



United States Government

Department of Energy

memorandum

Carlsbad Field Office
Carlsbad, New Mexico 88221

DATE: October 26, 2004
REPLY TO
ATTN OF: CBFO:QA:ALH:LC:04-1857:UFC 2300
SUBJECT: Transmittal of Audit Report for Audit A-04-24

TO: R. Paul Detwiler, CBFO, Acting Manager



The Carlsbad Field Office (CBFO) performed Audit A-04-24 of the CBFO Quality Assurance Program Document (QAPD) on September 7-9, 2004. The audit team concluded that the CBFO QAPD itself is adequate, but the implementing procedures are inadequate because they do not reflect the current CBFO organization and, in some cases, current CBFO practices. This is further described in CBFO Corrective Action Report (CAR) 04-046.

The audit team also concluded that select implementing procedures are satisfactorily implemented and effective, with the exception of CBFO Management Procedure (MP) 10.7, *Operational Assessments*. The implementation and effectiveness of MP 10.7 was determined to be unsatisfactory, as further described in CBFO CAR 04-047. The CARs were issued under separate cover.

The details of the audit as well as conclusions are detailed within the attached audit report.

If you have any questions or comments, please contact me at (505) 234-7423.

Ava L. Holland
Quality Assurance Manager

041024



Mr. Detwiler

2

October 26, 2004

Attachment

cc: w/attachment

L. Piper, CBFO	*ED
L. Chism, CBFO	*ED
D. Miehs, CBFO	*ED
M. Navarrete, CBFO	*ED
F. Huckeba, CBFO	*ED
G. Basabivazo, CBFO	*ED
C. F. Wu, CBFO	*ED
N. Frank, CTAC	*ED
M. Eagle, EPA	*ED
D. Winter, DNFSB	*ED
S. Zappe, NMED	*ED
S. Harrision, CTAC file A-04-24	
WIPP Operating Records, MS 486-06	
CBFO QA File	
CBFO M&RC	

U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE

AUDIT REPORT OF

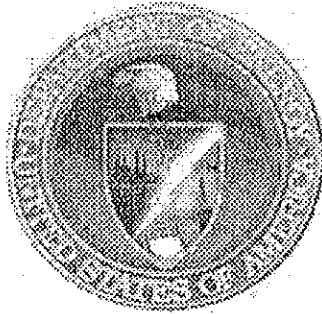
SELECT CBFO QA PROGRAM DOCUMENT SECTIONS,
ASSOCIATED IMPLEMENTING PROCEDURES AND
SELECT NQA-1 ELEMENTS

CARLSBAD, NEW MEXICO

AUDIT NUMBER A-04-24

September 7 – 9, 2004

CBFO QUALITY ASSURANCE PROGRAM



Prepared by: *Norman Frank*
Norman Frank, CTAC
Audit Team Leader

Date: 10/22/04

Approved by: *Ava L. Halland*
Ava L. Halland, CBFO
Quality Assurance Manager

Date: 10/26/04

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-04-24 was conducted to evaluate the adequacy, implementation, and effectiveness of selected CBFO Quality Assurance Program Document (QAPD) sections addressing criteria 1, 3, 10, 11, 15, 16, 17, and 18 of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1, 1989 edition, and NQA-2-1990a, part 2.7. Sections 1.1.1, 1.1.2.5, 1.3.2, 1.3.3, 1.5, 2.2, 2.3.7, 2.4, 2.4.3, 3.0, 4.0, 5.0, and 6.0 of the CBFO QAPD, and the associated implementing procedures were evaluated during the audit. The audit was conducted at the Skeen-Whitlock Building September 7 – 9, 2004.

Although the CBFO organizational structure appears to meet the intent of ASME/NQA-1-1989, the implementation and effectiveness of the organization were indeterminate because of the lack of implementing procedures reflecting the new organization.

