UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 27 2008

OFFICE OF
AIR AND RADIATION

David Moody, PhD.
Manager, Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Dear Dr. Moody:

The U.S. Environmental Protection Agency (EPA) conducted an inspection on January 15-16, 2008, of a Department of Energy (DOE) Carlsbad Field Office (CBFO) audit (A-08-07) of the Quality Assurance (QA) Program of the Central Characterization Project. The investigation of the activities selected for the inspection sample showed that CBFO Audit A-08-07 was properly executed in accordance with Nuclear Quality Assurance (NQA) standards. In the sample inspected, EPA did not find any nonconformance in the performance of Audit A-08-07. The inspection report is enclosed.

During the same time period, EPA conducted an audit of the QA Program of CBFO. The audit was focused on CBFO's Corrective Action System and on Revision 9 of CBFO's QA Plan. The investigation of the activities selected for EPA's audit sample showed that CBFO's QA Program continues to be properly executed. The EPA identified one finding of non-conformance with NQA standards. EPA also identified two concerns of possible future non-conformances. EPA needs a response from DOE regarding the finding and two concerns that are documented in the enclosed audit report prior to the next audit in January 2009.

The inspection and audit reports will be made available to the public through the Agency's public dockets. Please contact Mike Eagle at (202) 343-9376 if you have questions regarding the reports.

Sincerely,

Jonathan Edwards, Acting Director
Radiation Protection Division

cc: Ava Holland, CBFO
Duli Agarwal, DOE
New Mexico
WIPP Docket

DOCKET NO: A-98-49
II-A1-101

EPA INSPECTION OF THE QUALITY ASSURANCE PROGRAM OF THE CENTRAL CHARACTERIZATION PROJECT FOR THE WASTE ISOLATION PILOT PLANT

January 15-16, 2008

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation and Indoor Air
Center for Federal Regulations
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460
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6.2 Interviews The EPA audit team interviewed the following CCP personnel at LLNL: 1. A.J. Fisher, Central Characterization Project Quality Assurance Manager (SPQAO)The Central Characterization Project (CCP) Quality Assurance Manager is the Site Project Quality Assurance Officer for the CCP, including the CCP QA activities at LLNL. The Project Quality Assurance Manager provides quality assurance oversight and planning for the CCP and oversees the implementation of quality assurance requirements. In order to ensure strict independence, the Project Quality Assurance Manager reports to the Quality Assurance Manager, Washington TRU Solutions. This is a reporting chain completely separate from the CCP line organizational structure, and makes certain that the Project Quality Assurance Manager is sufficiently independent of cost and schedule to be able to perform the assigned responsibilities.Major assigned responsibilities include: reviewing, approving, and implementing CCP plans and procedures; tracking compliance data and evaluating trends; verifying and validating characterization data; stopping work if quality is not assured or controlled; ensuring nonconformances and conditions adverse to quality are tracked and resolved, and corrective actions are timely; reviewing procurement documentation, and; performing surveillances of CCP activities.The Project Quality Assurance Manager has over 30 years of experience in the quality assurance field, including quality assurance support to the Department of Defense, commercial nuclear construction and plant start-up, and senior quality assurance positions in contractor organizations at Hanford and Rocky Flats.The Project Quality Assurance Manager stated that he had adequate resources to perform the QA function. However, any loss of personnel through attrition would create a situation where extra effort would be required from the remaining members of the organization the manager characterized the situation as no resources in reserve.2. Dean Mooney, QA Engineer (delegate SPQAO)The CCP Project Quality Assurance Manager delegates certain responsibilities to qualified personnel within the quality assurance organization. Quality Assurance Engineering personnel are assigned the following major responsibilities: reviewing and verifying resolution of nonconforming conditions; reviewing and approving CCP procedures; stopping work if quality is not assured or controlled; reviewing procurement documentation for inclusion of appropriate quality assurance requirements; ensuring conditions adverse to quality are tracked and resolved, and that corrective actions are

