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OFFICE OF
AIR AND RADIATION

Mike Brown
Quality Assurance Manager
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Dear Mr. Brown:

The U.S. Environmental Protection Agency conducted a Quality Assurance audit of the Department of Energy's (DOE's) Carlsbad Field Office (CBFO) quality assurance (QA) program on September 1-3, 2015, at Los Alamos National Laboratory. The purpose of the audit was to verify implementation of CBFO's QA program relative to the requirements of American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1989,¹ "Quality Assurance Program Requirements for Nuclear Facilities." CBFO QA is responsible for ensuring that Waste Isolation Pilot Plant (WIPP) operations, including characterization of transuranic (TRU) wastes, are performed in compliance with the requirements of the NQA-1-1989 standard.

During this audit, the EPA auditor reviewed documents and records provided by CBFO and interviewed applicable CBFO personnel in Los Alamos, New Mexico. The EPA QA auditor evaluated the CBFO QA program against the NQA-1-1989 elements listed below to ensure compliance with EPA regulations at Title 40 of the Code of Federal Regulations (40 CFR) 194.22:

- Element 18, "Audits."

Based on this audit, the EPA determines that the CBFO QA program continues to comply with these NQA-1-1989 elements and continues to have sufficient independence, authority and resources to verify the quality of items and activities that are important to long-term isolation of TRU waste.

No concerns were identified.

¹ 40 CFR 194.22(a)(1) states that DOE's QA program shall comply with the requirements of the 1989 version of the ASME NQA-1 standard.



If you have any questions regarding this QA audit report, please contact Lindsey Bender at (202) 343-9479 or bender.lindsey@epa.gov.

Sincerely,



to r Tom Peake

Director

Center for Waste Management and Regulations

Enclosure

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**EPA ELEMENT 18 AUDIT OF THE LOS ALAMOS NATIONAL LABORATORY
CENTRAL CHARACTERIZATION PROGRAM
QUALITY ASSURANCE PROGRAM**

SEPTEMBER 1-3, 2015

**U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RADIATION AND INDOOR AIR
CENTER FOR WASTE MANAGEMENT AND REGULATIONS
WASHINGTON, DC 20460**

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ACRONYMS

AK	acceptable knowledge
ASME	American Society of Mechanical Engineers
CAR	corrective action report
CBFO	Carlsbad Field Office
CCP	Central Characterization Program
CFR	Code of Federal Regulations
CTAC	Carlsbad Field Office Technical Assistance Contractor
DC	Docket Center
DOE	U.S. Department of Energy
DTC	dose to curie
EPA	U.S. Environmental Protection Agency
LANL	Los Alamos National Laboratory
NDA	non-destructive assay
NQA	nuclear quality assurance
NWP	Nuclear Waste Partnership, LLC
PDP	Performance Demonstration Program
PL/V&V	project level validation and verification
QA	quality assurance
QAPD	Quality Assurance Program Document
QC	quality control
RTR	real time radiography
TRU	transuranic
VE	visual examination
WIPP	Waste Isolation Pilot Plant
WWIS/WDS	WIPP Waste Information System/Waste Data System

1.0 INTRODUCTION

This report presents results of the U.S. Environmental Protection Agency (EPA) audit of the Carlsbad Field Office (CBFO) quality assurance (QA) audit program conducted at the Department of Energy's (DOE) Los Alamos National Laboratory /Central Characterization Program (LANL/CCP September 1-2, 2015 (CBFO Audit A-15-21). The purpose of the audit was to determine CBFO's compliance with American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1989,¹ "Quality Assurance Program Requirements for Nuclear Facilities."

During this audit, the EPA QA auditor evaluated the CBFO QA program against NQA-1-1989 Element 18, "Audits," to ensure compliance with EPA regulations at Title 40 of the Code of Federal Regulations (40 CFR) 194.22. The EPA auditor observed the CBFO Office of Quality Assurance's annual recertification audit of LANL as performed by CBFO Technical Assistance Contractor (CTAC) personnel at the Los Alamos site. The EPA auditor also reviewed documents and records provided by CBFO and interviewed applicable CBFO and CTAC personnel in Los Alamos, New Mexico.

