WIPP Labs	X		
Hernandez, Jerome	NWP, Environmental Monitoring		X	
Holt, Victoria	NWP, Procedures		X	
Hubbard, Burton	NWP, Rad. Tech.		X	
Jamieson, Marty	NWP RADCON		X	
Johnson, Kevin	AGCOM, Counting Room Lead		X	
Jones, Ginny	URS, WIPP Laboratories	X	X	X
Klein, Brandon	URS, IT Programmer		X	
Klingler, Larry	NWP / QA		X	X
Lichty, Tom	NWP, Technical Training		X	
Marques, Frank	NWP, Rad. Tech.		X	
Mills, Charles	NWP RC&D Manager	X	X	X
Picazo, Ed	RES, NESHAP SME	X	X	
Waldram, Veronica	NWP, QA Integration Mgr.	X		X
Welch, Jesse	URS, Scientist II, WIPP Lab		X	

**DOCUMENTS REVIEWED**

<b>Number</b>	<b>Document Number</b>	<b>Revision Number</b>	<b>Document Title</b>
1.	SOW	4	<i>Environmental Radiochemistry Analyses at the WIPP Site for WIPP Laboratories</i>
2.	SOW	9	<i>Radiological Control WIPP Sample Analysis Requirements and Data Quality Objectives</i>
3.	IC041072	10 IA	<i>Effluent Monitoring Skids A-1, A-2, A-3 And B2 Flow Instrumentation Calibration</i>
4.	IC041096	6 1B	<i>Calibration of Station C Mass Flow</i>
5.	IC041097	4	<i>Effluent Monitoring Station C FAS Flow Annual Calibration</i>
6.	IC413000	7 1A	<i>Station B Mass Flow Measurement System Loop 41A001W2001</i>
7.	PM365001	5 TRN 1	<i>Inspection and Maintenance of Station B Rad Sample Probes</i>
8.	PM411050	0,1	<i>Inspection and Maintenance of Station C Radiological Sampler Rake</i>
9.	PM534006	5 TRN 2 ID	<i>Effluent Monitoring Fixed Air Sampler Vacuum Pumping System</i>
10.	WP 04-AD-3034	1	<i>Technical Procedure Compliance</i>
11.	WP 04-CO.01-11	4	<i>Conduct of Operations Program Logkeeping</i>
12.	WP 12-RE3004	6	<i>Periodic Confirmatory Analysis, Reporting, and Compliance Activities</i>
13.	WP 12-RL.01	20	<i>NWP Radiochemistry Quality Assurance Plan</i>
14.	WP 12-RL1001	12	<i>Sample Tracking and Custody</i>
15.	WP 12-RL1002	11	<i>Alpha Spectroscopy System</i>
16.	WP 12-RL1008	8	<i>Alpha Beta and Strontium Absorption Curves</i>
17.	WP 12-RL1009	7	<i>Gross Alpha/Beta Activity</i>
18.	WP 12-RL1010	14	<i>Sample Preparation</i>
19.	WP 12-RL1011	15	<i>Elemental Separation-Strontium 90</i>
20.	WP 12-RL1012	9	<i>Elemental Separation-Transuranic Products</i>
21.	WP 12-RL1015	18	<i>Canberra Alpha Analyst System Operation</i>
22.	WP 12-RL1016	15	<i>Oxford Series 5 Gas Proportional Counter</i>
23.	WP 12-RL1017	6	<i>Vacuum-Assisted Rapid Sequential Separation of Actinides and Strontium in Various Matrices</i>
24.	WP 12-RL1020	2	<i>Emergency Sample Processing</i>
25.	WP 12-RL1030	0	<i>Canberra Apex Alpha System Operation</i>
26.	WP 12-RL1332	11	<i>Genie 2000 Gamma Spectroscopy System Operation</i>
27.	WP 12-RL1550	13	<i>Control of Radioactive Standards</i>
28.	WP 12-RL2001	1	<i>Analysis of Actinides in Bioassay Samples by Agilent 7700x ICP/MS</i>
29.	WP 12-RL3002	11	<i>Radiochemistry Laboratory Validation and</i>

<b>Number</b>	<b>Document Number</b>	<b>Revision Number</b>	<b>Document Title</b>
			<i>Verification</i>
30.	WP 12-RL3003	15	<i>Data Reduction Reporting</i>
31.	WP 12-HP1245	9	<i>Tennelec Series 5XLB Low Background Alpha/Beta Counting System Operation</i>
32.	WP 12-HP1304	12	<i>Canberra iCAM Alpha/Beta Certified Air Monitor</i>
33.	WP 12-HP1306	9	<i>Canberra Alpha Sentry Continuous Air Monitor</i>
34.	WP 12-HP1307	16	<i>Portable Instrument and Portal Monitor Operability Checks</i>
35.	WP 12-HP1317	1	<i>Canberra iSolo Alpha/Beta Counting System</i>
36.	WP 12-HP1322	1	<i>Calibration of Rad Sources using NIST-Traceable Standard Sources</i>
37.	WP 12-HP1325	5	<i>Station B Canberra iCAM Alpha Continuous Air Monitor</i>
38.	WP 12-HP3500	21	<i>Airborne Radioactivity</i>
39.	WP 12-HP3201	2	<i>Radioactive Source Accountability and Control</i>
40.	WP 12-RC.01	11	<i>Quality Assurance Program Plan for the Sampling Emissions of Radionuclides to the Ambient Air at the Waste Isolation Pilot Plant</i>
41.	WP 12-RC.02	0	<i>WIPP Radiological Control and Dosimetry Department Training Program</i>
42.	WP 15-PS3002	36	<i>Controlled Document Processing</i>
43.	WP 15-RM	8	<i>WIPP Records Management Program</i>
44.	WP 16-2	14	<i>NWP Software Screening and Control</i>
45.	MSA-SO-2015-001	0	<i>CEMRC Management Self-Assessment</i>
46.	URS-PS-1A-15-001	0	<i>Quality Assurance Assessment Report</i>