

Allen, Pam, NMENV



From: Maestas, Ricardo, NMENV
Sent: Tuesday, May 08, 2012 2:41 PM
To: Allen, Pam, NMENV
Subject: FW: CBFO & SNL QA Reports
Attachments: CBFO-SNL QA 040912.pdf; CBFO QA Report 040912.pdf; SNL QA Report 040912.pdf

Email and attachments for WIPP File

From: Kliphuis, Trais, NMENV
Sent: Monday, April 09, 2012 11:02 AM
To: Holmes, Steve, NMENV; Hall, Timothy, NMENV; Maestas, Ricardo, NMENV
Subject: FW: CBFO & SNL QA Reports

From: Raymond Lee [<mailto:Lee.Raymond@epamail.epa.gov>]
Sent: Monday, April 09, 2012 10:35 AM
To: Franco, Jose - DOE
Cc: ed.ziemianski@wipp.ws; Unger, Randy - DOE; Fesmire, Courtland - DOE; Alton.Harris@em.doe.gov; Kliphuis, Trais, NMENV; Holmes, Steve, NMENV; Tom Peake; Mike Eagle; Lindsey Bender; Shankar Ghose
Subject: CBFO & SNL QA Reports

Hello,

Attached to this e-mail is EPA's letter transmitting QA reports for CY 2011 at Carlsbad Field Office (CBFO) and Sandia National Laboratories (SNL). If you have any questions or problems opening the attachments, please let me know.

Thank you,

Ray

(See attached file: CBFO-SNL QA 040912.pdf) (See attached file: CBFO QA Report 040912.pdf) (See attached file: SNL QA Report 040912.pdf)

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

APR - 9 2012

OFFICE OF
AIR AND RADIATION

Mr. Jose R. Franco, Manager
Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Dear Mr. Franco:

During calendar year 2011, the U.S. Environmental Protection Agency (EPA) performed three audits of the Department of Energy's Carlsbad Field Office (CBFO) Quality Assurance (QA) Program. The purpose of the EPA audits was to verify compliance with *Quality Assurance Program Requirements for Nuclear Facilities* (NQA-1-1989). The scope of the EPA audits was limited to items and activities that are important to the long-term isolation of transuranic waste. The audited samples showed that the CBFO QA Program continues to be properly executed. The EPA audits did not find any nonconformance with compliance with NQA-1-1989. An EPA report for the three audits is enclosed.

In addition, on December 7-8, 2011, the EPA witnessed an audit conducted by the CBFO QA organization that evaluated the QA Program of the Sandia National Laboratories Nuclear Waste Management Program. The EPA determined that this CBFO QA audit (A-12-05) was properly conducted in compliance with Basic Requirement 18, titled "Audits", of NQA-1-1989. The report for this EPA assessment is also enclosed.

No further response is required by EPA from CBFO to this letter or the two enclosed EPA reports. The EPA reports will be made available to the public through the Agency's Public docket. Please contact Mike Eagle at (202) 343-9376 if you have questions regarding the enclosed reports.

Sincerely,

A handwritten signature in black ink that reads "Tom Peake".

Tom Peake, Director
Center for Waste Management and Regulations

cc: E. Ziemianski, CBFO
R. Unger, CBFO
C. Fesmire, CBFO
A. Harris, DOE
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bcc: WIPP Team

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EPA Audit of CBFO QA Audit A-12-05 – December 7-8, 2011

On December 7-8, 2011, the U.S. Environmental Protection Agency (EPA) witnessed an audit conducted by the Quality Assurance Organization of the Department of Energy Carlsbad Field Office (CBFO QA). The CBFO QA audit (A-12-05) evaluated the quality assurance (QA) program of the Sandia National Laboratories Nuclear Waste Management Program (SNL) located at Carlsbad, New Mexico. The SNL QA Program provides internal quality controls over SNL items and activities that are important to the long-term isolation of transuranic waste inside the Waste Isolation Pilot Plant (WIPP). Based on the sample of audit activities evaluated, the EPA finds that Audit A-12-05 was properly conducted; the EPA auditor did not identify any non-conformance with applicable EPA requirements in the performance of Audit A-12-05.

The EPA auditor observed performance of Audit A-12-05, interviewed CBFO QA auditors and reviewed CBFO QA documents. Audit-012-05 was conducted in accordance with the requirements of Element 18, titled "Audits", of Nuclear Quality Assurance standard (NQA-1, 1989 edition). The EPA auditor verified that the CBFO QA audit was properly planned and scheduled. It was properly performed to verify compliance with aspects of the CBFO's QA program and to determine its effectiveness. The audit was performed by personnel who do not have direct responsibility for performing the activities being audited. The audit results were reported to and reviewed by responsible SNL management.

EPA also reviewed the qualification records of two Technical Specialists of the CBFO QA Audit Team, and found objective evidence of qualified technical experts in the areas of:

1. Data Validation and Verification (QA technical specialist Paul Gomez),
2. Nuclear Analytical Processes (QA technical specialist Jim Oliver),

The QA Lead Auditor (Greg Knox) provided objective evidence of Lead Auditor proficiency in accordance with NQA-1 requirements. Based on the review of the CBFO QA audit, the EPA Auditor concurs with the general finding of Audit A-12-05 that SNL continues to properly implement a QA Program for the qualification of items and activities that are important to long term isolation. The EPA also concurs with the two concerns identified by Audit A-12-05, described as follows:

1. *No objective evidence was provided by SNL QA to demonstrate that any trend Analysis Report was produced for FY 2011 as required by procedure, NP 16-1, Rev. 6, Corrective Action.*

2. *No objective evidence was provided to demonstrate that an internal audit of the overall SNL WIPP QA Program was conducted during the last year as required by procedure, NP 18-1, Rev. 8, Audits and Surveillance.*

In addition to witnessing the CBFO QA audit, the EPA auditor directly interviewed the SNL Manager (Paul Shoemaker), the SNL QA Lead (Steve Davis) and the SNL QA Specialist (Shelley R. Nielsen). All stated that the SNL QA Lead has sufficient authority and organizational independence to properly qualify SNL activities that are important to long-term isolation. The results of the EPA interviews of the two SNL QA personnel are as follows:

1. **Steve Davis** is currently the Quality Assurance Lead for SNL. He has been a QA professional for about 31 years. He has been an NQA-1, Certified Lead Auditor since 1986 when he worked for Texas Utilities Electric Company in support of the Comanche Peak Nuclear Power Station in Glen Rose, Texas with only one break in that certification for a period of one year. He has also worked at two other nuclear power plants. Mr. Davis had worked on the WIPP project since 1995 as a Lead QA Auditor for the Carlsbad Technical Assistance Contract, prior to coming to work at SNL as a QA Specialist and later as the Assessment Task Lead and then QA Lead. He has worked for SNL for approximately the last eight years as a contractor to SNL, employed by John Hart and Associates. Mr. Davis stated that he has "full independence and authority to verify compliance of the work activity of the staff to all QA requirements for the work performed by the technical staff."

2. **Shelly R. Nielsen** (QA Specialist reporting to Mr. Davis) stated that she has 20 + years of professional experience in quality assurance, 6 years of professional experience auditing for the DOE Consolidated Auditing Program and over 10 years experience providing internal surveillance support, in addition she has 10 years of experience managing the Rocky Flats Environmental Technology Site validation program.

Ms. Nielsen stated that her education was as a B.A., Chemistry and B.S., Biology, Metropolitan State College, Denver, CO, 1987

Ms. Nielsen provides internal independent oversight of the Performance Assessment, QA Software program, laboratory, and field activities that support the WIPP project. (2005-present) She performs independent surveillances to ensure that all QA requirements are met to satisfy quality directives. She performs independent QA reviews on scientific notebooks, procedures, analyses plans, test plans, milestone reports, and abstracts/presentations to ensure that each meets the WIPP program requirements and are technically correct. She initiates and/or consults with SNL staff to issue Corrective Action Reports (CAR). Subsequently, Ms. Nielsen follows-up from initiation to closure by tracking the corrective actions as stated in the Corrective Action Plan and during CAR closure verifies that there was no impact on the quality due to the adverse condition.

As a result of the interviews and subsequent document reviews, the EPA identified two concerns that may lead to future non-conformances with the NQA standards, as follows:

1. The SNL QA Lead and QA Specialist are not direct employees of SNL, and this situation may lead to a future decrease in their authority to qualify SNL items and activities that are important to the isolation of transuranic waste. The EPA does not require a response from DOE or SNL to this concern. However, EPA will continue to monitor this concern during future EPA audits.
2. A preliminary EPA analysis of the two concerns identified by CBFO QA audit (A-12-05) indicates that a contributing cause was likely a lack of resources for the SNL QA organization. SNL QA may require additional staff in the future to preclude recurrence of similar concerns. The EPA does not require a response from DOE or SNL to this concern. However, EPA will continue to monitor this concern during future EPA audits.

SNL items and activities are reviewed by EPA directly, and in a manner separate from CBFO QA audits. SNL activities are operational activities that are directly important to isolation (as compared to QA activities that qualify those operational activities). Therefore, EPA conducts its own reviews to approve SNL activities such as performance assessment and sensitivity analysis. CBFO QA and SNL QA are not responsible to demonstrate compliance of SNL operational activities to the EPA, and thus retain clear independence for qualifications of SNL operational activities prior to EPA reviews. The responsibility for compliance demonstrations are with operational groups that perform those operations.

EPA Auditor Mike Eagle, 12/09/2012

**DOCKET NO: A-98-49
II-A1-109**

EPA AUDITS OF CARLSBAD FIELD OFFICE
QUALITY ASSURANCE PROGRAM CONDUCTED DURING 2011:
JANUARY 25-27; MARCH 14-17; JULY 19-21

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

NOVEMBER 2011

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- Attachment A: Personnel Participating in Audit Meetings
- Attachment B: January Audit: Checklist for NQA-1 Element No. 1, *Organization*
- Attachment C: January Audit: Checklist for NQA-1 Element No. 6 *Document Control*
- Attachment D: March Audit: Checklist for NQA-1 Element No. 5, *Instructions, Procedures and Drawings*
- Attachment E: March Audit: Checklist for NQA-1 Element No. 6, *Document Control*
- Attachment F: March Audit: Checklist for NQA-1 Element No. 16, *Corrective Action*

EXECUTIVE SUMMARY

During calendar year 2011, the U.S. Environmental Protection Agency (EPA) audited the Department of Energy's Carlsbad Field Office (CBFO) Quality Assurance (QA) Program. The scope of EPA's audit of CBFO's QA Program consists of verifying compliance with *Quality Assurance Program Requirements for Nuclear Facilities*, American Society of Mechanical Engineers Nuclear Quality Assurance (NQA-1-1989 Edition). As regulator of the Waste Isolation Pilot Plant (WIPP), EPA performs audits of the CBFO QA Program's oversight of items and activities that are important to the long-term isolation of transuranic (TRU) waste.