timely, and; performing surveillances of CCP activities.The Quality Assurance Engineer, Dean Mooney, interviewed during the visit to LLNL has over 30 years of experience in the quality assurance field, including configuration management, design engineering, material management/control, corrective action management, quality assurance inspection, and test control. Mr. Mooney, who is a WTS employee, indicated that he has adequate time to perform his assigned job duties; and that he has been adequately trained to perform his job duties. Mr. Mooney indicated he has sufficient organizational freedom and authority to assess and verify the quality of CCP waste characterization activities; and that he has not observed any budget or schedule constraints on performing his assigned duties.3. Sheri Nance, Data Validator (delegate SPQAO) The CCP SPQAO delegates certain responsibilities to qualified personnel within the quality assurance organization. Quality Assurance Data Validation personnel are assigned the following major responsibilities: performing project level validation and verification of batch data reports, conducting data quality objective reconciliation, calculation of miscertification rates, reviewing and approving technical operating procedures, stopping work if quality is not assured or controlled, and performing surveillances of CCP activities.The Quality Assurance Data Validator, Ms. Sheri Nance, interviewed during the visit to LLNL has over 5 years of direct experience in the quality assurance field. Ms. Nance has specific experience serving as a Quality Assurance Data Validator for the Hanford Site WIPP Program, the Hanford CCP Site, the Los Alamos National Laboratories (LANL) CCP Site, and the LLNL CCP Site. The EPA audit team is aware of Ms. Nances qualifications and commendable performance as a QA Engineer in her previous job for the Hanford Site WIPP Program. Ms. Nance is currently a *TechSpec* employee subcontracted to WTS to provide SPQAO support. **6.3 Objective Evidence**The EPA audit team inspected LLNL facilities and reviewed LLNL documents to obtain objective evidence of the proper implementation of the requirements in the QA Plan. 1. Non-Conformance Reports (NCRs), Element 15 At LLNL, 77 NCRs have been written in the last 3 months. The EPA reviewed the following three NCRs:NCR-LLNL-0002-04. Failure to inspect gamma sources upon receipt and prior to use.NCR-LLNL-0032-04. Failure to follow procedures for timing of filter change-out within the waste characterization sequence.NCR-LLNL-0062-004. Incomplete inspection of filtered drum liner bags upon receipt at LLNL.All three NCRs reviewed by EPA were found to be in compliance with NQA-1-1989, Element 15 titled *Nonconformances*. In addition, the corrective actions taken for the three NCRs were appropriate and found to be in compliance with NQA-1-1989, Element 16 titled *Corrective Action*. 2. Records CenterThe EPA audit team toured LLNLs operational records area and verified compliance with NQA-1-1989. The Facility Records Custodian for LLNL is Shelley Jensen, who is responsible for maintaining the data generation in-process and completed characterization records. She maintains control of these records until they are transmitted to the CCP Records Center in Carlsbad, New Mexico. All records that are generated at the LLNL are stored in 1-hour

fire rated cabinets. The records are controlled and have posted access lists giving Ms. Jensen, Sheila Pearcy/CCP Lead Records Custodian, her supervisor, and Bob Billett, the site Vendor Project Manager, her on-site supervisor, access to the records. Upon receipt of the operational records, Ms Jensen generates a transmittal for transmission of records to CCP Central Records and, before sending the original record via Federal Express, makes copies of the record and attached transmittal. The copies are maintained as the record in controlled access files until receipt acknowledgment is received from the CCP Records Center in Carlsbad. Ms. Jensen, upon obtaining receipt acknowledgment of the record, no longer maintains the record at LLNL. The LLNL Operational Files were well organized and found to be in compliance with NQA-1-1989, Element 17 titled *Records Management*. 3. Surveillance ScheduleThe CCP Quality Assurance Manager provided a copy of the *CCP Quarterly Surveillance/Assessment Schedule*, which showed that LLNL was on the schedule, with a surveillance of Training & Qualification (SUR-LLNL-0001-04) to be performed in the third quarter (specific month to be determined). The cover letter by A.J. Fisher to the schedule indicated that a CCP QA Engineer had been assigned responsibility for surveillances at LLNL. The Surveillance Schedule provides objective evidence of QA oversight and planning.4. NCR LogThe CCP Quality Assurance Manager provided a copy of the *LLNL NCR Log 2004*. 5. Organizational ChartFigure 2-1 of the *CCP Transuranic Waste Certification Plan* demonstrates that the CCPs Site Project Quality Assurance Officer (SPQAO) has sufficient independence from waste characterization activities that are important to the containment of transuranic waste at the WIPP. **7.0**

