ENTERED

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

MAY 2 2 2019

OFFICE OF
AIR AND RADIATION

Donald C. Gadbury
Quality Assurance Manager
U.S. Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Dear Mr. Gadbury:

On February 26–28, 2019, the U.S. Environmental Protection Agency audited the U.S. Department of Energy's (DOE's) Carlsbad Field Office (CBFO) Quality Assurance (QA) Program's audit of the Sandia National Laboratories-Carlsbad Programs Group (SNL-CPG). The purpose of this audit was to verify that the CBFO QA program continues to properly implement Element 18, *Audits*, of ASME NQA-1-1989 and to ensure compliance with EPA regulations at Title 40 of the Code of Federal Regulations (40 CFR) §194.22.

CBFO is responsible for ensuring that Waste Isolation Pilot Plant (WIPP) operations, including characterization of transuranic waste, are performed in compliance with the requirements of NQA-1-1989. The scope of this audit was limited to QA oversight of activities that are important to the long-term isolation of transuranic waste, as represented by records and documentation provided by CBFO. During this audit, the EPA audit team reviewed documents and records, and interviewed applicable Carlsbad Field Office Technical Assistance Contractor personnel at the SNL-CPG and CBFO locations in Carlsbad, New Mexico.

There were no findings or concerns identified. Based on this audit, the EPA has determined that the CBFO QA program continues to comply with the NQA-1-1989 Element 18, *Audits* standard, and continues to have adequate independence and authority to verify the quality of items and activities that are important to the long-term isolation of transuranic waste.

If you have any questions about this audit (EPA Audit Report No. CBFO-AUD-FEB-2019), please don't hesitate to contact Jerry Ellis of my staff at 202-564-2766. Thank you.

190519

Sincerely,

for Tom Peake
Director
Center for Waste Management and Regulations

Enclosure

cc: Electronic Distribution
Alton Harris, DOE HQ
Betsy Forinash, DOE HQ
Todd Shrader, CBFO Manager
Martin Navarrete, CBFO QA
Dennis Miehls, CBFO QA
Ricardo Maestas, NMED
Lee Ann B. Veal, EPA RPD Director
Rick White, RPD Deputy Director
Jennifer Mosser, EPA ORIA QA Manager
Ed Feltcorn, EPA HQ
Jon Walsh, EPA HQ
Raymond Lee, EPA HQ
Nick Stone, EPA Region 6
Site Documents

EPA DOCKET NO. A-98-49; II-A1-127
EPA AIR E-DOCKET NO: EPA-HQ-OAR-2001-0012-0486

EPA AUDIT OF THE CARLSBAD FIELD OFFICE QUALITY ASSURANCE PROGRAM

AUDIT NO. AUD-CBFO-FEB-2019

February 26–28, 2019

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

May 2019

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TABLES

ATTACHMENTS

ACRONYMS AND ABBREVIATIONS

ASME	American Society of Mechanical Engineers
CAR	Corrective Action Report
CBFO	Carlsbad Field Office
CFR	Code of Federal Regulations
CRA	Compliance Recertification Application
CTAC	Carlsbad Field Office Technical Assistance Contractor
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
FAR	Federal Acquisition Regulations
ICE	Issues Collection and Evaluation
M&TE	Measuring and Test Equipment
NQA	Nuclear Quality Assurance
OQA	Office of Quality Assurance
QA	Quality assurance
QAPD	Quality Assurance Program Document
QAPP	Quality Assurance Project Plan
SNL	Sandia National Laboratories
SNL-CPG	Sandia National Laboratories-Carlsbad Programs Group
TRU	Transuranic
WIPP	Waste Isolation Pilot Plant

1.0 EXECUTIVE SUMMARY

This report provides the results of the U.S. Environmental Protection Agency's audit of the U.S. Department of Energy's (DOE's) Carlsbad Field Office (CBFO) Quality Assurance (QA) Program's audit of the Sandia National Laboratories-Carlsbad Programs Group (SNL-CPG). The EPA conducted this audit on February 26–28, 2019. The purpose of the audit was to verify implementation of CBFO's QA program relative to the requirements of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1989, "Quality Assurance Program Requirements for Nuclear Facilities."[1] CBFO is responsible for ensuring that Waste Isolation Pilot Plant (WIPP) operations, including characterization of transuranic (TRU) wastes, are performed in compliance with the requirements of NQA-1-1989.

