



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

DEC 20 2006

OFFICE OF
AIR AND RADIATION

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

Dear Dr. Moody:

In accordance with §194.8(a)(4), the Environmental Protection Agency (EPA) conducted an inspection from September 12-14, 2006, of the Central Characterization Project's (CCP) Quality Assurance (QA) Program at the Argonne National Laboratory (ANL) in Illinois. The CCP's QA Program at ANL assesses the quality/reliability of activities to characterize transuranic waste destined for disposal at the Waste Isolation Pilot Plant (WIPP), including transuranic waste that is remote handled (RH).

During this inspection, EPA directly audited the CCP's QA Program and found that it continues to properly implement Element 1, titled *Organization*, of the Nuclear Quality Assurance (NQA) standards. EPA's inspection sample showed that the CCP QA Program at ANL continues to be properly executed. EPA also observed Department of Energy (DOE) Audit A-06-27 to verify that the audit was conducted in accordance with element 18, titled *Audit*, of the same NQA standards. Audit A-06-27 was conducted by DOE to verify CCP QA Program's conformance with all the applicable Elements of the NQA standards.

EPA did not identify any instances of non-conformance with the NQA standards during this inspection. EPA does not require any further response from DOE or CCP regarding this inspection.

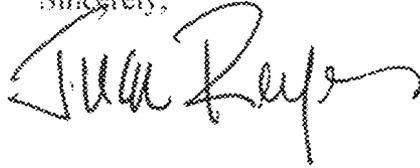
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C. FESHIRE ✓	G. BASABRYAZO ✓	WIPP OPE. REC - 486-86

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This EPA inspection report will be made available to the public through the Agency's docket. Please contact Mike Eagle at (202) 343-9346 if you have questions regarding this report.