SUMMA

RY OF FINDINGS AND CONCERNS

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Attachment 1: Element 18 checklist

1.0 EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) conducted an inspection on January 15-16, 2008, of a Department of Energy (DOE) Carlsbad Field Office (CBFO) audit (A-08-07) of the Quality Assurance Program of the Central Characterization Project (CCP). The investigation of the activities selected for the inspection sample showed that CBFO Audit A-08-07 was properly executed in accordance with Element 18, titled "Audits", of the Nuclear Quality Assurance (NQA) standards. The activities selected for the inspection include personal interviews, document and record reviews, observations of audits and assessment of independence and qualifications of the auditors. The EPA inspectors did not find any nonconformance in the performance of audit A-08-07.

This audit report will be made available to the public through the Agency's public dockets.

2.0 BACKGROUND

2.1 Regulatory Background

In accordance with 40 CFR 194.8(a), the EPA will determine the proper execution of Quality Assurance (QA) Programs for the sites that will send Transuranic (TRU) -waste to the Waste Isolation Pilot Plant (WIPP), including the Central Characterization Project's (CCP) QA Program. In October 15-18, 2001, the EPA conducted an initial audit to verify the proper execution of the CCP's QA Program at the DOE's Savannah River Site (SRS), as required under §194.8(a) (2). In accordance with §194.8(a) (3), EPA determined that the CCP QA Program at SRS complied with the requisite QA requirements for a TRU-waste site. Since EPA's initial audit in 2001 of the CCP QA program at DOE's Savannah River Site, EPA has conducted several audits and inspections at different Waste Generator sites to verify continued compliance of the CCP's QA Program. The inspection documented by this report was to confirm continued compliance at the CCP's central QA Program located in Carlsbad NM.

At §194.22(a)(1), EPA requires the Department of Energy (DOE) to adhere to a QA Program that invokes the following standards of Nuclear Quality Assurance (NQA): 1) American Society of Mechanical Engineers (ASME) NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The EPA verified that DOE established these NQA standards in their Quality Assurance Program Document (QAPD) included in the Compliance

Certification Application for the WIPP. The QAPD is the documented QA Plan for the WIPP, as a whole, to establish the NQA standards. The QAPD is maintained by the QA Organization of DOE's Carlsbad Field Office (CBFO), which has the authority to audit all other organizations associated with TRU-waste disposal at the WIPP to ensure that the lower-tier QA Programs establish and implement the applicable requirements of the QAPD. The DOE's generator sites, which will characterize TRU-waste for disposal in the WIPP, must prepare site-specific QA Plans that establish the applicable NQA requirements.

The EPA annually audits DOE's QA Program at CBFO (reference EPA Air Docket No. A-93-02, Document Nos. II-A-43 and IV-A-4, and EPA Air Docket No.A-98-49, Document No. II-A-1-4) and has found that DOE properly adheres to a QA Program that implements the NQA standards. The EPA determined in its WIPP Certification Decision (63 FR 27354, May 18, 1998) that the CBFO QAPD is in conformance with the NQA standards and that the DOE's QA organization can properly perform audit activities to internally check the QA Programs of the CCP.

The EPA may either conduct its own audits or inspect audits conducted by DOE. The difference between an audit and an inspection lies in the role that EPA performs. During an audit, EPA assumes all responsibilities associated with assessing a QA Program, while in an inspection, the EPA also performs some oversight of DOE's checks of a QA Program. This is the first EPA inspection or audit of the CCP's central QA Program at Carlsbad N.M. Previously, EPA assessed CCP QA Program implementation at each of the CCP Waste Generator sites.

Table 1 - List of EPA's Inspections of the CCP's Central QA Program

Activity	Date	Purpose
Inspection of CCP's Central QA Program	January 16-17, 2008	Initial inspection of CCP QA Program central office.