EPA conducted the initial QA audit of CBFO in January 2011, with follow-up audits in March and July of 2011. The follow-up audit in March was performed for two reasons. First, based on the January audit, EPA wanted to expand the sample size to ensure its evaluation was representative and to close an open issue identified in January regarding NQA-1 Element 6, *Document Control* (See Section 5.1.2 for description of issue). Second, there were several changes to the CBFO QA organization (See Section 5.1.1.1 for description of changes to organization), and EPA wanted to verify CBFO's continued compliance with NQA-1 Element No. 1, *Organization*, in light of these changes. EPA also closed an open issue related to the implementation of the Los Alamos National Laboratory's QA Program for WIPP-related work at the Los Alamos National Laboratory-Carlsbad Office (LANL-CO) that had been identified in 2009 (See Section 5.2.4). EPA performed another follow-up QA audit of CBFO in July 2011 in response to a CBFO waste characterization nonconformance (See Section 5.3.2). During the July 2011 audit, EPA determined there was no impact on the long-term isolation of TRU waste from the nonconformance identified in CBFO Corrective Action Report (CAR) 11-043; sampled three elements of the 1989 NQA-1 standard; and addressed one open issue from the January 2011 Audit.

As a result of these three audits, EPA determined that the CBFO QA Program continues to comply with the applicable requirements of the NQA-1 standard, including maintaining sufficient independence, authority, and resources to verify the quality of items and activities that are important to long-term isolation of TRU waste. These three audits occurred over calendar year 2011, as described below, and each report is representative of conditions at CBFO at the time of the audit. There may have been additional organizational and personnel changes at CBFO since the last EPA Audit in July 2011, as well as changes in other areas. EPA will conduct a QA audit of CBFO in January 2012 to assess current conditions, including the effects of all organizational or personnel changes, if any.

The EPA conducts periodic audits of the CBFO QA Program (see Table 1, below) and has found that CBFO properly adheres to a QA program that implements the 1989 NQA-1 standard. EPA may either conduct its own audits or witness CBFO audits. This report documents the results of EPA's audit activities and will be made available to the public through the Agency's public docket.

1.0 BACKGROUND

1.1 Regulatory Background

In accordance with 40 CFR Part 194.22(a)(1), the EPA requires the DOE to execute a QA program that implements the applicable requirements of the NQA standards developed by the ASME, as follows:

1. ASME NQA-1-1989 edition
2. ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition
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 a QA program to all items and activities that are important to the long-term isolation of TRU waste within the WIPP. Part 194.22(e) provides EPA with the authority to conduct audits to verify the proper establishment and implementation of QA programs for the WIPP.

1.2 Organizational Background

The mission of the DOE CBFO is to protect human health and the environment via the long-term isolation of TRU waste inside the WIPP. The CBFO is responsible for the management of the WIPP, including oversight of the characterization of WIPP-bound TRU waste. 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 programs at waste-generating sites and national laboratories, as well as among other participants involved with the characterization and permanent disposal of defense-related TRU waste. The CBFO QA Manager reports directly to the CBFO Manager. Table 1 lists the EPA audits of CBFO's QA program that have been performed since 1996. CTAC is the support contractor for CBFO's QA organization.

Table 1. List of EPA's Audits of the Carlsbad Field Office's QA Program: 1996 to Present

Activity	Date	Audit Purpose
Certification Audit	December 9-13, 1996	Initial audit of CBFO QA program: Conformance with 40 CFR 194.22(a)
Audit	January 6-8, 1998	Annual audit: Maintenance of QA program, conformance with 40 CFR 194.22(a)
Audit	January 6-8, 1999	Annual audit: Maintenance of QA program, conformance with 40 CFR 194.22(a)
Audit	January 4-6, 2000	Annual audit: Maintenance of QA program, conformance with 40 CFR 194.22(a)
Audit	January 9-10, 2001	Annual audit: Maintenance of QA program, conformance with 40 CFR 194.22(a)
Audit	January 8-9, 2002	Annual audit: Maintenance of QA program, conformance with 40 CFR 194.22(a)
Surveillance	January 24, 2002	Follow-up: Status of findings and concerns from January 2002 audit
Audit	February 20-21, 2002	Follow-up: Status of findings from January 2002 audit
Audit	May 14-16, 2002	Follow-up: Status of findings from January and February 2002 audits
Audit	January 7-9, 2003	Annual audit: Maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	December 2-4, 2003	Annual audit: Maintenance of QA program for conformance with 40 CFR 194.22(a)
Informational Visit	February 10-12, 2004	Follow-up: Obtain information regarding new CBFO organizational; no report issued
Audit	November 16-17, 2004	Follow-up audit: Assess the implemented re-organization of CBFO
Audit	February 8-9, 2005	Follow-up audit: Assess corrective action by CBFO; Audits of SNL and WTS
Audit	July 19-21, 2005	Follow-up audit: Assess corrective action by CBFO; Organizational element audits of SNL, LANL-CO, CEMRC and WTS
Audit	December 13-20, 2005	Audit of CBFO: NQA-1 Elements 16 and 18
Audit	February 7-9, 2006	Audit of CBFO: Revision 7 of CBFO QA Plan
Audit	January 23, 2007	Audit of CBFO QA Program
Audit	March 26-29, 2008	Audit of CBFO: NQA-1 Element 18 (CBFO Audit A-08-13, LANL-CO)
Audit	October 21-24, 2008	Audit of CBFO: CCP QA Program & NQA-1 Elements 1, 2, 15, 17 and 18
Audit	February 24-26, 2009	Audit of CBFO: NQA-1 Elements 4, 6, 10, 15 & 18 (CBFO Audit A-09-10)
Audit	December 1-3, 2009	Audit of CBFO: CBFO, CPP, CTAC, WTS, LANL-CO and SNL-CO
Audit	January 27-29, 2011	Audit of CBFO: NQA-1 Elements 1 & 6
Audit	March 15-17, 2011	Follow-Up audit: NQA-1 Elements 5, 6, & 16
Audit	July 19-21, 2011	Follow-Up audit: NQA-1 Elements 1, 2, 15, 16, 17 & 18; Evaluation of CBFO CAR 11-043

2.0 PURPOSE AND SCOPE

The purpose of each of the three EPA audits discussed in this report was to verify CBFO’s implementation of specific elements of the NQA-1 standard, and to assess the status of corrective actions taken to address an EPA issue or concern from a previous EPA audit. These are discussed in detail in the report sections that follow. The scope of each EPA audit was limited to the CBFO QA Program that qualifies activities and items that are important to the long-term isolation of TRU waste.

3.0 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.

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

4.0 EPA AUDIT TEAM MEMBERS

The EPA audit teams consisted of one EPA employee supported by three or four SC&A contractors. All members of the EPA audit team, along with each person’s affiliation and function during these audits, are listed in Table 2 below.

Table 2. EPA Quality Assurance Audit Team Members

Audit Team Member	Audit Responsibility	Affiliation	January	March	July
Mike Eagle	EPA Audit Team Leader	U.S. EPA	✓	✓	✓
Patrick Kelly	Quality Assurance Auditor	SC&A, Inc.	✓	✓	✓
Greg Beronja	Quality Assurance Auditor	SC&A, Inc.	✓	✓	✓
Dorothy Gill	Quality Assurance Auditor	SC&A, Inc.	✓	✓	✓
Kira Darlow	Quality Assurance Auditor, Trainee	SC&A, Inc.		✓	✓

Prior to the January audit, Mike Eagle (EPA) evaluated the qualifications of the SC&A Auditors listed in Table 2, above. Based on his evaluation, Mike Eagle found that three of the four SC&A auditors were qualified based on:

- A working knowledge and understanding of the NQA standards
- Training programs
- On-the-job training

In addition, Mike Eagle evaluated the SC&A auditors relative to their qualifications as Lead Auditors in oversight of DOE QA audits specific to Element No. 18 of the NQA-1 standard, and found they were qualified in this capacity based on:

- Communication skills
- Technical qualifications
- Specific understanding of NQA-1, Element No. 18, titled *Audits*

Ms. Darlow was an Auditor-In-Training and her qualifications will be addressed in a subsequent EPA QA audit report. All personnel who were contacted or participated in these audits are listed in Attachment A.

5.0 PERFORMANCE OF THE AUDITS

Each of the three QA audits of CBFO is discussed in a separate section, below. While NQA-1 checklists were used for all three audits, checklist copies are included for the January 2011 and March 2011 audits.

5.1 January 25-27, 2011

5.1.1 NQA-1 Element No. 1, *Organization*

The EPA audit team conducted personnel interviews and document reviews during the audit of the CBFO QA program for the purpose of evaluating the implementation of the requirements stated in ASME NQA-1-1989, Element 1, *Organization*. Based on recent organizational changes at CBFO, EPA decided to revisit this important element of the NQA-1 standard during this audit using an NQA-1 checklist that is included as Attachment B to this report. A summary of the organizational changes is presented below.

5.1.1.1 Summary of Organizational Changes (as of January 25-27, 2011)

- The CBFO Manager, David C. Moody, left this position on December 5, 2010, to take another position as the Manager of DOE-SR. The CBFO Manager position remains open. Acting in the CBFO Manager position is the CBFO Deputy Manager, Mr. Edward Ziemainski. Mr. Oba Vincent, CBFO Senior Strategist, is currently acting in the role of the CBFO Deputy Manager.
- The CBFO Quality Assurance Director, Ava L. Holland, took a position as the CBFO Senior Technical Advisor for the Authorization Basis, effective November 22, 2010. The CBFO Quality Assurance Director position remains open. Currently, the CBFO QA Director position is being temporarily filled by the two Senior Quality Assurance Specialists, Mssrs. Dennis Miehl and Martin Navarrete, who are acting in this position alternating on a month-by-month basis.
- The contract to the CBFO Technical Assistance Contractor (CTAC), formerly held by Navarro Research and Engineering, was rebid and awarded to Portage Inc. on August 11, 2010. A protest to the contract award was filed. In spite of the protest, CBFO asked

Portage Inc. to begin the transition until resolution of the protest. During this time, the CTAC Senior Manager and the CTAC Audit and Assessment Manager positions were left open due to the uncertainty of the award. The CTAC Senior Manager position was temporarily filled during that time by the Portage Transition Manager, Mr. Richard Toft. Mr. Toft continued to act in that role until the protest was resolved on January 18, 2011. Mr. Toft is now the official CTAC Senior Manager working under Portage.