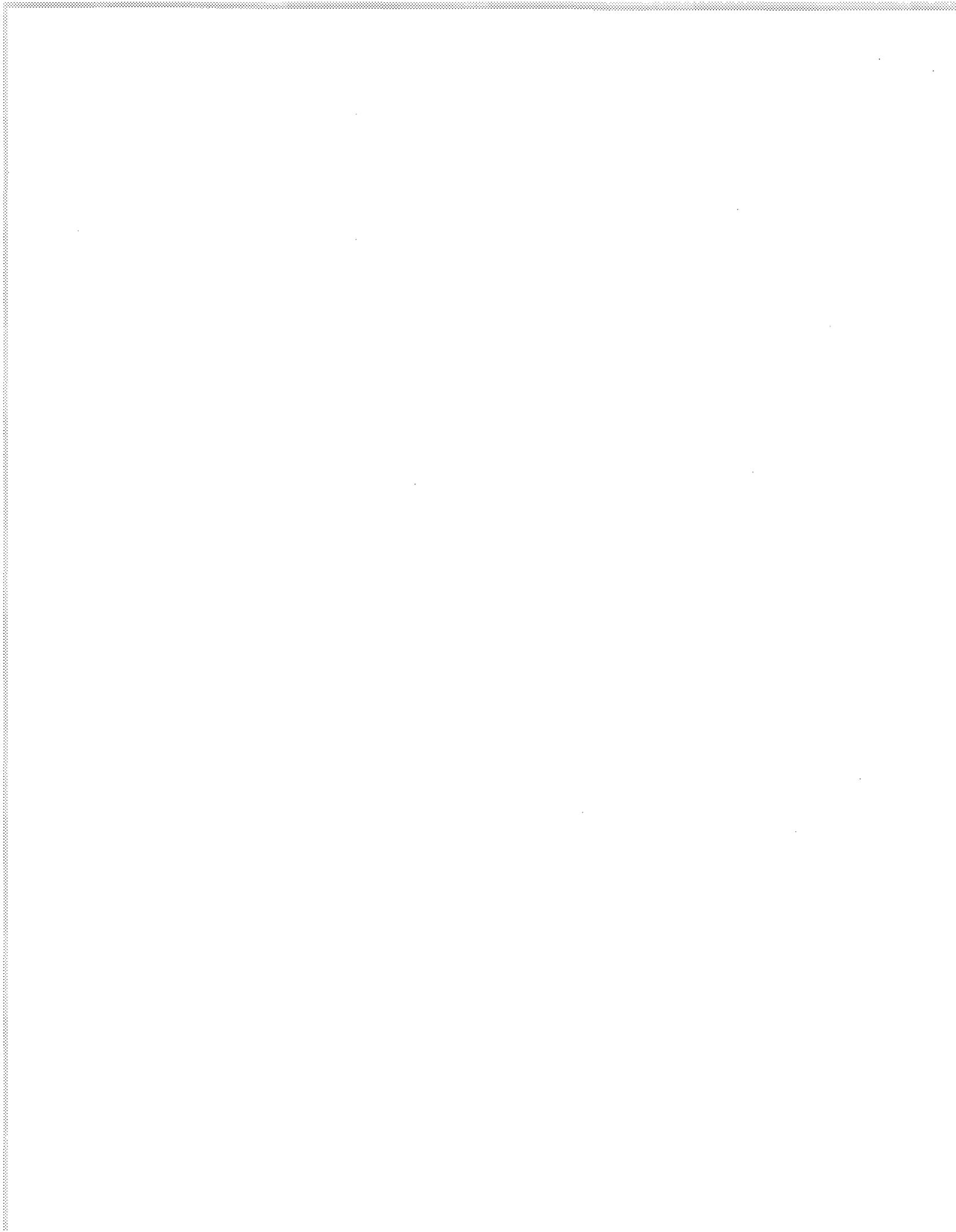
Sincerely,

A handwritten signature in black ink, appearing to read "Juan Reyes". The signature is written in a cursive style with a large, sweeping initial "J".

Juan Reyes, Director
Radiation Protection Division

Enclosure

cc: Ava Holland, CBFO
Steve Zappe, NMED
Duli Agarwal, DOE



DOCKET NO: A-98-49
H-A1-88

**EPA INSPECTION OF THE ARGONNE NATIONAL LABORATORY
QUALITY ASSURANCE PROGRAM
FOR THE WASTE ISOLATION PILOT PLANT
September 12-14, 2006**

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

December 2006

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1.0 EXECUTIVE SUMMARY

In accordance with §194.8(a)(4), the Environmental Protection Agency (EPA or Agency) conducted an inspection from September 12-14, 2006, of the Central Characterization Project's (CCP) Quality Assurance (QA) Program the at the Argonne National Laboratory (ANL) in Illinois. The CCP's QA Program at ANL assesses the quality/reliability of activities to characterize transuranic waste destined for disposal at the Waste Isolation Pilot Plant (WIPP), including transuranic waste that is remote handled (RH).

During this inspection, EPA directly audited the CCP's QA Program and found that it continues to properly implement Element 1, titled *Organization*, of the Nuclear Quality Assurance (NQA) standards. EPA's inspection sample showed that the CCP QA Program at ANL continues to be properly executed. EPA also observed Department of Energy (DOE) Audit A-06-27 to verify that the audit was conducted in accordance with element 18, titled *Audit*, of the same NQA standards. Audit A-06-27 was conducted by DOE to verify CCP QA Program's conformance with all the applicable Elements of the NQA standards.

EPA did not identify any instances of non-conformance with the NQA standards during this inspection. EPA does not require any further response from DOE or CCP regarding this inspection.

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

2.0 BACKGROUND

2.1 Regulatory Background

In accordance with 40 CFR 194.8(a), the Environmental Protection Agency (EPA or Agency) will determine compliance with requirements of waste generator Quality Assurance (QA) Programs, including the Central Characterization Project (CCP) QA Program at the Argonne National Laboratory (ANL) in Illinois. In September 9-10, 2002, the Agency conducted an inspection to verify the proper establishment and implementation of the CCP QA Program at ANL, as required under §194.8(a)(1)&(2). In accordance with §194.8(a)(3), EPA provided its written decision finding that the QA Program complied with the requisite QA requirements for a Department of Energy (DOE) transuranic (TRU) waste generator site. Subsequent to this determination of compliance, this is EPA's first inspection in accordance with §194.8(a)(4) to confirm continued compliance of the ANL QA Program. This report documents the Agency's subsequent inspection to confirm continued compliance of the ANL QA Program.

At §194.22(a)(1), EPA requires DOE to adhere to a QA program that implements the requirements of the following standards: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The Agency verified that DOE established these requirements in the Quality Assurance Program Document (QAPD) included in the Compliance Certification Application (CCA) for the Waste Isolation Pilot Plant (WIPP). The QAPD is the documented QA Plan for the WIPP project, as a whole, that establishes the applicable elements of the National Quality Assurance (NQA) Standards. The QAPD is implemented by DOE's Carlsbad Field Office (CBFO), which has the authority to audit all other organizations associated with TRU waste disposal at the WIPP to ensure that their lower-tier QA programs establish and implement the applicable requirements of the QAPD. DOE waste generator sites, which characterize and ship waste for disposal in the WIPP, must prepare site-specific QA Plans that establish the applicable NQA elements.