2.2 CCP Background

CCP's main offices are located in Carlsbad, New Mexico. The CCP is a program run by Washington TRU Solutions (WTS), the DOE's performance-based management and operating (M&O) contractor at the WIPP. CCP performs most of its activities related to waste characterization at the generator sites.

3.0 PURPOSE AND SCOPE

Section 194.22(a) (1) requires that the CCP establish and implement the requirements of the following Nuclear Quality Assurance standards:

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

The purpose of the EPA inspection was to inspect DOE Audit A-08-07 to confirm the continued implementation of the above standards by CCP's QA Program.

194.22(a) (2) requires that CCP execute a QA Program for all its items and activities that are important to the long-term isolation of TRU-waste in the WIPP. The scope of this EPA inspection was limited to the CCP QA Program's oversight of items and activities that are important to the long-term isolation of TRU-waste at the WIPP. Thus, the EPA observed that, for the CCP, only the TRU-waste characterization activities are of importance to long-term isolation.

Section 194.22(a) (2) reads as follows:

Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:

(i) Waste characterization activities and assumptions;
(ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;
(iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;
(iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;
(v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;
(vi) Design of the disposal system and actions taken to ensure compliance with design specifications;
(vii) The collection of data and information used to support compliance application(s); and
(viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.

4.0 DEFINITIONS

Finding: A determination that a specific item or activity does not meet a requirement under

applicable elements of the NQA standards. 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.

Quality: The reliability of a specific item or activity that is important to the long-term isolation of TRU waste inside the WIPP. *Quality achievement* is the responsibility of Operational Organizations that directly produce such an item or perform such an activity. *Quality verification/assurance* is the responsibility of QA Organizations that do not produce such items or perform such activities. A failure to achieve quality is not the responsibility of the QA Organization that verifies quality achievement.

5.0 INSPECTION TEAM

The inspection team consisted of the following:

Inspection Team Member	Position	Affiliation
Mike Eagle	QA Inspector	EPA
Shankar Ghose	QA Inspector	EPA

6.0 PERFORMANCE OF THE EPA INSPECTION

The EPA witnessed the performance of CBFO Audit A-08-07 of CCP QA Program. The primary objective of the EPA Inspection team was to observe that every aspect of element 18 (NQA-1-1989) was properly followed. This requires that the audit to be performed in accordance with written procedures and checklists by personnel who did not have responsibility for performing the activities being audited. And, the audit results were reported to responsible CCP management. The audit was properly planned and scheduled and performed accordingly.

The EPA auditor interviewed the Lead Auditor for DOE Audit A-08-07 and reviewed a DOE document titled "Lead Auditor Maintenance of Proficiency Record." Berry Pace was the Lead Auditor for Audit A-08-07. He has the capability to communicate effectively, both in writing and orally. Mr. Pace has knowledge and understanding of the following:

1. The NQA standards and the EPA regulations regarding the WIPP,
2. General structure of WIPP QA Programs as a whole,

3. Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings,
4. Audit planning in the quality-related functions for the WIPP, and
5. Substantial on-the-job training that includes applicable elements of the audit program.

Mr. Pace's "Lead Auditor Maintenance of Proficiency Record" provides objective evidence that Mr. Pace has maintained his proficiency through the following: regular and active participation in the audit process; review and study of applicable codes and standards; and participation in training programs.

7.0 SUMMARY OF FINDINGS AND CONCERNS

The EPA did not identify any findings or concerns as a result of the inspection of the CCP QA Program.