- The CTAC Audit and Assessment Manager position was temporarily filled by Mr. Porforio Martinez, CTAC Lead Auditor, from August 11, 2010, through October 17, 2010.
- Beginning on October 18, 2010, through January 21, 2011, Mr. Charles Riggs, CTAC Lead Auditor, acted as the Audit and Assessment Manager. Currently the CTAC Audit and Assessment Manager position has been filled by Mr. Randall Allen who is the permanent manager working under Portage.

Based on these changes, the EPA audit team interviewed key individuals relative to NQA-1 Element 1, *Organization*. Synopses of the interviews are presented below.

5.1.1.2 Interviews with Key Personnel

Edward Ziemianski, CBFO Manager (Acting), CBFO Deputy Manager: Mr. Edward Ziemianski has been appointed the Deputy Manager of the Carlsbad Field Office. Mr. Ziemianski is also fulfilling the role of Acting Manager of the Carlsbad Field Office until a permanent manager is selected. Mr. Ziemianski's position is shown on the DOE EM organizational chart, inserted as Figure 1, below. He was interviewed and found to be knowledgeable of the concepts of nuclear QA. He is familiar with the quality standards, including NQA-1 and the regulatory requirements associated with nuclear quality assurance. His background includes experience with nuclear QA programs in the DOE complex, NRC-regulated power plants, and nuclear Navy construction.

Dennis Miehl, CBFO Senior QA Specialist: Mr. Miehl is temporarily filling the QA Director position, alternating on a monthly basis with Martin Navarrete, effective November 22, 2010. Memoranda of delegation (or designation) were provided to appropriate staff on November 19, 2010, designating Mr. Miehl as Acting Director for the remainder of November and December, and on January 3, 2011, designating Mr. Navarrete as Acting Director for January 2011. This is not the first time Messrs. Miehl and Navarrete have temporarily filled the QA Director position and they have prior experience in directing the organization. Mr. Miehl was comfortable that the existing CBFO QA personnel are still able to perform their required functional responsibilities. He does not think that the QA organization's levels of authority, lines of communication, and independence have changed with the departure of the QA Director or with the temporary filling of the QA Director position with the two Senior QA Specialists.

There are currently several positions open in the CBFO QA organization, including the Director position and two Senior QA positions. Mr. Miehl believes the QA Department will be able to expand its role once these positions are filled.

Martin Navarrete, CBFO Senior QA Specialist/Acting CBFO QA Manager: As with Mr. Miehls, discussed above, Mr. Navarrete has taken on additional responsibilities in the CBFO QA organization. Mr. Navarrete provided similar comments to Mr. Miehls' comments regarding the capabilities and function of the CBFO QA organization. Mr. Navarrete's experience in temporarily filling the QA Director position is that it takes approximately 80 to 90% of his time. The remainder of his time is devoted to his responsibilities as a Senior QA Specialist. He stated that Mr. Miehls has been able to perform the Senior QA functions that he has not been able to perform. Messrs. Navarrete and Miehls stated that the CTAC organization will be able to perform its QA responsibilities despite the loss of several key staff in the last several months. Their positions are shown on the CBFO organizational chart, inserted as Figure 2, below.

Randall Allen, CTAC Audit and Assessment Manager: Mr. Allen became the CTAC Audit & Assessment Manager on January 24, 2011. The CTAC Audit and Assessment Manager's position description requires "either a bachelor of science degree with three years management experience or meets the requirements of a Lead Quality Assurance Auditor with five years management experience." Mr. Allen provided us with a copy of his resume. He has a B.S., Industrial Technology, with an emphasis on Quality Assurance & Waste Management; is a Lead Quality Assurance Auditor and has approximately seven years of experience¹. Therefore, he meets both criteria for the Audit and Assessment Manager. His position is shown on the CTAC organizational chart, inserted as Figure 3, below.

The staffing of CTAC has slowed due to the recent award of the contract in which Portage was selected, but the selection was protested and is only now being resolved. Given how recently Mr. Allen has joined CTAC, he was not able to comment on the ability of the CTAC resources to perform the required work. He mentioned that they have two open positions in the QA area, one position in the software area and the other position in packaging and transportation. He also mentioned that the CTAC staff has gone through some auditor training and refresher training. He provided an organizational chart of CTAC and additional position descriptions, inserted as Figure 3, below.

5.1.1.3 Compliance with NQA-1 Element No. 1, *Organization*

Based on these interviews and other objective evidence, the EPA audit team concluded that despite the organizational changes, the CBFO QA Program continues to comply with NQA-1 Element No. 1, titled *Organization*. The changes have not diminished the independence and authority of the CBFO QA Program personnel. Due to the recent nature and importance of these changes, the EPA will continue to assess CBFO's QA organization. Regarding resources, EPA is interested in the number of current open positions within the CBFO QA organization and EPA expects these positions will be filled in a manner that allows CBFO to continue operating in compliance with the NQA-1 standard.

¹ Mr. Allen's resume shows that he was the Corporate Environmental, Safety & Health, and Quality Manager, Portage, Inc., Idaho Falls, Idaho, from 2010 to the present. In addition, he was the Corporate Quality Assurance Manager, Portage, Inc., from 2008 to 2009. His resume shows he was the Lead Quality Assurance Engineer from 2003 to 2007 for S.M. Stoller Corporation, Idaho Falls, Idaho. During the interview, Mr. Allen stated that he had a second title while he was with Stoller—Northwest QA Lead Manager.

The EM Leadership Pyramid

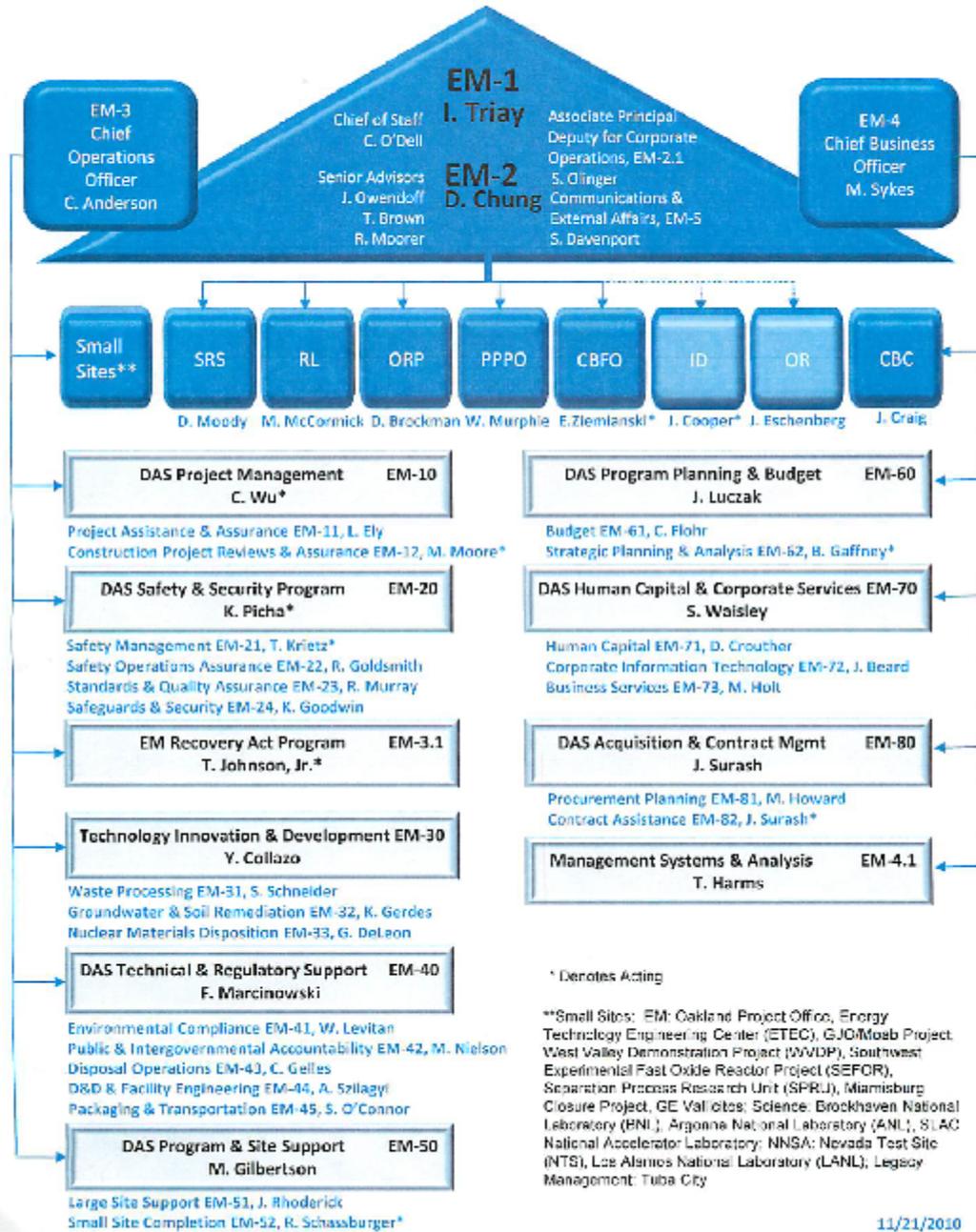
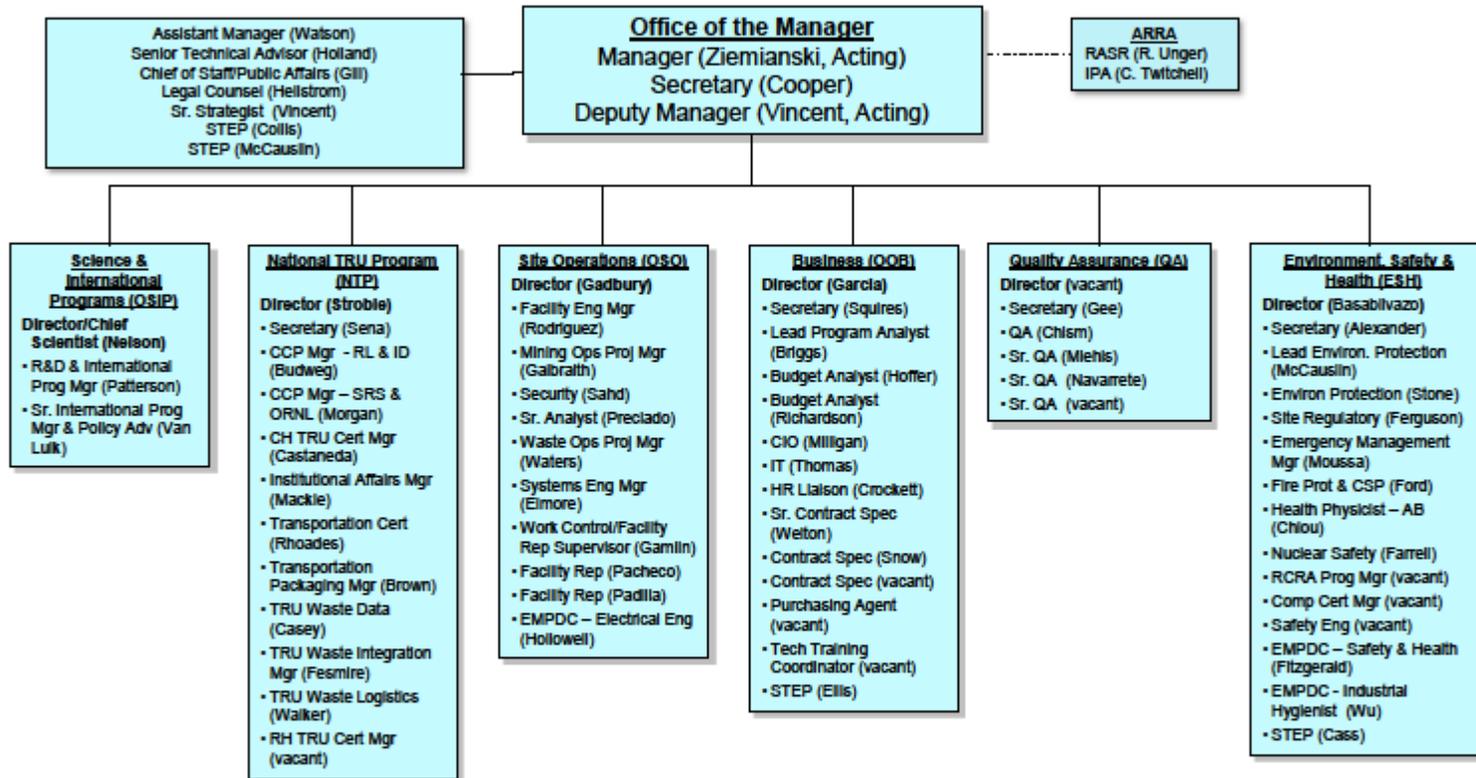