EPA annually audits DOE's QA program at CBFO (EPA Air Docket No. A-98-49, Document No. II-A1-79) and has found that DOE properly adheres to a QA program that implements the NQA standards. The Agency determined in its WIPP Certification Decision that the CBFO QAPD is in conformance with the NQA standards and that DOE's QA organization can properly perform audits to internally check the QA programs of the TRU waste generator sites (43 FR 27345).

2.2 ANL Background

Argonne National Laboratory is one of the U.S. Department of Energy's largest research centers. It is also the nation's first national laboratory, chartered in 1946.

Argonne is a direct descendant of the University of Chicago's Metallurgical Laboratory, part of the World War Two Manhattan Project. It was at the Met Lab where, on Dec. 2, 1942, Enrico Fermi and his band of about 50 colleagues created the world's first controlled nuclear chain reaction in a racquets court at the University of Chicago. After the war, Argonne was given the mission of developing nuclear reactors for peaceful purposes. Over the years, Argonne's research expanded to include many other areas of science, engineering and technology. Argonne is not and never has been a weapons laboratory.

Argonne occupies 1,500 wooded acres in DuPage County, Ill. The site is surrounded by forest preserve about 25 miles southwest of Chicago's Loop. The site also houses the U.S. Department of Energy's Chicago Operations Office.

The TRU-waste stored at ANL is destined for disposal at WIPP, the nation's first geologic repository for the disposal of TRU waste. CBFO is responsible for the management of WIPP and for assuring that generator sites and programs such as the CCP have quality assurance programs that provide adequate oversight of TRU waste characterization activities.

3.0 PURPOSE AND SCOPE

The purpose of EPA's inspection was to verify the CCP QA Program's continued compliance at ANL with the following standards: (1) ASME NQA-1-1989 edition; (2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and (3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1).

The scope of this EPA inspection was limited to the CCP QA Program's oversight of TRU-waste characterization activities at ANL that are important to the long-term isolation of TRU-waste at WIPP.

4.0 DEFINITIONS

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

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

Quality: The reliability of a specific item or activity that is important to the long-term isolation of TRU-waste at the WIPP. *Quality Achievement* is the responsibility of Operational Groups that directly produce such an item or perform such an activity. *Quality Verification/Assurance* is the responsibility of QA Organizations that do not produce such an item nor perform such an activity. For example, a failure to achieve quality is not the responsibility of the QA Organization that verifies quality achievement.

5.0 INSPECTION TEAM AND PARTICIPANTS

The inspection team consisted of one EPA employee.

<u>Inspection Team Member</u>	<u>Position</u>	<u>Affiliation</u>
Mike Eagle	QA inspector	EPA

Numerous DOE and ANL personnel participated in the EPA inspection. CBFO was supported by the CBFO Technical Assistance Contractor (CTAC).

6.0 PERFORMANCE OF THE INSPECTION

EPA's inspector reviewed documents and interviewed cognizant personnel to verify the following:

1. ANL's QA Program properly establishes and implements the requirements of the *Organization* element of the NQA standards, and
2. DOE CBFO's QA Organization properly conducted Audit A-06-27 of ANL's QA Program and of ANL's Operational Program that characterize remote handled (RH) TRU-waste.

The following discussions present a more detailed description of EPA's activities.

6.1 Organization

EPA reviewed ANL's QA Plan and interviewed QA staff to verify that ANL's QA Program continues to properly establish and implement the requirements of Element 1, titled *Organization*, of the NQA standards. EPA's inspector did not identify any findings or concerns related to this review.

ANL's QA Plan is found in Chapter 5 of the *Central Characterization Project Transuranic Waste Certification Plan*, CCP-PO-002. For the proper establishment of the *Organization* element, the QA Plan states that the organizational structures and the responsibility assignments of program participants shall be such that those organizations that have been assigned responsibility for performing the work are responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, and supporting the workers pursuit of quality. The QA Organization is responsible for verifying the achievement of quality.