ATTACHMENT 1

NQA-1 CHECKLIST

ELEMENT: 18 (with Supplement 18S-1) TITLE: Audits INSPECTOR: Shankar Ghose

Does the reference document adequately define, describe, address, or satisfy the following:	**Yes**	**No**	**Applicable Procedure & Para.**
Basic Requirements			
1. Are planned and scheduled audits performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness?	X		DOE/CBFO-94-1012, Rev 9, Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD) Section(s) 3.2.A, 3.2.2.1.A, 3.2.C
2. Are audits performed: • in accordance with written procedures or checklists; and • by personnel who do not have direct responsibility for performing the activities being audited?	X		CBFO QAPD Rev 9, Section(s) 3.2.2.7.A and 3.2.2.3.A
3. Are audit results documented and reported to and reviewed by responsible management? Is follow-up action taken where indicated?	X		CBFO QAPD Rev 9, Section(s) 3.2.2.8.A and 3.2.2.9

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
Supplementary Requirement (18S-1)			
1. Are internal or external quality assurance audits scheduled to provide coverage and coordination with ongoing quality assurance program activities?	X		CBFO QAPD Rev 9, Section(s) 3.2A and 3.2.2.1.A
1.1_ Are audits scheduled at a frequency commensurate with the status and importance of the activity? (18S-1 Section 2)	X		CBFO QAPD Rev 9, Section 3.2.2.1.A
1.2 Are audit schedules to be reviewed periodically and revised as necessary to assure that coverage is maintained current? (18S-1 Section 2)	X		CBFO QAPD Rev 9, Section 3.2.2.1.A
1.3. Are regularly scheduled audits supplemented by additional audits of special subjects when necessary to provide adequate coverage? (18S-1 Section 2)	X		CBFO QAPD Rev 9, Section 3.2.2.1.B
2. Are audit plans developed and documented for each audit which identify: • the audit scope • requirements • audit personnel • activities to be audited • organizations to be notified • applicable documents • schedule • written procedures or checklists (18S-1 Section 3.1)	X		CBFO QAPD Rev 9, Section 3.2.2.2.A

Does the reference document adequately define, describe, address, or satisfy the following:		Yes	No	Applicable Procedure & Para.
3.	Does the auditing organization select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit? Note: this is a repeat of a BR-18 requirement (see Item 2 above). In the case of internal audits, Are personnel having direct responsibility for performing the activities being audited not be involved in the selection of the audit team?	X		CBFO QAPD Rev 9, Section 3.2.2.3.A
3.1	Are audit personnel provided sufficient authority and organizational freedom to make the audit process meaningful and effective? (Section 3.2)	X		CBFO QAPD Rev 9, Section 3.2.2.3.A
4.	Is the audit team identified prior to the beginning of each audit, with one individual appointed lead auditor? Does the lead auditor: • organize and direct the audit; • coordinate the preparation and issuance of the audit report; • evaluate responses; • ensure that the audit team is prepared prior to the initiation of the audit? (Section 3.3)	X		CBFO QAPD Rev 9, Section(s) 3.2.2.3.A and 3.2.2.3.B CBFO QAPD Rev 9, Section(s) 3.2.2.3.B and 3.2.2.9
5.	Are audits performed in accordance with written procedures or checklists? (Section 4) Note: this is a repeat of a BR-18 requirement (see Item 2 above).	X		CBFO QAPD Rev 9, Section 3.2.2.7.A
5.1	Does auditing begin as early in the life of the activity as practical and continued at intervals consistent with the schedule for accomplishing the activity? (Section 4)	X		CBFO QAPD Rev 9, Section 3.2.2.1.A NOTE: This is one of many ongoing annual audits of the CCP QA program, which is considered mature.
6.	Are the elements that have been selected			CBFO QAPD Rev 9, Section 3.2.2.7.B

Does the reference document adequately define, describe, address, or satisfy the following:		Yes	No	Applicable Procedure & Para.
	for audits evaluated against specified requirements?	X		
6.1	Is objective evidence examined to the depth necessary to determine if the elements audited for have been implemented effectively? (Section 4)	X		CBFO QAPD Rev 9, Section 3.2.2.7.B
7.	Are audits results documented by auditing personnel and reviewed by management having responsibility for the area audited? Note: this is a repeat of a BR-18 requirement (see Item 3 above).	X		CBFO QAPD Rev 9, Section 3.2.2.8.A
8.	Is the audit report signed by the lead auditor prior to issuance?	X		CBFO QAPD Rev 9, Section 3.2.2.8.A
9.	Does the audit report include: • description of the audit scope; • identification of the auditors; • identification of persons contacted during audit activities; • summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; and • description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization?	X		CBFO QAPD Rev 9, Section 3.2.2.8.A.1-6
10.	Does the management of the audited organization or activity investigate adverse audit findings, schedule corrective action	X		CBFO QAPD Rev 9, Section 3.2.2.9