The audit team identified two conditions adverse to quality resulting in the issuance of two CBFO Corrective Action Reports (CARs) (04-046 and 04-047) that require corrective action. These CARs relate to criterion 5 concerning the adequacy of the QA program and criterion 18 concerning assessments. No isolated deficiencies were identified and corrected during the audit. No Observations, Recommendations, or Exemplary Practices were identified.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of selected QA processes related to the CBFO QA Program. The audit included NQA-2-1990a, part 2.7, and the following criteria from NQA-1-1989:

Criterion 1	Organization
Criterion 3	Design
Criterion 10	Inspection
Criterion 11	Test Control
Criterion 15	Control of Nonconforming Items
Criterion 16	Corrective Actions
Criterion 17	Quality Assurance Records
Criterion 18	Audits

The CBFO QAPD sections and implementing procedures included in the scope of the audit are listed in Attachment 2.

3.0 AUDIT TEAM AND OBSERVERS

CBFO AUDIT TEAM

M. Lea Chism	CBFO QA Management Representative and Auditor
Norman Frank	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC)
Pete Rodriguez	Auditor, CTAC

Tammy Bowden	Auditor, CTAC
Jim Schuetz	Auditor, CTAC
Charlie Riggs	Auditor, CTAC

OBSERVERS/INSPECTORS

None

4.0 AUDIT PARTICIPANTS

Individuals contacted during the audit are identified in Attachment 1. A preaudit conference was held in the Skeen-Whitlock Building on September 7, 2004. The audit was concluded with a postaudit conference held in the Skeen-Whitlock Building on September 9, 2004.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team evaluated the CBFO QAPD against the requirements from criteria 1, 3, 10, 11, 15, 16, 17, and 18 of the ASME/NQA-1, 1989 edition, and NQA-2-1990a, part 2.7. The current revision of the CBFO QAPD is Revision 5. Revision 6 was issued for comment on August 27, 2004 with comments due on September 13, 2004. Revision 6 incorporates the changes required by the new CBFO organization. The audit team concluded that the QAPD overall is adequate relative to the flow-down of requirements from NQA documents. Revision 6, when issued, will adequately address the new organization.

However, the audit team determined that the applicable implementing procedures do not reflect the current organization and, in some cases, do not reflect the current work processes. The implementation and effectiveness of MP 10.7, *Operational Assessments*, was determined to be unsatisfactory, as further described in section 5.2. Taking into account the revised organization, the audit team concluded that, with the exception of CBFO Management Procedure (MP) 10.7, the implementing procedures are satisfactorily implemented and effective.

Attachment 3 summarizes the results for each area audited

5.2 QA Program Audit Details

The evaluation to ASME/NQA-1-1989 and NQA-2-1990a, part 2.7 requirements entailed the review of the CBFO QAPD, Team Procedures (TPs), and MPs to ensure the flow-down of applicable NQA requirements. The QAPD was found to be adequate in addressing the NQA requirements.

The CBFO QAPD was evaluated for adequacy against Criteria 1, 3, 10, 11, 15, 16, 17, and 18 from NQA-1-1989 and Part 2.7 of NQA-2-1990a.

The CBFO QA implementing documents were evaluated for adequacy against the CBFO QAPD, DOE-CBFO-94-1012, Revision 5, Sections 1.1.1, 1.1.2.5, 1.3.2, 1.3.3, 1.5, 2.2, 2.3.7, 2.4, 2.4.3, 3.0, 4.0, 5.0, and 6.0.

CBFO implementing procedures and QAPD sections included in the audit are identified in Attachment 2. The audit was conducted through interviews with key personnel and review of objective evidence.

Criterion 1 – Organization

The audit team evaluated the flow-down of requirements from the CBFO QAPD to the implementing procedures. One Corrective Action Report (CAR 04-046) was written concerning the adequacy of the CBFO implementing procedures. Most procedures do not reflect the current CBFO organization and some procedures do not reflect current practices.