During this audit, the EPA audit team reviewed documents and records, and interviewed applicable Carlsbad Field Office Technical Assistance Contractor (CTAC) personnel at the SNL-CPG and CBFO locations in Carlsbad, New Mexico. The EPA auditors evaluated the CBFO QA's program to conduct audits in accordance with NQA-1-1989 Element 18, *Audits,* to ensure compliance with EPA regulations at Title 40 of the Code of Federal Regulations §194.22. Based on this audit, the EPA audit team determined that the CBFO QA program continues to comply with the NQA-1-1989 Element 18 and continues to have adequate independence and authority to verify the quality of items and activities that are important to long-term isolation of TRU waste.

This document and audit activities will be made available to the public through the Agency's general Waste Isolation Pilot Plant (WIPP) docket at regulations.gov (Docket No: EPA-HQ-OAR-2001-0012). A summary of all WIPP-related EPA inspection activities can also be found on the EPA website at www.epa.gov/radiation/waste-isolation-pilot-plant-wipp-inspections, and any interested party can get these and other WIPP updates via the WIPP-NEWS e-mail listserv at www.epa.gov/radiation/wipp-news.

2.0 BACKGROUND

2.1 Regulatory Background

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

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

The regulation at 40 CFR 194.22(a)(2) requires DOE to implement its QA plan for all items and activities that are important to the long-term isolation of TRU waste within the WIPP. The regulation at 40 CFR 194.22(e) provides the EPA with the authority to conduct audits to verify the proper establishment and implementation of QA programs for the WIPP.

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

2.2 Organizational Background

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

3.0 PURPOSE AND SCOPE

The purpose of this EPA audit was to verify that the CBFO QA program continues to properly implement Element 18, *Audits*, of ASME NQA-1-1989. The scope of this audit was limited to QA oversight of activities that are important to the long-term isolation of TRU waste, as represented by records and documentation provided by CBFO. The EPA interviewed and observed CBFO or CBFO's Technical Assistance Contractor (CTAC) conducting CBFO Audit A-19-23. The scope of DOE's audit was the adequacy, implementation, and effectiveness of the SNL-CPG QA Program, in accordance with the CBFO QAPD.

CBFO's evaluation of SNL-CPG included QA and technical reviews of completed and in-process records packages associated with the WIPP Compliance Recertification Application (CRA), hydrology field program, performance assessment and sensitivity analysis activities, and related processes. CBFO also evaluated the implementation of procedures developed by SNL-CPG to ensure compliance with the following CBFO QAPD requirements:

1. Organization/QA Program and Management Assessments
2. Personnel Qualification and Training
3. Independent Assessment (Audits/Surveillances)
4. Procurement
5. Document Control
6. Records Management
7. Work Processes
8. Inspection and Testing
9. Quality Improvement
10. Software Requirements
11. Sample Control Requirements
12. Scientific Investigation Requirements

4.0 DEFINITIONS

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

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

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

of operational groups that directly produce such an item or perform such an activity. "Quality assurance/verification" is the responsibility of QA groups that do not produce such an item or perform such an activity.

5.0 EPA AUDIT LOGISTICS

5.1 Team Members

The audit team consisted of two EPA employees and one support contractor working remotely who joined the audit opening and closing meetings via telephone and was consulted via telephone throughout the audit. Table 1 lists the EPA audit team, along with each person's affiliation and function during this audit.

5.2 Location

On February 26–28, 2019, the EPA conducted a QA audit of one aspect of the CBFO QA Program. During this audit, the EPA audit team reviewed documents and records provided by CBFO and interviewed applicable CTAC staff at the SNL-CPG and CBFO locations in Carlsbad, New Mexico. The interviews with the CTAC staff were mainly conducted in the SNL-CPG location; however, one visit to the CBFO location was required to review electronic records. Table 2 lists all personnel participating in audit meetings along with each person's affiliation.