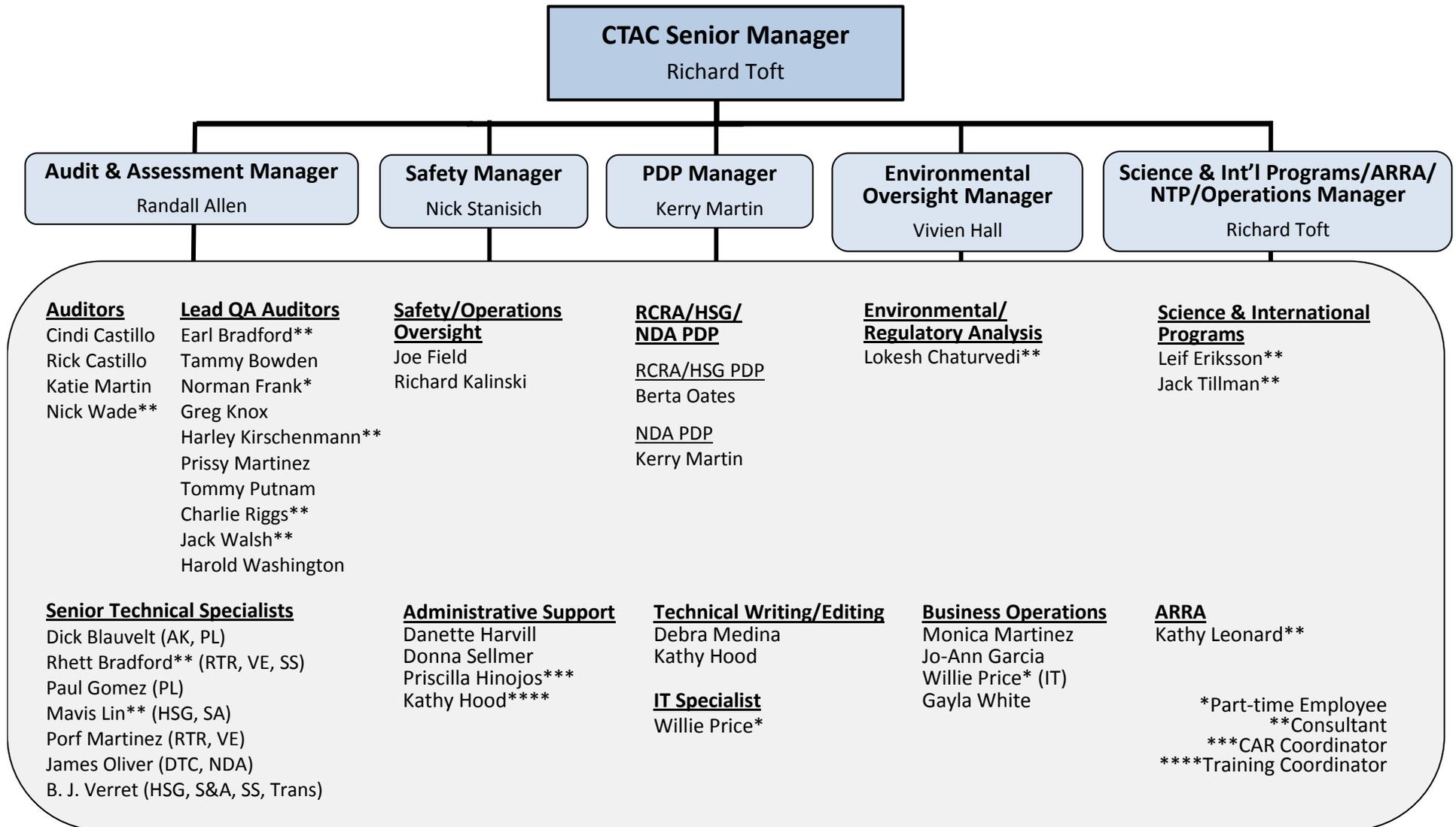
Figure 1. DOE EM Organizational Chart as of 11/21/2010

Carlsbad Field Office



Signature on File
Edward Ziemianski
12/06/2010

Figure 2. Carlsbad Field Office Organizational Chart as of 12/06/2010



AK = acceptable knowledge
 CAR = Corrective Action Report
 DTC = dose-to-curve
 HSG = headspace gas
 NDA = nondestructive assay
 PDP = Performance Demonstration Program
 PL = project level

RCRA = Resource Conservation and Recovery Act
 RTR = real-time radiography
 S&A = sampling and analysis
 SA = solids analysis
 SS = solids sampling
 Trans = transportation
 VE = visual examination

Updated 1/26/2011

Figure 3. CTAC Organizational Chart as of 1/26/2011

5.1.2 NQA-1 Element No. 6, *Document Control*

EPA audited CBFO's document control system against the requirements in NQA-1 Element No. 6, titled *Document Control*, using an NQA-1 checklist that is included as Attachment C to this report. During this audit, EPA found one instance where document control procedures were not followed as required by NQA-1 Element No. 5, titled *Instructions, Procedures, and Drawings*, which states: *Activities affecting quality shall be... performed in accordance with... procedures....* Specifically, the records package for procedure CBFO MP 10.3, Revision 7 was incomplete and did not contain the documents required by procedure CBFO MP 4.2, Document Review, Section 6.0, *Records*. EPA does not require a response at this time, but will evaluate this issue in a follow-up audit scheduled for March 15-17, 2011 (see Section 5.2.1).

5.1.3 Follow-up Activities

During this audit, the EPA audit team focused on NQA-1 Element No. 1, *Organization* and No. 6, *Document Control*. In future audits, EPA will assess other elements to verify that the CBFO QA Program continues to comply with the NQA-1 standard. EPA will conduct a follow-up audit that includes other NQA-1 elements on March 15-17, 2011. Additionally, EPA will evaluate the CBFO-sponsored Nondestructive Assay Performance Demonstration Program in 2012.

5.1.4 Findings and Concerns

The EPA team did not identify any findings and identified one minor concern relative to NQA-1 Element No. 5, *Instructions, Procedures and Drawings*, as discussed above. This concern does not require a response and will be evaluated during the March 2011 follow-up audit.

5.1.5 Conclusions

The EPA audit team reviewed documents and records and interviewed personnel to determine the continued compliance of the CBFO QA Program with Element 1, *Organization* and Element No. 6, *Document Control* of the ASME NQA standard. Based on this audit, the EPA determined that the CBFO QA Program continues to comply with these two elements of the standard.

5.2 March 14-17, 2011

EPA conducted an audit of the Department of Energy's CBFO QA Program, focusing on NQA-1-1989 Element Nos. 5, 6, and 16, *Instructions, Procedures and Drawings*, *Document Control* and *Corrective Action*, respectively. The EPA audit team completed a review of documents and records, interviewed QA and operational personnel, and evaluated two open issues from previous audits. EPA determined that the CBFO QA Program continues to comply with NQA-1-1989 Elements Nos. 5, 6, and 16. Additionally, the EPA audit team closed two open concerns and identified one new concern requiring a response, as described below.

5.2.1 NQA-1 Element No. 5, *Instructions, Procedures and Drawings*

EPA audited CBFO's QA Program against the requirements in NQA-1 Element No. 5, titled *Instructions, Procedures and Drawings*, using an NQA-1 checklist that is included as Attachment D to this report. During this audit, EPA combined this evaluation with an evaluation of the open concern from the January 2011 CBFO audit, discussed in Section 5.1.2., above, and Section 5.2.4., below. During this audit, EPA found all aspects of the CBFO QA Program to be in compliance with this element of the 1989 NQA-1 standard. EPA's evaluation and closing of the open issue is discussed below.

5.2.2 NQA-1 Element No. 6, *Document Control*

EPA audited CBFO's document control system against the requirements in NQA-1 Element No. 6, titled *Document Control*, using an NQA-1 checklist that is included as Attachment E to this report. During this audit, EPA combined this evaluation with an evaluation of the open issue from the January 2011 audit, discussed in Section 5.1.2, above and also in Section 5.2.4, below. During this audit, EPA found all aspects of the CBFO QA Program to be in compliance with this element of the 1989 NQA-1 standard. EPA's evaluation and closing of the open issue is discussed below.

5.2.3 NQA-1 Element No. 16, *Corrective Action*

EPA audited CBFO's corrective action system against the requirements in NQA-1 Element No. 16, titled *Corrective Action*, using an NQA-1 checklist that is included as Attachment F to this report.