The audit team investigated the new organization for compliance with NQA-1-1989, basic requirement 1, *Organization*. CBFO & EPA are in the process of evaluating the adequacy of the organization as reflected in the following correspondence:

- 1 Environmental Protection Agency (EPA) letter from Frank Marcinowski, Director, Radiation Protection Division, EPA, to Paul Detwiler, Acting Director, CBFO, dated March 9, 2004 forwarding EPA audit of Docket No. A-98-49, II-A1-57
- 2 DOE letter (CBFO:QA:ALH:GS:04-0080:UFC 2300.00) from R. Paul Detwiler, Acting Director, CBFO, to Frank Marcinowski, Director, Radiation Protection Division, EPA, dated April 16, 2004 forwarding Rev. 6 of the DOE "*Safety Management Functions, Responsibilities, and Authorities Manual*"
- 3 EPA letter from Bonnie C. Gitlin, Acting Director, Radiation Protection Division, EPA, to R. Paul Detwiler, Acting Director, CBFO, dated June 17, 2004, discussing EPA's expectation of the reorganization
- 4 DOE letter (CBFO:OOM:RPD:VW:04-0442:UFC 2300) from R. Paul Detwiler, Acting Director, CBFO, to Bonnie C. Gitlin, Acting Director, Radiation Protection Division, EPA, dated July 12, 2004, providing additional information regarding the CBFO reorganization

Based on a review of the organization and discussions with affected personnel, the audit team found that the CBFO organization appears to meet the intent of ASME/NQA-1-1989, basic requirement 1, *Organization*. However, the implementation and effectiveness of the organization were indeterminate because of the lack of implementing procedures reflecting the new organization.

Criterion 3 – Design Control

The audit team determined through interviews with responsible CBFO personnel that no design activities are performed by CBFO personnel. When design is needed,

Washington TRU Solutions (WTS) or other contractor performs the design and provides the results to the CBFO procurement.

Criterion 10 – Inspection

The audit team determined through interviews with responsible CBFO personnel that no inspection activities are performed by CBFO personnel. When inspection is needed, WTS performs the inspection and provides the results along with a recommendation to the CBFO procurement regarding acceptance.

Criterion 11 – Test Control

The audit team determined through interviews with responsible CBFO personnel that no testing activities are performed by CBFO personnel. When testing is needed, WTS performs the testing and provides the results along with a recommendation to the CBFO procurement regarding acceptance.

5.2.5 Criterion 15 – Control of Nonconformances

The audit team determined through interviews with responsible CBFO personnel that no nonconformance reports are written by CBFO personnel. WTS performs item-related activities and initiates appropriate documentation, including reports of nonconformances when necessary.

Criterion 16 – Corrective Actions (Including Trend Identification)

The audit team assessed CBFO QA program activities associated with corrective actions as described in QAPD section 1.3.3. The evaluation and review of objective evidence to verify adequacy, implementation, and effectiveness of the program was performed in accordance with audit checklists. These checklists were prepared from the requirements of the QAPD and CBFO MP 3.1, *Corrective Action Reporting* and TP 3.2, *Trend Identification and Reporting*.

The corrective action process (including the process for trending and reporting) was evaluated through review of the requirements of the CBFO QAPD section 1.3.3, *Corrective Action Reports* and MP 3.1 and TP 3.2. The audit team examined a sampling of CARs, trend reports, and associated correspondence containing proposed actions; evaluations, verifications, and ultimate resolution.

The audit team determined that the CBFO implementing procedures established and documented for this criterion adequately address the CBFO QAPD and NQA-1-1989 requirements, and is satisfactorily implemented and effective.

Criterion 17 – Quality Assurance Records

The audit team reviewed records management activities to verify adequacy, implementation, and effectiveness of the records program. Records management procedures were found to be adequate in addressing the requirements of ASME-NQA-

1-1989 and the CBFO QAPD. In reviewing records and management procedures for implementation and effectiveness, the audit team interviewed personnel and reviewed objective evidence to verify compliance. Records management activities associated with in-process and completed records were reviewed, including collection, protection, access control, the records inventory and disposition schedule (RIDS), and the Records Transmittal and Index (RTI) of records in various departments. The audit team was unable to find any records for the 2004 Operational Assessments. These assessments were not being sent through the mail and records center. This concern was combined with additional concerns in the Operational Assessments area (see section 5.2.8). The audit team concluded that, overall, QA records management was adequate, satisfactorily implemented, and effective.