Based on this audit, the EPA auditor determined that the CBFO QA audit program complies with NQA-1-1989 Element 18 and continues to have sufficient independence, authority and resources to verify the quality of items and activities that are important to long-term isolation of transuranic (TRU) waste.

EPA did not identify any nonconformances in CBFO's QA program relative to the requirements of ASME NQA-1-1989. This report documents these audit activities. This information will be made available to the public through EPA's Electronic Docket (via regulations.gov) and the official Air Docket, in accordance with 40 CFR 194.22 (a)(1). EPA's Air Docket A-98-49 is located at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), WJC West, Room 3334, 1301 Constitution Avenue, NW, Washington, DC, 20004.

2.0 BACKGROUND

2.1 Regulatory Background

In accordance with 40 CFR 194.22(a)(1), EPA requires DOE to implement a QA plan that establishes the following NQA standards developed by ASME:

1. ASME NQA-1-1989.
2. ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989.
3. ASME NQA-3-1989 (excluding section 2.1(b) and (c) and section 17.1).

The regulation at 40 CFR 194.22(a)(2) requires DOE to implement its QA plan for all items and activities that are important to the long-term isolation of TRU waste within the Waste Isolation Pilot Plant (WIPP). The regulation at 40 CFR 194.22(e) provides EPA with the authority to

¹ 40 CFR 194.22(a)(1) states that DOE's QA program shall comply with the requirements of the 1989 version of the ASME NQA-1 standard.

conduct audits to verify the proper establishment and implementation of QA programs for the WIPP.

2.2 Organizational Background

CBFO is responsible for management of the WIPP. This responsibility includes oversight of the characterization of TRU waste bound for the WIPP and emplacement of the waste at the disposal site near Carlsbad, New Mexico. As stated in the DOE/CBFO-94-1012, Revision 11, "Quality Assurance Program Document" (QAPD), "The mission of the CBFO is to protect human health and the environment by operating the WIPP for safe disposal of TRU waste and by establishing an effective system for management of TRU waste from generation to disposal."

CTAC provides expert technical advice, assistance and support to CBFO in the areas of QA, auditing and assessment, safety and nuclear safety, site operations, environmental and nuclear compliance, scientific and international programs, and the performance demonstration program (PDP). In accordance with the QAPD, CTAC, under the CBFO Office of QA, also performs certification and recertification audits and assessments of CBFO and other CBFO program participants. CTAC supports CBFO in ensuring that applicable federal and state codes and standards are met and that all procedures and activities are in compliance with DOE QA, safety, health, security and environmental standards.

3.0 PURPOSE AND SCOPE

The purpose of this EPA audit was to verify that the CBFO QA audit program properly implements Element 18 of ASME NQA-1-1989. CBFO had two teams of auditors, one at Los Alamos and one at the Carlsbad Field Office. The scope of this EPA audit was limited to observation of CBFO's recertification audit of the Central Characterization Program's (CCP's) waste characterization activities at LANL (audit number A-15-21) and review of related documents.

4.0 DEFINITIONS

Finding: A determination that a requirement of the NQA standards has not been properly established or implemented. A finding requires a response.

Concern: A judgment that a finding may occur in the future and, depending on the magnitude of the issue, may or may not require a response.

Observation: The recognition and notation of a fact or occurrence that does not require a response.

Quality: The reliability of a specific item or activity that is important to the long-term isolation of TRU waste in the WIPP. "Quality achievement" is the responsibility of operational groups that directly produce such an item or perform such an activity. "Quality assurance/verification" is the responsibility of QA groups that do not produce such an item or perform such an activity.

5.0 EPA AUDIT TEAM MEMBERS

The audit team consisted of one EPA employee. Table 1 lists the EPA auditor.

Table 1. EPA Quality Assurance Audit Team Member

Audit Team Member	Audit Responsibility	Affiliation
Lindsey Bender	EPA QA Audit Team Leader / Lead QA Auditor	EPA

Table 2 lists all CBFO and CTAC personnel who performed the observed audit of LANL-CCP.