Does the reference document adequately define, describe, address, or satisfy the following:		Yes	No	Applicable Procedure & Para.
	(including measures to prevent recurrence), and notify the appropriate organization in writing of action taken or planned?			
10.1	Is the adequacy of the audit responses evaluated by or for the auditing organization? (Section 6)	X		CBFO QAPD Rev 9, Section 3.2.2.9
11.	Is follow-up action taken to verify that corrective action is accomplished as scheduled?	X		CBFO QAPD Rev 9, Section 3.2.2.9
12.	Do audit records include • audit plans, • audit reports, • written replies, and • the record of completion of corrective action? END	X		CBFO QAPD Rev 9, Section 3.2.2.10

DOCKET NO: A-98-49
II-A1-100

EPA AUDIT OF THE QUALITY ASSURANCE PROGRAM OF THE DEPARTMENT OF ENERGY'S CARLSBAD FIELD OFFICE

January 15-17, 2008

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation and Indoor Air
Center for Federal Regulations
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

February 2008

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1.0 EXECUTIVE SUMMARY

On January 15-17, 2008, the Environmental Protection Agency (EPA) conducted an audit of the Quality Assurance (QA) Program of the Department of Energy's (DOE) Carlsbad Field Office (CBFO). An investigation of the audit sample showed that the QA Program continues to be properly established and implemented.

EPA identified one finding of non-conformance with the Nuclear Quality Assurance (NQA) standards. CBFO management properly responded to this finding, and EPA will verify implementation of corrective action during a future audit. EPA also identified two concerns regarding possible non-conformances. CBFO responded properly to the concerns, and EPA will continue to investigate the two concerns during future audits.

Additionally, EPA conducted a review of changes to the QA Plan of CBFO and determined that Revision 9 of the QA Plan continues to properly establish the invoked Nuclear Quality Assurance (NQA) standards.

2.0 BACKGROUND

2.1 Regulatory Background

In accordance with 40 CFR Part 194.22(a)(1), the U.S. Environmental Protection Agency (EPA or Agency) requires the Department of Energy's (DOE) Waste Isolation Pilot Plant (WIPP) activities to adhere to a quality assurance (QA) program that implements the Nuclear Quality Assurance (NQA) standards developed by the American Society of Mechanical Engineers (ASME), as follows:

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

Part 194.22(a)(2) requires DOE to apply its QA program to all items and activities that are important to the long-term isolation of transuranic (TRU) waste at the Waste Isolation Pilot Plant (WIPP). Part 194.22(e) provides EPA with the authority to conduct audits to verify the proper execution of the QA programs for WIPP.

In December 1996, EPA has conducted an audit that determined that CBFO had properly executed a
QA Program. During the 1996 audit the EPA verified that CBFO established the applicable requirements of the NQA standards in its Quality Assurance Program Document (QAPD). The QAPD is the QA Plan for the WIPP that establishes the applicable requirements of the NQA standards. The implementation of the QAPD is enforced by the QA organization of CBFO, which audits all other WIPP-related organizations to verify that they implement the applicable NQA requirements.

Subsequent to the 1996 audit, the EPA has conducted periodic audits to verify proper maintenance of CBFO's QA program. Table 1 provides a list of the EPA audits of CBFO's QA program.

2.2 Carlsbad Field Office Background

The CBFO is responsible for the management of the WIPP. This responsibility includes oversight of the characterization of TRU-waste bound for the WIPP and long-term isolation of the waste at the disposal site near Carlsbad, New Mexico. For program and policy direction, the CBFO Manager reports to the DOE Assistant Secretary for Environmental Management in Washington, D.C. The CBFO Manager receives administrative support from DOE's Albuquerque Operation Office and the DOE's Environmental Management Consolidated Business Center (EMCBC) in Cincinnati, Ohio. CBFO coordinates the TRU waste program at waste generating sites and national laboratories, as well as among other participants involved in the permanent disposal of this man-made radioactive waste.