5.2.8 Criterion 18 – Audits

The Office of the Manager, CBFO, directed the conduct of an Integrated Safety Management System Annual Review of the CBFO and WTS. The Annual Review included Quality Assurance and meets the intent of a Management Assessment. The audit team verified that CBFO/CTAC have performed audits and/or surveillances of CBFO, WTS, Sandia National Laboratories (SNL), Los Alamos National Laboratories – Carlsbad (LANL-C), the Carlsbad Environmental Monitoring and Research Center (CEMRC), and the transuranic (TRU) Waste Generating Sites. A review of training folders demonstrated that Lead Auditors, Auditors, and Technical Specialists were properly trained and qualified/certified for the activities they performed on audits and surveillances. The area of CBFO audits, surveillances, and management assessments was adequate, satisfactorily implemented, and effective.

Operational assessments may have been performed in the past year, but only eight Communication Reports have been entered into the tracking database maintained by the Office of Disposal. One person was responsible for seven of the eight reports. There is no schedule developed by the Assistant Manager or Office Directors of operational assessments to be performed. There are no Communication Reports for calendar year 2004 in the records system. This deficiency is documented in CAR 04-047.

5.2.9 Software Control

The audit team determined that no software activities are directly performed by CBFO personnel. When software is needed, Washington TRU Solutions or other contractor performs the work and provides the results to the CBFO.

The audit team determined through interviews with CBFO Transportation and Packaging personnel and WTS Transportation Packaging Engineering personnel that there are software applications in use at CBFO, but that these are “management tools” used to coordinate activities and not used for decision-making related to waste characterization or transportation. The audit team also determined through interview with WTS Transportation Packaging Engineering personnel that there is a spreadsheet used to verify TRUCON code assignment and that this application is tested and

controlled. Data entry into the application and subsequent results from software operation are independently verified, and then reviewed by Subject Matter Experts (SMEs) prior to accepting and submitting to records. The audit team determined that assessment of this activity under controlling document CBFO QAPD Section 6 is not applicable at this time.

The audit team determined through interviews with CBFO Transportation and Packaging personnel that there have been no peer reviews of software conducted during the 12-month term of this audit activity, and there are no peer reviews currently in progress. The audit team determined that assessment of this activity under controlling documents CBFO QAPD Section 6.7.3C and MP 10.5, Rev. 5, Peer Review is not applicable at this time.

5.2.10 Sample Control

The audit team determined through interviews with responsible CBFO personnel that no sampling activities are performed by CBFO personnel. When sampling is needed, WTS performs the sampling and provides the results to the CBFO.

5.2.11 Scientific Investigation

The audit team determined through interviews with responsible CBFO personnel that no scientific investigations are directly performed by CBFO personnel. When scientific investigation is needed, SNL or other contractor performs the scientific investigation and provides the results to the CBFO.

CARs, CDAs, OBSERVATIONS, RECOMMENDATIONS, AND EXEMPLARY PRACTICES

Corrective Action Reports

CARs 04-046 and 04-047 were initiated as a result of Audit A-04-24 and have been transmitted to CBFO under separate cover. A brief description of the CARs is provided below.

CBFO CAR 04-046

Some of the CBFO implementing procedures are out of date and do not reflect current practices. Examples are:

- MP 10.2, *Surveillance*, effective 9/4/98
- MP 10.3, *Audits*, effective 11/24/99

Most of the CBFO implementing procedures have not been updated to reflect the current organization.

CBFO CAR 04-047

There is minimal objective evidence that MP 10.7, *Operational Assessments*, has been implemented in the past year. Only eight Communication Reports have been developed and seven of those were done by one person. There is no schedule developed by the Assistant Manager or Office Directors of operational assessments to be performed. There are no Communication Reports in the records system.

Deficiencies Corrected During the Audit (CDA)

No deficiencies, requiring remedial action only, were identified during the audit.

6.3 Observations

None.

Recommendations

None.