EPA Concern

NQA-1-1989 Element 16, Corrective Action requires: *Conditions adverse to quality shall be identified and corrected as soon as practical.* This NQA-1 requirement was included in the CBFO QAPD, Revision 11, Section 1.3.3.3.B, which states: *...complete remedial action as soon as practical.* However, this requirement is not found in implementing procedure MP 3.1, Corrective Action Reports, Revision 11. Section 5.6.1.A of this procedure does require: *Verification shall be accomplished as soon as practicable*, but this does not reflect the NQA-1-1989 requirement for identification and correction. EPA reviewed the CAR Records Package for CAR10-053 and followed the process to conclusion to verify the timeliness of the process. Although the process is performed as required by NQA-1-1989, EPA is concerned that the implementing procedure MP 3.1 does not properly establish the requirement for corrective action to be *identified and corrected as soon as practical.*

CBFO Response

The CBFO QA Manager acknowledges EPA's concern and will propose a schedule for revising procedure MP 3.1 within thirty days.

EPA Evaluation of CBFO Response

EPA accepts CBFO's response and no further response is required at this time. EPA will verify revision of MP 3.1 at a future audit.

5.2.4 Concerns from Previous EPA Audits of CBFO

LANL-Carlsbad Office QA Concern from EPA Audit of CBFO, 2009

In 2009, Los Alamos National Laboratory (LANL) requested that LANL Carlsbad Operations Group (LANL-CO) implement all or portions of the LANL QA Program for their WIPP-related work. The DOE CBFO became aware of this request and sent a letter to LANL-CO on March 4, 2010, stating that it was unacceptable to have the work LANL-CO performs for the WIPP be performed under a QA program that does not strictly comply with the requirements of Title 40 of the Code of Federal Regulations (CFR) Part 194 *Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations, Section 194.22 Quality Assurance*. LANL-CO recalled the LANL-CO WIPP Quality Assurance Plan on April 21, 2010, and sent a letter to CBFO on March 24, 2010, stating that they had developed a plan to transition the LANL-CO QA program to operate directly under the requirements of the CBFO *Quality Assurance Program Document* and to discontinue use of the LANL-CO WIPP Quality Assurance Plan. The transition plan includes an evaluation of the extent of the revisions this change will have on LANL-CO procedures and program documents. LANL-CO submitted a letter to CBFO QA on February 28, 2011, that stated that they have completed implementation of the plan to transition the LANL-CO QA program to operate directly under the requirements of the CBFO *Quality Assurance Program Document*. The original transition plan with objective evidence was attached to the letter.

EPA performed a QA audit of the CBFO operations in December 2009. During this audit, EPA learned about the LANL request to have LANL-CO implement the LANL QA program for WIPP-related work. Concerned that the adoption of the LANL QA program would not meet NQA-1, EPA cited this issue as a concern. The EPA audit team examined the transition plan during this audit and conducted additional discussions with personnel from CBFO QA (Dennis Meihls and Martin Navarrete) and LANL-CO QA (Laurie Smith, LANL-CO QA Manager). Based on EPA's review during this audit, EPA believes that this issue has been addressed. EPA may perform an NQA-1-1989 Element 18 audit of CBFO's QA audit of LANL-CO in the future to verify that the program is compliant with NQA-1-1989.

Document Control Concern from EPA Audit of CBFO, January 2011

During EPA's January 2011 audit of CBFO, as discussed in 5.1.2, above, EPA identified two instances where document control procedures were not followed as required by NQA-1-1989 Element 5, which states: *Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances*. Specifically, the records package for Revision 7 of procedure MP 10.3 was incomplete and did not contain the draft document as required by procedure MP 4.2, Document Review, Section 6.0, Records. Section 5.1.1 of MP 4.2 requires identification of document

reviewers and the completion of the Document Review/Approval Matrix. The matrix was incomplete and did not contain all personnel providing review comments on the procedure. During this audit, EPA reviewed additional document control records and determined that the procedure's requirements had been followed. EPA has closed this concern; no further action is required by CBFO.

5.2.5 Follow-Up Activities

During this audit, the EPA audit team focused on NQA-1 Element No. 5, *Instructions, Procedures and Drawings*; Element No. 6, *Document Control*; and Element No. 16, *Corrective Action*. In future audits, EPA will assess other elements to verify that the CBFO QA Program continues to comply with the NQA-1 standard. EPA will conduct a follow-up audit that includes other NQA-1 elements.

5.2.6 Findings and Concerns

The EPA team did not identify any findings and identified one concern relative to NQA-1 Element No. 16, *Corrective Action*, as discussed above. CBFO provided a response to this concern and EPA accepts CBFO's response. No further response is required at this time. EPA will verify revision of MP 3.1 at a future audit. Additionally, the EPA audit team closed two open issues from previous CBFO audits in December 2009 and January 2011, as discussed above.

5.2.7 Conclusions

The EPA audit team reviewed documents and records and interviewed personnel to determine the continued compliance of the CBFO QA Program with NQA-1 Element No. 5, *Instructions, Procedures and Drawings*; Element No. 6, *Document Control*; and Element No. 16, *Corrective Action*. Based on this audit, the EPA determined that CBFO QA Program continues to comply with these three elements of the standard.

5.3 July 19-21, 2011

5.3.1 Interviews with Key QA Personnel

The EPA audit team interviewed Val Cannon, CCP QA Manager, and Randal Unger, the newly appointed CBFO QA Director. The EPA audit team verified the title and function of CCP personnel responsible for QA-related functions related to the long-term isolation of TRU wastes. Additionally, the EPA audit team found that Mr. Unger has sufficient training, education and experience to perform the duties of CBFO QA Director. Specifically, Mr. Unger is familiar with the requirements of the NQA-1 standards, and he reports directly to the CBFO Manager, Ed Ziemanski. EPA had no concerns relative to the independence, authority and qualifications of the CBFO QA Director.

5.3.2 Evaluation of CBFO CAR 11-043

On July 19-21, 2011, EPA evaluated the nonconformance documented in CBFO CAR 11-043 that was identified during CBFO Audit A-11-14. EPA conducted its evaluation from the standpoint of the CAR's potential impact on the long-term isolation of TRU waste.

Summary of Evaluation

CBFO CAR 11-043 stated that:

AK records are not getting into the CCP Records system. For example, the auditor requested the CCP Records Manager to verify that the source documents listed on Attachment 4, Acceptable Knowledge Source Document Reference List, for selected waste streams were in the hard copy CCP Records files.

During interviews and reviewing the documents listed above, the EPA audit team determined that the documents, which were not in the records system and whose absence generated the CAR, were used and accessible by the Acceptable Knowledge (AK) Experts in the waste characterization process. The EPA audit team learned during the interviews that some of the information had not been captured through AK documentation process but, instead, was documented through the Process Knowledge (PK) documentation process. The conclusion that CBFO CAR 11-043 did not have a significant impact on the long-term isolation of TRU waste assumes that the AK experts relied on the PK documentation, which would not have changed in the conversion from PK to AK documentation. Accordingly, the waste characterization process was not impacted and, therefore, the long-term isolation of TRU waste would not be impacted.

Documents Reviewed

The EPA audit team reviewed the following documents:

- June 28, 2011 Memorandum, "Issuance of CARs 11-042 and 11-043 Identified During Audit A-11-14," from Mr. Dennis S. Miehl, Senior Quality Assurance Specialist, DOE Carlsbad Field Office to Mr. D. K. Ploetz, Manager, Washington TRU Solutions Central Characterization Project Retrieval, Characterization and Transportation
- June 30, 2011 Memorandum, "Evaluation of the CAP for CBFO CAR 11-043, Audit A-11-14, INL/CCP Activities," from Dennis S. Miehl, Senior Quality Assurance Specialist, DOE Carlsbad Field Office to Mr. D. K. Ploetz, Manager, Washington TRU Solutions Central Characterization Project Retrieval, Characterization and Transportation
- June 30, 2011 Memorandum, "Impact Evaluation of Accelerated Corrective Action Report 11-043," from J. R. Stroble, Director, Office of the National TRU Program to Edward Ziemianski, Acting Carlsbad Field Office Manager
- June 30, 2011 Memorandum, "Corrective Action Plan for Corrective Action Report 11-043 Resulting from Audit A-11-14 of Idaho National Laboratory Central Characterization Project Activities," from Mr. D. K. Ploetz, Manager, Washington TRU Solutions Central Characterization Project Retrieval, Characterization and Transportation to Dennis S. Miehl, Senior Quality Assurance Specialist, DOE Carlsbad Field Office

- July 1, 2011 Memorandum, “Review and Verification of the Corrective Actions Submitted in Response to CBFO CAR 11-043, Identified During Audit A-11-14, INL/CCP Characterization Project Activities,” from Dennis S. Miehls, Senior Quality Assurance Specialist, DOE Carlsbad Field Office to Mr. D. K. Ploetz, Manager, Washington TRU Solutions Central Characterization Project Retrieval, Characterization and Transportation
- July 1, 2011 Letter, “Resumption of Shipments from Idaho National Laboratory WIPP Hazardous Waste Facility Permit EPA I.D. Number NM 4890139088,” from John E. Kieling, Acting Bureau Chief, Hazardous Waste Bureau, New Mexico Environment Department to Edward Ziemianski, Acting Manager, DOE Carlsbad Field Office and Farok Sharif, Washington TRU Solutions LLC

Interviews with Key Personnel

The EPA audit team interviewed several individuals in evaluating CBFO CAR 11-043. The interviews are summarized below.

Dennis Miehls and Martin Navarrete, CBFO Senior QA Specialists: EPA interviewed Messrs. Dennis Miehls and Navarrete as part of the evaluation of CBFO CAR 11-043. They provided EPA with information on how this CAR was initiated, discussed, processed and ultimately dispositioned. The timeline for processing of CBFO CAR 11-043 is listed below:

- June 7-9 CBFO QA Recertification Audit of INL where this concern is identified
- June 9-28 Numerous discussions between CBFO QA, CBFO management, CTAC, CCP operations and QA, NMED and CBFO contractors took place
- June 28 CAR was issued
- June 29 NMED issued a stop shipment order
- June 30 Corrective Action Plan (CAP) was submitted and evaluated by CBFO QA personnel
- July 1 CAP approved and NMED letter allowing resumption of shipping
- July 7 Interim audit report generated

Messrs. Miehls and Navarrete described how CBFO QA determined that the issue was a significant condition adverse to quality (CAQ) and RCRA related, but that suspension of work was not warranted. The CAR process was completed over a very short period of time, but Messrs. Miehls and Navarrete stated that the correctness and effectiveness of the CAR process were not negatively impacted because of this schedule. Mr. Miehls stated that his independence and authority were not compromised during this process.