The CBFO QA Program applies to all programs and projects managed by the CBFO which require a QA program, including activities related to compliance applications, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility.

Table 1 - List of EPA's Audits of the Carlsbad Field Office's QA Program

Activity	Date	Purpose
Initial Certification Audit	December 9-13, 1996	Initial audit of QA program for conformance with 40 CFR 194.22(a)
Audit	January 6-8, 1998	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 6-8, 1999	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 4-6, 2000	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 9-10, 2001	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 8-9, 2002	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Surveillance	January 24, 2002	Follow-up evaluation of findings and concerns from January 2002
Audit	February 20-21, 2002	Follow-up audit to determine actions on EPA findings from January 2002 audit
Audit	May 14-16, 2002	Follow-up audit to determine actions on EPA findings from January and February 2002 audits
Audit	January 7-9, 2003	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	December 2-4, 2003	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Informational Visit	February 10-12, 2004	Follow-up visit to obtain information regarding newly established CBFO organizational chart. No report was issued.
Audit	November 16-17, 2004	Follow-up audit to assess the implemented re-organization of CBFO.
Audit	February 8-9, 2005	Follow-up audit to assess a corrective action by CBFO.
Audit	July 19-21, 2005	Follow-up audit to assess a corrective action by CBFO
Audit	December 13-20, 2005	Audit of CBFO auditing and corrective action processes.
Audit	February 7-9, 2006	Audit of Revision 7 of CBFO QA Plan.
Audit	January 23, 2007	Annual Audit of CBFO QA Program.
Audit	January 15-17, 2008	Annual Audit of CBFO. Revision 9 of QA Plan.

3.0 PURPOSE AND SCOPE

Part 194.22(a)(1) requires that the WIPP adhere to a QA program that establishes and implements the requirements of: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The main purpose of this EPA audit was to confirm that revision 9 of the CBFO QA Plan, titled "Quality Assurance Program Document (QAPD)", properly establishes the requirements of the NQA standards. The scope of this EPA audit was limited to the QA Program's oversight of items and activities that are important to long-term isolation at WIPP and identified in Part 194.22(a) (2). Part 194.22(a) (2) reads as follows:

Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:

- *(i) Waste characterization activities and assumptions;*
- *(ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;*
- *(iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;*
- *(iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;*
- *(v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;*
- *(vi) Design of the disposal system and actions taken to ensure compliance with design specifications;*
- *(vii) The collection of data and information used to support compliance application(s); and*
- *(viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.*

4.0 DEFINITIONS

Finding: A determination that a specific item or activity does not meet a requirement under applicable elements of the NQA standards. 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.

Quality: The reliability of a specific item or activity that is important to the long-term isolation of

TRU-waste at 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 Organizations that do not produce such items or perform such an activity.

5.0 AUDIT TEAM

The audit team consisted of two EPA:

Audit Team Member	Affiliation
Mike Eagle	EPA (Audit Team Leader)
Shankar Ghose	EPA auditor

6.0 PERFORMANCE OF THE AUDIT

During the audit, EPA assessed CBFO's QAPD and Corrective Action System. The Corrective Action System described in NQA-1-1989, Element 16 requires that "conditions adverse to quality shall be identified promptly and corrected as soon as practical".

6.1 Assessment of the CBFO's QAPD

EPA thoroughly reviewed all changes to CBFO's QAPD from Revision 8 to Revision 9. EPA did not discover any instance of diminishing the establishment of the NQA standards. The EPA finds that the QAPD continues to properly establish all the applicable requirements under the NQA standards invoked by EPA. There were no EPA findings or concerns with Revision 9 of the QAPD.

6.2 Assessment of the Corrective Action System

EPA performed document reviews and personnel interviews to assess compliance with Element 16, titled *Corrective Action*, of the NQA-1 standard. EPA found two concerns regarding CBFO's Corrective Action System. In addition, a review of past corrective actions led to one EPA finding of non-conformance regarding Management Assessments under Element 2 , titled *Quality Assurance Program*, of the NQA-1 standard.