Table 2. Personnel Observed Performing Audit

Name	Affiliation and Title/Position
Dennis Miehls	CBFO Office of QA – Management representative
Martin Navarrete*	CBFO Office of QA- Management representative
Greg Knox	CTAC – Audit Team Leader
Wayne Ledford*	CTAC – Auditor (Program Status)
Tammy Ackman*	CTAC – Auditor (AK)
Barry Pace	CTAC – Auditor (VE)
Katie Martin	CTAC – Auditor (RTR)
Cindi Castillo	CTAC – Auditor (NDA)
Jim Schuetz	CTAC – Auditor (WWIS/WDS)
Prissy Martinez*	CTAC – Auditor (C6 QA)
Dick Blauvelt*	CTAC – Technical Specialist (AK/Waste Certification/Load Management)
Judith Stewart*	CTAC – Technical Specialist (AK)
Rhett Bradford**	CTAC – Technical Specialist (VE)
Paul Gomez*	CTAC – Technical Specialist (PL/V&V)
Porf Martinez	CTAC – Technical Specialist (RTR)
Jim Oliver	CTAC – Auditor Technical Specialist (NDA/DTC)
B.J. Verret**	CTAC – Technical Specialist (Container Mgmt/FGA/Shipping Documentation)

*Denotes audit team members working in Carlsbad. The EPA auditor did not directly observe them but was apprised of their activities through the daily caucuses by teleconferencing.

** Persons the EPA auditor interviewed in addition to observing.

6.0 PERFORMANCE OF THE AUDIT

EPA interviewed the personnel indicated in Table 2 and reviewed the objective evidence listed below to determine whether the CBFO QA audit program, as represented by performance of CBFO Audit A-15-21, continues to comply with NQA-1-1989 Element 18, “Audits.”

Copies of the following documents were provided to the EPA auditor before and after the audit at LANL on September 1-3, 2015. EPA reviewed copies of the official QA records, as the records are physically located in Carlsbad, New Mexico.

- CBFO Quality Assurance Program Document, Revision 11
- CBFO Management Procedure 10.3, Audits, Revision 7
- Audit Plan and schedule for CBFO Audit A-15-21
- CBFO Audit schedule for 2015 and 2016
- CBFO Procedure 10.3, Revision 7
- AK Checklists from Dick Blauvelt
- C.6 Checklists
- Interim Audit Report: Previous LANL Audit (A-15-21)
- Final Audit Report: Previous LANL Audit (A-14-19 including:
 - Corrective Action Report (CAR)
 - Corrective Action Plan
 - CAR closure
 - Verification of closure
 - Completed C.6 Checklists
- Comprehensive list of all CBFO Audits and Surveillances performed during last year
- Interim Audit Report: this LANL Audit (A-15-21) when available
- Lead Auditor and Auditor Maintenance of Proficiency Records:
 - Greg Knox, Lead Auditor, CTAC, Maintenance of Proficiency,
 - Wayne Ledford, Auditor, CTAC (RTR), Lead Auditor qualifications and certification
- Qualification records for technical specialists:
 - Jim Oliver, Auditor/Technical Specialist NDA Qualification with Resume,
 - Porf Martinez, Auditor/Technical Specialist RTR Qualification with Resume, CBFO Auditor Qualification.
- Distribution List for Interim and Final CBFO audit reports concerning LANL Records Inventory and Disposition Schedule pages showing record type for: (to be performed as a follow-up at Carlsbad, NM, at a later date. The records management process was observed at the July 2014 audit of Sandia National Laboratory).
 - Interim Audit Report
 - Final Audit Report
 - Audit Plans
 - CARs and closure, including communications records

As a result of these audit activities, EPA determined that the CBFO QA audit program complies with NQA-1-1989 Element 18 and has sufficient independence, authority and resources to verify the quality of items and activities that are important to long-term isolation of TRU waste.

7.0 FINDINGS, CONCERNS AND OBSERVATIONS

The EPA auditor did not identify any findings, concerns or observations relative to NQA-1-1989 Element 18 as discussed above.

8.0 CONCLUSIONS

The EPA auditor reviewed documentation and interviewed personnel to determine the compliance of the CBFO QA audit program with ASME NQA-1-1989 Element 18. Based on

observation of CBFO Audit A-15-21 and the sample of documentation reviewed during this audit, EPA determines that CBFO complies with the standard.