Val Cannon, Manager of Quality Programs for WTS QA/CCP: EPA interviewed Mr. Val Cannon to evaluate CCP’s interaction with CBFO QA with regard to CBFO CAR 11-043. Mr. Cannon described how this CBFO CAR was initiated, processed and dispositioned, and the discussions held prior to CAR issuance. The CAP was developed by CCP operational personnel

and approved by CBFO QA. Mr. Cannon stated that some of the previous WTS internal audits of CCP had identified similar AK records non-conformances. These were reported on WIPP Forms WF 10-224 and WF 10-225, both dated September 14, 2010. A follow-up audit was performed in April 2011, which determined that the corrective action implemented for WF 10-224 was ineffective. A subsequent WIPP Form, WF 11-051, was generated to address this continuing non-conformance. Mr. Cannon told the EPA audit team that part of the reason CBFO CAR 11-43 was elevated to a CAQ was because of these previously identified non-conformances. Mr. Cannon stated that his independence and authority were not compromised during the processing and closure of CBFO CAR 11-043.

Tamara Bowden, CTAC Audit Team Leader for INL Recertification Audit A-11-14: EPA interviewed Ms. Tamara Bowden as part of the evaluation of CAR 11-043. Ms. Bowden provided information to EPA about the initiation of the concern by Mr. Norman Frank, and described the iterative process that took place post-inspection to determine the final classification of the audit concern. She told EPA that after the inspection and before the CAR was issued, she was involved in discussions with CBFO QA management about the concern. They conducted additional research and discussions to ensure full understanding of the non-conformance. During this time, they determined that the same issue had been found twice before during internal CCP QA audits, and therefore was a significant CAQ. They also determined that the concern resulted in a violation of the Hazardous Waste Facility Permit (HWFP). The CAR, as finalized by CBFO QA management, was published and NMED issued a stop shipment order the following day. Ms. Bowden said that she and her CTAC team then worked almost solidly for the following 48 hours to ensure that they were available to CCP whenever requested in order to disposition the CAR as soon as possible. Ms. Bowden told EPA that she would not have done anything differently during this process.

Sheila Percy, Manager, CCP Records: Sheila Percy was interviewed regarding CBFO CAR 11-043 and also her general records management procedures. Ms. Percy stated that there was an issue with locating some of the records cited in CBFO CAR 11-043. Ms. Percy stated that she and the AK personnel did not know what happened to a set of records that AK personnel thought they had transferred to CCP Records and that since the transmittal letter process is no longer used, it is difficult to determine what happened to these documents. Prior to November 2010, AK personnel prepared a transmittal letter for items being transferred to CCP Records Management. The transmittal letter was signed and dated by Records Management upon receipt, with a copy of the signed transmittal letter returned to the appropriate AK person. The use of transmittal letters was terminated because it was determined that this process was unnecessary, given that records were transferred within the CBFO building. Ms. Percy noted that since CAR 11-043 was issued, the AK organization generates a “print screen” of all source documents that are associated with an AKSR before the AKSR is finalized. The AK organization retains the “print screens” with the other AK information to confirm that the records have been transferred. All records that are received by CCP Records Management are logged in by site name and reviewed for completeness; this is not a technical review but is an assessment that all pages/information are present and legible. In addition, all documents are scanned and placed in either Garrison (Attachment 3’s and Source Documents) or Dixon (other AK information).

Findings and Concerns

Based on the personnel interviews conducted and the documents reviewed, the EPA audit team did not identify any findings or concerns relative to the manner in which CBFO addressed CAR 11-043.

Conclusion

EPA concluded that CBFO CAR 11-043 did not have any impact on the long-term isolation of transuranic waste. EPA also concluded that the issuance of CBFO CAR 11-043 is objective evidence that the CBFO QA Program has the organizational freedom to identify Conditions Adverse to Quality in accordance with ASME Nuclear Quality Assurance (NQA)-1-1989, Element 1.

5.3.3 NQA-1 Element Nos. 1 and 2, *Organization and Quality Assurance Records*

As part of this evaluation, the EPA audit team reviewed documents and records and interviewed personnel to determine compliance with selected aspects of the following elements of the 1989 ASME NQA-1 standard:

- Element 1, *Organization*
- Element 2, *Quality Assurance Records*

The EPA audit team did not identify any findings or concerns relative to these two elements of the NQA-1 standard.

Findings and Concerns

The EPA team did not identify any findings or concerns relative to CBFO CAR 11-043. During this audit, WTS personnel noted that while they are “contractually” subject to the “Basic Requirements” of ASME NQA-1-1989, they are not “contractually” subject to the “Supplements” of ASME NQA-1-1989. EPA plans to review this issue at the next EPA QA audit in January 2012.

Conclusion

The investigation of the activities selected for EPA’s audit sample showed that the QA Program continues to be executed in accordance with the 1989 ASME NQA-1 standard.

5.3.4 Findings and Concerns

Based on the personnel interviews conducted and the documents reviewed, the EPA audit team did not identify any findings or concerns relative to the manner in which CBFO addressed CAR 11-043.

5.3.5 Conclusions

EPA evaluated the nonconformance documented in CBFO CAR 11-043 that was identified during CBFO Audit A-11-14 from the standpoint of its impact on the long-term isolation of transuranic waste. EPA has concluded that this nonconformance did not have any impact on the long-term isolation of transuranic waste. EPA also concludes that the issuance of CAR 11-043 is objective evidence that the CBFO QA Program has the organizational freedom to identify Conditions Adverse to Quality in accordance with NQA-1 Element 1, *Organization*. Additionally, the EPA audit team reviewed documents and records and interviewed personnel to determine compliance with Element 1, *Organization*, and Element 2, *Quality Assurance Records*. The investigation of the activities selected for EPA's audit sample showed that the CBFO QA Program continues to be executed in accordance with the 1989 NQA-1 standard.

6.0 FOLLOW-UP ACTIVITIES

EPA will conduct a QA audit of CBFO in January 2012 to assess current conditions, including the effects of all organizational or personnel changes, as appropriate.

7.0 FINDINGS AND CONCERNS

During these audits, EPA closed two open concerns from previous EPA audits in 2009 and 2011. EPA identified two concerns that remain open:

- During the March 2011 audit, EPA identified one concern relative to NQA-1 Element No. 16
- During the July 2011 audit, EPA identified one minor concern relative to whether WTS personnel are “contractually” subject to the “Supplements” of ASME NQA-1-1989

EPA plans to review these issues with CBFO QA staff at the 2012 EPA QA audit.

8.0 CONCLUSIONS

As a result of three audits conducted during calendar year 2011, EPA determined that the CBFO QA Program continues to comply with the applicable requirements of the NQA-1 standard, including maintaining sufficient independence, authority, and resources to verify the quality of items and activities that are important to long-term isolation of TRU waste. These three audits occurred over a one-year period and each is representative of conditions at CBFO at the time of

the audit. EPA will conduct its yearly QA audit of CBFO in January 2012 to assess current conditions, including the effects of all organizational or personnel changes, if any.

ATTACHMENT A

PERSONNEL PARTICIPATING IN AUDIT MEETINGS

NAME	AFFILIATION/AUDIT FUNCTION	JANUARY 25, 2011			MARCH 14-17, 2011			JULY 19-21, 2011		
		ENTRANCE MEETING	INTERVIEWED	EXIT MEETING	ENTRANCE MEETING	INTERVIEWED	EXIT MEETING	ENTRANCE MEETING	INTERVIEWED	EXIT MEETING
Mike Eagle	EPA, Audit Team Leader	✓	-	✓	✓	-	✓	✓	-	-
Greg Beronja	EPA/SC&A	✓	-	✓	✓	-	✓	✓	-	✓
Patrick Kelly	EPA/SC&A	✓	-	✓	✓	-	✓	✓	-	✓
Dorothy Gill	EPA/SC&A	✓	-	✓	✓	-	✓	✓	-	✓
Kira Darlow	EPA/SC&A		-		✓	-	✓	✓	-	✓
Lea Chism	CBFO QA Specialist	✓		✓						✓
Martin Navarrete	CBFO Senior QA Specialist, Acting QA Manager	✓	✓		✓	✓	✓	✓	✓	✓
Dennis Miehl	CBFO Senior QA Specialist	✓	✓	✓	✓	✓	✓		✓	✓
Randall Allen	CTAC QA Manager	✓	✓	✓	✓		✓			✓
Porfirio Martinez	CTAC Auditor	✓		✓						
Mike Brown	CBFO PDP Coordinator, Transportation Packaging Manager			✓	✓					
Edward Ziemianski	CBFO Acting Manager		✓							✓
Cindi Castillo	CTAC Auditor, Observer				✓		✓	✓		
Alberta Farmer	Records Clerk				✓					
Oba Vincent	Acting Department Manager				✓					
Ava Holland	CBFO Senior Technical Advisor						✓			✓
George Basabilvazo	CBFO ES&H Director						✓			
David Garcia	CBFO OOB Director						✓			
Laurie Smith	LANL-CO QA Manager					✓	✓			
DK Ploetz	CCP Manager							✓	✓	✓
Tamara Bowden	CTAC/CBFO Lead Auditor							✓	✓	
A.J. Fisher	Senior Technical Advisor – Training							✓		✓

NAME	AFFILIATION/AUDIT FUNCTION	JANUARY 25, 2011			MARCH 14-17, 2011			JULY 19-21, 2011		
		ENTRANCE MEETING	INTER-VIEWED	EXIT MEETING	ENTRANCE MEETING	INTER-VIEWED	EXIT MEETING	ENTRANCE MEETING	INTER-VIEWED	EXIT MEETING
Randal Unger	CBFO QA Director							✓	✓	
Val Cannon	WTS/CCP QA Manager							✓	✓	✓
Court Fesmire	CBFO							✓		✓
Sheila Percy	CCP/Stoller								✓	✓
Laura Nelson	CCP RH Site Project Manager									✓
Trey Greenwood	CCP/TechSpecs								✓	✓