7.0 SUMMARY OF FINDINGS AND CONCERNS

The EPA identified 1 finding and 2 concerns during this audit.

7.1 Finding

NQA-1 Element #2, titled *Quality Assurance Program* states "...Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible..." CBFO's procedure MP 9.1 titled *Management Assessments* Section 4.2.1 which establishes this NQA-1 requirement requires CBFO supervisors to "(s)chedule and have management assessments performed, including a report for the areas assessed." However, the CBFO Management Assessment Log indicates that insufficient assessments were scheduled and performed for FY 2007, and an insufficient number have been scheduled for FY 2008. Although CBFO's Office of the Manager issued a memo to remind CBFO managers of the requirement to schedule and perform management assessments, only 4 management assessments are identified on the CBFO Assessment Schedule for FY 2008 maintained by QA. Of these 4, 3 were scheduled by the QA organization and 1 by the Office of the Manager. The Office of Site Operations and the Office of the Manager have each initiated an additional assessment which appears on the Management Assessment Log. The CBFO Office of Business and Office of National TRU Programs have not scheduled nor performed any management assessments during 2007 and 2008. Schedule and performance of management assessments is a repeat finding, identified by EPA in January 2001 (finding), January 2002 (finding), March 2002 (concern) and again identified by CBFO as CAR 06-013 in December 2005.

A response regarding the finding and two concerns is required from CBFO prior to the next audit in January 2009.

7.2 Concerns

CONCERN #1 NQA-1 element #16, *Corrective Action* states "Conditions adverse to quality shall be identified promptly...." The EPA is concerned that conditions adverse to quality that were identified in a Management Assessment of the groundwater monitoring program performed September 2007 have not been documented in Corrective Action Reports.

A response is required from CBFO prior to the next audit in January 2009.

CONCERN #2 In the EPA Letter dated 2/22/07, EPA identified the following concern: "NQA-1 Basic Requirement 16, titled 'Corrective Actions', states 'Conditions adverse to quality shall be ... corrected as soon as practical.' EPA's review of CBFO Corrective Action Reports (CARs) showed that some corrective action could have been corrected sooner by CBFO Manager. No CBFO response is required for this concern. However, EPA will follow-up during a future audit." This concern was related to CARs issued to CBFO internal organizations. During this audit, the EPA finds that there has been some improvement. Three CARs recently

issued to CBFO were reviewed, and 2 had been responded to and closed in a timely fashion. However, the initial response to the 3rd CAR is overdue, and no request for extension has been received. EPA will continue to follow-up during future audits.

A response is required from CBFO prior to the next audit in January 2009.

8.0 CONCLUSIONS

An investigation of the audit sample showed that the QA Program continues to be properly established and implemented. Responses are required from CBFO regarding the finding and two concerns prior to the next audit in January 2009.

Attachment 1 – Audit Checklist
NQA-1 CHECKLIST

ELEMENT: 16 TITLE: Corrective Action Auditor: Mike Eagle

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
Basic Requirements			
1. Are conditions adverse to quality identified promptly and corrected as soon as practical?	Yes		Section 1.1.1.2, Employees, makes "Each program participant employee is responsible for...promptly reporting all existing, developing or potential conditions adverse to quality..." Section 1.3.3.3.B (Conditions Adverse to Quality) requires "Responsible management...[to] complete remedial action as soon as practical".
2. In the case of a significant condition adverse to quality, is the cause of the condition determined and corrective action taken to preclude recurrence?	Yes		Section.1.3.3.5 (Corrective Action Planning) Section 1.3.3.5.C requires SCAQ CAPs to address Root Cause Determination Section 1.3.3.5.D requires SCAQ CAPs to address Actions to Preclude Recurrence
3. Are the identification, cause and corrective action for significant conditions adverse to quality documented and reported to appropriate levels of management?	Yes		Section 1.3.3.3.A (Conditions Adverse to Quality) requires that all CAQs "...be documented and reported to the appropriate levels of management....".
4. Is follow-up action taken to verify implementation of corrective action?	Yes		Section 1.3.3.7, Corrective Action Follow-up
Supplementary Requirement - None			