EPA interviewed the following QA staff to verify proper implementation of the *Organization* element:

Mr. A. J. Fischer, CCP Quality Assurance Technical Advisor

Mr. Fischer serves as a Technical Advisor for the QA Organization of the CCP at ANL. Mr. Fischer's QA activities include providing support to the following activities at ANL:

- Repeat of the data generation level review, validation, and verification process
- Plan and conduct scheduled surveillances
- Direct formal annual audit process
- Track NCRs and Deficiency Reports
- Station CCP QA staff at ANL

Mr. Fischer has the authority to stop work based upon identification of quality problems. This authority is codified in the ANL QA Plan. He indicated that any on-site CCP Quality Assurance Representative also has this authority.

Mr. Fischer is comfortable that he has sufficient authority, organizational freedom, and management access to perform the duties of his position.

1.3 CBFO Audit

The EPA witnessed performance of CBFO Audit A-06-027. A formal checklist was employed by the EPA inspector and is provided as Attachment 1. EPA determined that the CBFO audit was properly performed in accordance with NQA-1 Element 18, *Audits*. CBFO's audit of ANL was well planned and scheduled. CBFO auditors developed and completed checklists for each activity associated with the CCP QA program at ANL. The checklists were developed based on the requirements of the top-tier document, the CBFO QAPD, and lower-tier implementing documents.

EPA's auditor observed the CBFO auditors conducting interviews and document reviews. EPA's auditor also reviewed documents regarding the qualifications of the CBFO auditors. EPA determined that CBFO's auditing team consisted of qualified auditors who are independent of the CCP.

7.0 SUMMARY OF FINDINGS AND CONCERNS

EPA did not identify any findings or concerns regarding the CCP QA Organization at ANL or regarding the conduct of Audit A-06-027 by CBFO's QA organization.

ATTACHMENT 1
 NQA-1 CHECKLIST
 CBFO Audit A-06-27, September 12-14, 2006

ELEMENT: 18

TITLE: Audits

INSPECTORS: Mike Eagle

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<u>Basic Requirements</u>			
1. Are planned and scheduled audits performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness?	X		CBFO Audit Schedule CBFO QAPD, CAO-94-1012, Rev. 6, Paras. 3.2.1 and 3.2.2
2. Are audits performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited?	X		Audit Plan A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6 Paras. 3.2.2.3 and 3.2.2.7
3. Are audit results documented and reported to and reviewed by responsible management? Is follow-up action taken where indicated?	X		Reports for CBFO Audit A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Paras. 1.3.1, 3.2.2.8, 3.2.2.9
<u>Supplementary Requirement (18S-1)</u>			
1. Are internal or external quality assurance audits scheduled to provide coverage and coordination with ongoing quality assurance program activities?	X		Audit Plan A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.1, 3.2.2.2

2.	Are audit plans developed and documented for each audit?	X		Audit Plan A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.2
3.	Does the auditing organization select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit? In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team.	X		CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.3
4.	Is the audit team identified prior to the beginning of each audit, with one individual appointed lead auditor?	X		Audit Plan A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Paras.3.2.2.3, 3.2.2.3B
5.	Are audits performed in accordance with written procedures or checklists?	X		CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.7A
6.	Are the elements that have been selected for audits evaluated against specified requirements?	X		CBFO Audit A-05-14 CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.7B
7.	Are audits results documented by auditing personnel and reviewed by management having responsibility for the area audited?	X		CBFO Audit A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.7C

8.	Is the audit report signed by the lead auditor prior to issuance?	X	Report for CBFO Audit A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.8A
9.	Does the audit report include: <ul style="list-style-type: none"> ■ description of the audit scope; ■ identification of the auditors; ■ identification of persons contacted during audit activities; ■ summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; and ■ description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization? 	X	CBFO Audit A-06-27 CBFO QAPD, CAO-94-1012, Rev. 6, Paras. 3.2.2.8 A through B
10.	Does the management of the audited organization or activity investigate adverse audit findings, schedule corrective action (including measures to prevent recurrence), and notify the appropriate organization in writing of action taken or planned?	X	CBFO QAPD, CAO-94-1012, Rev. 6, Para 3.2.2.9
11.	Is follow-up action taken to verify that corrective action is accomplished as scheduled?	X	CBFO QAPD, CAO-94-1012, Rev. 6, Para 3.2.2.9
12.	Do audit records include audit plans, audit reports, written replies, and the record of completion of corrective action?	X	CBFO QAPD, CAO-94-1012, Rev. 6, Para. 3.2.2.10