ATTACHMENT B

JANUARY AUDIT: CHECKLIST FOR NQA-1 ELEMENT 1, *ORGANIZATION*

• **Carlsbad Field Office Quality Assurance Program Document, Revision 11**

NQA-1 ELEMENT: No. 1 with Supplement 1S-1, *Organization*

EPA AUDITORS: M. Eagle, D. Gill, G. Beronja, P. Kelly

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph; and Objective Evidence
Basic Requirements			
1. Are the organizational structure, functional responsibilities, levels of authority, and lines of communication documented for activities affecting quality?	Y		<p>CBFO QAPD, R. 11¹: Section 1.1, Appendices C, D, and E provide a discussion of the organizational structure, functional responsibilities, and levels of authority; communication channels at all levels are briefly mentioned. Appendix C, “Authority for execution of the QA function, which ensures effective implementation, is delegated to the CBFO QA Manager in accordance with the allowable delegations as defined by EM-1.”</p> <p>Additional Review/Interviews: NQA-1 implementation documents: Interviews with CBFO and CTAC QA Managers; Task Order DE-DT0001674, GSA Contract GS-10E-0353M, Section 19, page 31</p>
2. Do persons or organizations responsible for performing quality assurance functions have sufficient authority, access to work areas, and organizational freedom to: <ul style="list-style-type: none"> • Identify quality problems; • Initiate, recommend, or provide solutions to quality problems through designated channels; • Verify implementation of solutions; and • Assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred? 	Y		<p>CBFO QAPD, R. 11: Section 1.1.1.3 A and B, Appendix D (QA Manager) describe the QA Manager’s responsibilities.</p> <p>Additional Review/Interviews: Interviews with CBFO and CTAC QA Managers: CBFO & CTAC organization charts</p>
3. Do persons or organizations responsible for performing quality assurance functions have direct access to responsible management at a level where appropriate action can be affected?	Y		<p>CBFO QAPD, R. 11: Appendix C, “Authority for execution of the QA function, which ensures effective implementation, is delegated to the CBFO QA Manager in accordance with the allowable delegations as defined by EM-1.” (from the CBFO Manager). The QAPD does not include an organization chart.</p> <p>Additional Review/Interviews: CBFO & CTAC organization charts: Interviews with CBFO & CTAC QA Managers</p>

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph; and Objective Evidence
4. Do persons or organizations responsible for performing quality assurance functions report to a management level that provides the required authority and organizational freedom, including sufficient independence from cost and schedule considerations?	Y		CBFO QAPD, R. 11: Section 1.1.1.3 A & B, Nos. 7-10, Appendix D (QA Manager) Additional Review/Interviews: CBFO & CTAC organization charts
Supplementary Requirements (1S-1)			
1. Are the organizational structure and the responsibility assignments such that: <ul style="list-style-type: none"> • Quality is achieved and maintained by those who have been assigned responsibility for performing work, and • Quality achievement is verified by persons or organizations not directly responsible for performing the work? (Section 2) 	Y		CBFO QAPD, R. 11: Section 1.1.1.2, employees are responsible for the quality of their work. Section 1.1.1.3, QA management is responsible to independently assess the organization’s effective implementation of the QA program and to verify the achievement of quality. Appendix D. Additional Review/Interviews Interviews with CBFO & CTAC QA Managers: CBFO & CTAC organization charts
2. Does the individual(s) or organization(s) responsible for establishing and executing a quality assurance program delegate any or all of the work to others and, if so, does the individual(s) or organization(s) retain responsibility for the quality assurance program? (Section 2.2)	Y		CBFO QAPD, R. 11: Section 1.1.1.5 allows delegation of any work (including, presumably, the QA program), but clearly notes the retention of responsibility. Additional Review/Interviews: Interviews with CBFO & CTAC QA Managers
3. Is responsibility for the control of further processing, delivery, installation, or operation of nonconforming items designated in writing? (Section 2.3)	Y		CBFO QAPD, R. 11: Section 1.3.2.1.E requires that implementing procedures shall “...specify responsibility and authority for reviewing, evaluating, approving the disposition, and closure of nonconformances.” Section 1.1.1.3, B, #4, QA management is responsible for ensuring that unsatisfactory conditions are controlled until proper disposition has occurred. Additional Review/Interviews Interviews with CBFO & CTAC QA Managers
4. Where more than one organization is involved in the execution of quality assurance activities, is the responsibility	Y		CBFO QAPD, R. 11: Section 1.1.1.4.B, Appendix C, CBFO Organization, Responsibilities, and Interfaces, page C-2, “Where more than one CBFO organization is involved in the execution of activities covered by the QAPD, the responsibility and authority of each organization shall be clearly established and documented.”

NQA-1 ELEMENT: No. 1 with Supplement 1S-1, Organization

EPA AUDITORS: M. Eagle, D. Gill, G. Beronja, P. Kelly

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph; and Objective Evidence
and authority of each organization clearly established and documented? (Section 3.1)			Additional Review/Interviews: Interviews with CBFO & CTAC QA Managers: CBFO & CTAC organization charts
5. Are the external interfaces between organizations, as well as the internal interfaces between organizational units, documented? (NQA-1 Supp. 1S-1 Section 3.2.1) Are interface responsibilities defined and documented? (NQA-1 Supp. 1S-1 Section 3.2.2)	Y		CBFO QAPD, R. 11: Appendix C, page C-2 states: “CBFO external interfaces include other DOE elements, CBFO program participants, suppliers, the Environmental Protection Agency, the Evaluation Group, and the New Mexico Environment Department.” Section 1.1.1.4.B, No. 1 requires external interfaces be defined and changes documented. Also, responsibility and authority of each organization must be clearly established, defined, and documented. Additional Review/Interviews: Interviews with CBFO & CTAC QA Managers: CBFO & CTAC organization charts

CTAC has historically had a Quality Assurance Plan, Quality Assurance Policy, and associated procedures. The 2010 Portage CTAC contract states: “In the conduct of the work performed under this task order, the Contractor agrees to comply with the CBFO quality assurance program, and work under the direction of and perform work in accordance with DOE CBFO procedures.” Given this, Portage does not plan to maintain its own Quality Assurance Plan, Policy or procedures and will follow the documents established by CBFO.

ATTACHMENT C

JANUARY AUDIT: CHECKLIST FOR NQA-1 ELEMENT 6, *DOCUMENT CONTROL*

NQA-1 ELEMENT: No. 6 with Supplement 6S-1, Document Control EPA AUDITORS: M. Eagle, D. Gill, G. Beronja, P. Kelly

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph and Objective Evidence
<u>Basic Requirements</u>			
1. Are the preparation, issue and change of documents, which specify quality requirements or prescribe activities affecting quality, controlled?	Y		QAPD, Revision 11: Section 1.4.1, Document Preparation, Review, Approval, and Issuance, Section 1.4.3, Document Changes CBFO MP 4.1, Revision 8, Preparation and Maintenance of CBFO Procedures CAR 10-032 was issued by CBFO QA on 5/10/10, because of non-compliance with requirements in CBFO MP 4.1. This CAR remained open at the time of the audit. EPA interviewed the Chief Information Officer (CIO) who is responsible for CBFO document control procedures. The CIO had many years of experience and was able to provide all required information. EPA generated a concern, not requiring a response, to address two instances where document control procedures were not followed. The concern was written against Element 5 Instructions, Procedures, and Drawings of NQA-1, 1989. EPA will revisit this issue at a follow-up audit scheduled for March 15-17, 2011.
2. Are such documents, including changes thereto, reviewed for adequacy and approved for release by authorized personnel?	Y		QAPD, R.11, Section 1.4.1, Document Preparation, Review, Approval, and Issuance CBFO MP 4.2, Section 5 provides instructions for document review prior to document issuance, together with a required Document Review/Approval Matrix. CBFO CAR 08-003 was issued on 12/06/07, because the procedure was not followed for all document reviews. This CAR remained open at the time of the on-site audit.
<u>Supplementary Requirements (6S-1)</u>			
1. Are documents controlled to assure that correct and applicable documents are available at the location where they are to be used?	Y		QAPD, Revision 11, Section 1.4.2, Document Distribution and Use Procedures are available on the intranet. Only the current revision of any procedure is available.
2. Is the control system documented and does it provide for: <ul style="list-style-type: none"> • Identification of documents to be controlled and their specified distribution; • Identification of personnel, positions, or organizations responsible for preparing, reviewing, approving, and issuing documents; and 	Y		Documents are numbered, for example, MP 4.2. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures include instructions for format and responsibilities. QAPD, Revision 11, Section 1.4.1, Document Preparation, Review, Approval, and Issuance. CBFO MP 4.2, Document Review

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph and Objective Evidence
<ul style="list-style-type: none"> Review of documents for adequacy, completeness, and correctness prior to approval and issuance? 			
<p>3. Are major changes to documents reviewed and approved by the same organization that performed the original review and approval, or is another organization specifically designated to review and approve the major change?</p> <p>Does the reviewing organization have access to pertinent background data or information upon which to base their approval?</p>	Y		<p>CBFO MP 4.2 has a Document Review/Approval Matrix that identifies reviewers and the type of review performed. This was incomplete for review of procedure MP 10.3, Revision 7 and EPA generated a concern not requiring a response. This concern will be further evaluated at the follow-up audit scheduled for March 15-17, 2011.</p>
<p>4. Are minor changes to documents defined (i.e., those changes that do not require a review as a major change)? Are the persons who can authorize a minor change clearly delineated?</p>	Y		<p>CBFO MP 4.2, Section 4.5</p>

ATTACHMENT D

MARCH AUDIT: CHECKLIST FOR NQA-1 ELEMENT 5, *INSTRUCTIONS, PROCEDURES, AND DRAWINGS*

NQA-1 ELEMENT: No. 5, Instruction, Procedures, and Drawings

EPA AUDITORS: M. Eagle, D. Gill, G. Beronja, P. Kelly

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph and Objective Evidence
Basic Requirements			
1. Are activities affecting quality prescribed by and performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances?	Y		CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 CBFO uses written procedures that are adequate, complete and implemented. EPA reviewed selected documents to verify compliance. <u>Objective evidence:</u> 1. CBFO MP 3.1, Corrective Action Reports, Revision 11 2. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 3. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 4. CBFO MP 4.2, Document Review, Revision 6 5. CBFO MP 4.4, Document Preparation and Control, Revision 7 6. List of controlled CBFO procedures, dated 3/17/11
2. Do the above referenced documents include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished?	Y		CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 CBFO uses written procedures that are adequate, complete and implemented. EPA reviewed selected documents to verify compliance. <u>Objective evidence:</u> 1. CBFO MP 3.1, Corrective Action Reports, Revision 11 2. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 3. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 4. CBFO MP 4.2, Document Review, Revision 6 5. CBFO MP 4.4, Document Preparation and Control, Revision 7 6. List of controlled CBFO procedures, dated 3/17/11
Supplementary Requirements – None			