Exemplary Practices

None

7.0 LIST OF ATTACHMENTS

- Attachment 1 Personnel Contacted During the Audit
- Attachment 2 CBFO Implementing Documents

PERSONNEL CONTACTED DURING THE AUDIT				
CBFO PERSONNEL CONTACTED				
NAME	ORGANIZATION	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Basabivazo, George	CBFO/Office of Disposal	X	X	
Biscaino, D.	L&M/PRS		X	
Brown, Michael R.	CBFO/OC&T		X	
Charlet, Pat	L&M		X	
Colt, Stanley	CBFO/OOB		X	
Cruickshank, Herbert	CBFO/OC&T		X	
Fox, Michael	L&M		X	
Harrison, Sandra	CTAC/QA		X	
Huckeba, Freida	CBFO/OOB	X	X	
Italiano, Marc	CBFO		X	
Lipinski, Richard	WTS/Transportation and Packaging Engineering		X	
McCallister, Russell	CBFO/OC&T		X	
Milligan, Meg	CBFO – Chief Information Officer	X	X	
Miehls, Dennis	CBFO/QA	X	X	X
Navarrete, Martin	CBFO/QA		X	
Nelson, Roger A.	CBFO		X	
Pangle, Allison	CTAC		X	
Waldram, Veronica	CBFO		X	
Wolff, Judi	CBFO (contractor)		X	
Wu, Chuan-Fu	CBFO		X	

CBFO Implementing Procedures Included In Audit A-04-24	
Activities	Applicable CBFO Documents
Criterion 1 - Organization	MP 10.5, <i>Peer Review</i> QAPD Section 1.1.1
Criterion 3 - Design Control	MP - N/A QAPD Section 2.3.7
Criterion 10 - Inspection	MP - N/A QAPD Section 2.4
Criterion 11 - Test Control	MP - N/A QAPD Section 2.4.3
Criterion 15 - Control of Nonconformances	MP - N/A QAPD Sections 1.3.2
Criterion 16 - Corrective Actions	MP 3.1, <i>Corrective Action Reporting</i> TP 3.2, <i>Trend Identification and Reporting</i> CBFO QAPD Section 1.3.3
Criterion 17 - Quality Assurance Records	MP 4.5 - <i>Generating, Receiving, Storing, and Controlling Active CBFO Project Records</i> MP 4.6 - <i>Records Filing, Inventorying, Scheduling, and Dispositioning</i> MP 4.7 - <i>Disposal of Temporary Records</i> MP 4.8 - <i>Records Transfer and Retrieval</i> MP 4.9 - <i>Quality Assurance Records</i> CBFO QAPD Section 1.5
Criterion 18 - Audits	MP 9.1 - <i>Management Assessment</i> MP 10.2 - <i>Surveillances</i> MP 10.3 - <i>Audit</i> MP 10.7, <i>Operational Assessments</i> CBFO QAPD Section 3.0
Sample Control	MP N/A CBFO QAPD Section 4.0
Scientific Investigation	MP N/A CBFO QAPD Section 5.0
Software	MP N/A CBFO QAPD Section 6.0

EVALUATED QA AND TECHNICAL ELEMENTS	Team	Concern Classification				QA / Technical Evaluation		
		CARs	CDAs	OBSs	RECs	Program Adequacy	Program Implementation	Program Effectiveness
Organization MP 10.5 and 10.7	Chism/ Frank					A	I	I
Design	Chism/ Frank					N/A	N/A	N/A
Inspection	Chism/ Frank					N/A	N/A	N/A
Test Control	Chism/ Frank					N/A	N/A	N/A
Control of Nonconforming Items MP 3.1 and 10.7 TP 3.2	Rodriguez					N/A	N/A	N/A
Corrective Action MP 3.1 and 10.7 TP 3.2	Rodriguez					A	S	E
QA Records MP 4.5 through 4.9, and 10.7	Bowden					A	S	E
Audits & Assessments MP 9.1, 10.2, 10.3 and 10.7 TP 10.1	Riggs					A	S	E
Sample Control	Bowden					N/A	N/A	N/A
Scientific Investigation	Bowden					N/A	N/A	N/A
Software QA MP 10.5 and 10.7	Schuetz					N/A	N/A	N/A
MP 10.7	Frank	X				A	U	U
CBFO Adequacy of Program	All	X				U	See Above	See Above
OVERALL						M	S	E

LEDGEND: CARs = Corrective Action Reports; CDAs = Concerns Corrected During the Audit; OBSs = Observations; RECs = Recommendations
 ADEQUACY/EFFECTIVENESS STATEMENTS: A = Adequate; S = Satisfactory; U = Unsatisfactory; E = Effective; I = indeterminate; M = Marginal;