ATTACHMENT E

MARCH AUDIT: CHECKLIST FOR NQA-1 ELEMENT 6, *DOCUMENT CONTROL*

NQA-1 ELEMENT: No. 6 with Supplement 6S-1, *Document Control*

EPA AUDITORS: M. Eagle, D. Gill, G. Beronja, P. Kelly

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph and Objective Evidence
<u>Basic Requirements</u>			
1. Are the preparation, issue and change of documents, which specify quality requirements or prescribe activities affecting quality, controlled?			<p>QAPD, R.11, section 1.4.1, Document Preparation, Review, Approval, and Issuance Section 1.4.3, Document Changes CBFO MP 4.1, Revision 8, Preparation and Maintenance of CBFO Procedures <u>January 2011 audit:</u> EPA interviewed the Chief Information Officer (CIS) who is responsible for document control for CBFO procedures. The CIS has many years of experience and was able to provide all required information. EPA generated a concern, not requiring a response, to address two instances where document control procedures were not followed. The concern was written against Element 5 Instructions, Procedures, and Drawings of NQA-1, 1989 (see body of report). EPA will revisit this issue at a follow-up audit scheduled for March 15-17, 2011. <u>March 2011 audit:</u> EPA interviewed the Chief Information Officer (CIO) for CBFO and reviewed selected records to demonstrate compliance with NQA-1 document control requirements. In January 2009 document control responsibilities were transferred to CTAC but then returned to the CIO in August 2010. EPA determined, through the review of documents and records, that the requirements of CBFO procedures and NQA-1 were met by the CIO. The concern, generated during the January 2011 audit, is closed and requires no further action. <u>Objective evidence:</u> 1. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 2. CBFO MP 4.2, Document Review, Revision 6 3. CBFO MP 4.4, Document Preparation and Control, Revision 7 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 5. Document packages for procedures MP 4.5, revision 2, 3, 4; MP 4.6, revision 2, 3, 4</p>
2. Are such documents, including changes thereto, reviewed for adequacy and approved for release by authorized personnel?	Y		<p>Document reference: QAPD, R.11, section 1.4.1, Document Preparation, Review, Approval, and Issuance. <u>January 2011 audit:</u> CBFO MP 4.2, section 5 provides instructions for document review prior to document issuance, together with a required Document Review/Approval Matrix. CBFO CAR 08-003 was issued on 12/06/07 because the procedure was not followed for all document reviews. This CAR remained open at the time of the on-site audit. CBFO QA personnel informed EPA that the concern was ready for closure verification after receipt of</p>

NQA-1 ELEMENT:

No. 6 with Supplement 6S-1, Document Control

EPA AUDITORS:

M. Eagle, D. Gill, G. Beronja, P. Kelly

		<p>requested information (see Corrective Action checklist). EPA generated a concern, not requiring a response, to address two instances where document control procedures were not followed. The concern was written against Element 5 Instructions, Procedures, and Drawings of NQA-1, 1989 (see body of report). EPA will revisit this issue at a follow-up audit scheduled for March 15-17, 2011. <u>March 2011 audit:</u> EPA interviewed the Chief Information Officer (CIO) for CBFO and reviewed selected records to demonstrate compliance with NQA-1 document control requirements. In January 2009 document control responsibilities were transferred to CTAC but then returned to the CIO in August 2010. EPA determined, through the review of documents and records, that the requirements of CBFO procedures and NQA-1 were met by the CIO. The concern, generated during the January 2011 audit, is closed and requires no further action. <u>Objective evidence:</u> 1. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 2. CBFO MP 4.2, Document Review, Revision 6 3. CBFO MP 4.4, Document Preparation and Control, Revision 7 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 5. Document packages for procedures MP 4.5, revision 2, 3, 4; MP 4.6, revision 2, 3, 4</p>
<u>Supplementary Requirements (6S-1)</u>		
<p>1. Are documents controlled to assure that correct and applicable documents are available at the location where they are to be used?</p>	Y	<p>Document reference: QAPD, R.11, section 1.4.2, Document Distribution and Use Procedures are available on the intranet and only the current revision of any procedure is available. <u>Objective evidence:</u> 1. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 2. CBFO MP 4.2, Document Review, Revision 6 3. CBFO MP 4.4, Document Preparation and Control, Revision 7 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 5. List of controlled CBFO procedures, dated 3/17/11</p>
<p>2. Is the control system documented and does it provide for:</p> <ul style="list-style-type: none"> • identification of documents to be controlled and their specified distribution; • identification of personnel, positions, or organizations responsible for preparing, reviewing, approving, and issuing documents; and • review of documents for adequacy, completeness, and correctness prior to approval and issuance? 	Y	<p>CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, includes instructions for format and responsibilities of procedures. QAPD, R.11, section 1.4.1, Document Preparation, Review, Approval, and Issuance. CBFO MP 4.2, Document Review The EPA auditors reviewed controlled documents to verify compliance with these requirements. No issues were identified. <u>Objective evidence:</u> 1. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 2. CBFO MP 4.2, Document Review, Revision 6 3. CBFO MP 4.4, Document Preparation and Control, Revision 7 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11</p>

NQA-1 ELEMENT:

No. 6 with Supplement 6S-1, Document Control

EPA AUDITORS:

M. Eagle, D. Gill, G. Beronja, P. Kelly

<p>3. Are major changes to documents reviewed and approved by the same organization that performed the original review and approval, or is another organization specifically designated to review and approve the major change?</p> <p>Does the reviewing organization have access to pertinent background data or information upon which to base their approval?</p>	<p>Y</p>	<p><u>January 2011 audit:</u> CBFO MP 4.2 has a Document Review/Approval Matrix that identifies reviewers and the type of review performed. This was incomplete for review of procedure MP 10.3, revision 7. EPA generated a concern not requiring a response (see 2. above). This concern will be further evaluated at the follow-up audit scheduled for March 15-17, 2011</p> <p><u>March 2011 audit:</u> The EPA auditors reviewed the Document review/Approval Matrix for MP 4.5, revision 2, 3, and 4 and MP 4.6, revision 2, 3, and 4 and determined that these records are complete. EPA determined, through the review of documents and records, that the requirements of CBFO procedures and NQA-1 were met by the CIO. The concern, generated during the January 2011 audit, is closed and requires no further action.</p> <p><u>Objective evidence:</u></p> <ol style="list-style-type: none"> 1. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 2. CBFO MP 4.2, Document Review, Revision 6 3. CBFO MP 4.4, Document Preparation and Control, Revision 7 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11 5. Document packages for procedures MP 4.5, revision 2, 3, 4; MP 4.6, revision 2, 3, 4
<p>4. Are minor changes to documents defined (i.e., those changes that do not require a review as a major change)? Are the persons who can authorize a minor change clearly delineated?</p>	<p>Y</p>	<p>Document reference: CBFO MP 4.2, Section 4.5</p> <p>The EPA auditors reviewed controlled documents to verify compliance with these requirements. No issues were identified.</p> <p><u>Objective evidence:</u></p> <ol style="list-style-type: none"> 1. CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 9 2. CBFO MP 4.2, Document Review, Revision 6 3. CBFO MP 4.4, Document Preparation and Control, Revision 7 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11

ATTACHMENT F

MARCH AUDIT: CHECKLIST FOR NQA-1 ELEMENT 16, *INSTRUCTIONS, PROCEDURES, AND DRAWINGS*

NQA-1 ELEMENT: No. 16, Corrective Action

EPA AUDITORS: M. Eagle, D. Gill, G. Beronja, P. Kelly

Does the reference document adequately define, describe, address, or satisfy the following:	Y	N	Applicable Procedure and Paragraph and Objective Evidence
Basic Requirements			
1. Are conditions adverse to quality identified promptly and corrected as soon as practical?		N	<p>QAPD, Revision 11, Section 1.3.3.3.B states "...complete remedial action as soon as practical." QAPD, Revision 11, Section 1.3.3.7 "...complete corrective actions in a timely manner" CBFO MP 3.1, Revision 11, Section 5.6.1.A "Verification shall be accomplished as soon as practicable." This requirement did not flow down correctly to procedure, MP 3.1. The procedure does not require implementation of corrective action "as soon as practical." The EPA generated a concern requiring a response to address this issue. CBFO QA responded to the concern during the audit and the response was accepted by EPA.</p> <p><u>Objective evidence:</u></p> <ol style="list-style-type: none"> 1. Documentation package for CAR 10-053 2. CBFO MP 3.1, Corrective Action Reports, Revision 11 3. Open EPA Findings list, dated 2/24/11 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11
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?	Y		<p>Document references: QAPD, Revision 11, Section 1.3.3.4 & 1.3.3.5 CBFO MP 3.1, Revision 11, Sections 5.3 & 5.4. Att I-VI CBFO QA personnel described the CAR closure process and EPA reviewed records to verify implementation.</p> <p><u>Objective evidence:</u></p> <ol style="list-style-type: none"> 1. Documentation package for CAR 10-053 2. CBFO MP 3.1, Corrective Action Reports, Revision 11 3. Open EPA Findings list, dated 2/24/11 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11
3. Are the identification, cause and corrective action for significant conditions adverse to quality documented and reported to appropriate levels of management?	Y		<p>Document reference: CBFO MP 3.1-1, Section 5.1-5.2, Audit team leader, CBFO QA Director Section 5.9, evaluation of accelerated CAR impact sent to CBFO Manager, CBFO QA Director, responsible organization</p> <p><u>Objective evidence:</u></p> <ol style="list-style-type: none"> 1. Documentation package for CAR 10-053 2. CBFO MP 3.1, Corrective Action Reports, Revision 11 3. Open EPA Findings list, dated 2/24/11 4. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11

<p>4. Is follow-up action taken to verify implementation of corrective action?</p>	<p>Y</p>	<p>CBFO MP 3.1, Revision 11, Section 5.6.1.A “Verification shall be accomplished as soon as practicable.” The EPA reviewed the status of CARs that have remained open for significant time periods. CBFO QA has initiated use of “Weekly CBFO CAR Status” report that updates progress towards closure of each CAR. The CAR status provided to EPA at the audit follows: CAR 08-003: Verification will be performed after receiving information from the manager. CAR 08-027: Waiting for revised CAP. Was due 2/26/11. Manager informed of late status. CAR 08-029: Will be closed after the closure of CAR 08-003. CAR 10-030: MP 5.4 revision has been posted. CAR 10-031: AN extension request was received and granted. CAR 10-032: Ready for verification. CAR 10-033: Ready for verification. EPA will monitor CAR closure times during a future audit. <u>Objective evidence:</u> 1. Weekly CBFO CAR Status, dated 3/8/11 2. Documentation package for CAR 10-053 3. CBFO MP 3.1, Corrective Action Reports, Revision 11 4. Open EPA Findings list, dated 2/24/11 5. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11</p>
<p>Supplementary Requirement - None</p>		