Table 1. EPA Quality Assurance Audit Team Members

Audit Team Members	Audit Responsibility	Affiliation
Jerry Ellis	QA Audit Team Lead	EPA
Jennifer Mosser	QA Auditor	EPA
Patrick Kelly	QA Auditor	SC&A, Inc.

Table 2. Personnel Participating in Audit Meetings

Name	Affiliation and Title/ Position	Attended Preaudit Meeting	Interviewed	Attended EPA Closeout Meeting
Donald C. Gadbury	CBFO, QA Manager	No	Yes	Yes
Dennis Miehls	CBFO QA Management Representative	Yes	Yes	Yes
Martin Navarrete	CBFO, Senior QA Specialist	No	Yes	Yes
Mike Stapleton	CBFO, Quality Improvement Specialist	Yes	No	No
Ricardo Chavez	Audit Team Leader, CTAC	Yes	Yes	No
Rick Castillo	Auditor, CTAC	Yes	Yes	No
Cindi Castillo	Auditor, CTAC	Yes	Yes	No
Tim Boswell	Auditor, CTAC	Yes	Yes	No
Joe Lopez	Auditor, CTAC	Yes	Yes	No
Dustin Stegman	Auditor, CTAC	Yes	No	No
Ernie Tellez	Auditor-in-Training, CTAC	Yes	No	No
Berry Pace	Auditor-in-Training, CTAC	Yes	Yes	No
Shelly Martinez	Auditor-in-Training, CTAC	Yes	No	No
James Oliver	Technical Specialist, CTAC	Yes	No	No
Priscilla Yanez	Auditor, CTAC	Yes	No	No

Name	Affiliation and Title/ Position	Attended Preaudit Meeting	Interviewed	Attended EPA Closeout Meeting
Steve Davis	Assessment Lead, SNL	Yes	No	No
Shelly R. Nielson	QA Team Lead, SNL	Yes	No	No
V. Dina Howell	Q&T Database Coordinator, SNL	Yes	No	No
Denise Chacon	Procurement, SNL	Yes	No	No
Lisa Hernandez	Records, SNL	Yes	No	No
Sean Dunagan	Manager, SNL	Yes	No	No
Grace Duran	Records Team Lead, SNL	Yes	No	No
Jennifer Long	SCM Coordinator, SNL	Yes	No	No
Antonio Triventi	Manager, SNL	Yes	No	No
Chris Camphouse	Manager, SNL	Yes	No	No

6.0 PERFORMANCE OF THE AUDIT

During this audit, the EPA evaluated the audit capability of the CBFO QA program to ensure that it has the appropriate independence and authority to oversee WIPP-related operations. The EPA audit team reviewed records provided by CBFO and interviewed CTAC personnel to evaluate the CBFO's audit team's proper implementation of ASME NQA-1-1989 Element 18, *Audits*. The audit team gathered objective evidence in the form of written documentation, answers to questions obtained during personnel interviews and review of computer systems to support the audit's conclusion presented in this report. The CTAC staff were organized into six audit teams and the auditors interviewed SNL-CPG staff, covering the following areas:

- Team 1: Organization/QA Program; audits; corrective action
- Team 2: Software QA
- Team 3: Equipment; Test Plans/Notebooks
- Team 4: Control of Measuring and Test Equipment
- Team 5: Procurement; Training
- Team 6: Document Control; Records

The CTAC audit teams were in different locations when conducting interviews. The EPA audit team interviewed the CTAC Lead Auditor and others on the CTAC audit team to obtain objective evidence for evaluating the implementation of NQA-1-1989 Element 18. The EPA observed the software QA specialist interview SNL-CPG staff in the records center. Another CTAC auditor demonstrated the "Barton Folder" in a computer system, which showed audit plans, reports, responses to Corrective Action Reports (CARs) and CAR closure documentation.

7.0 FINDINGS AND CONCERNS

The EPA audit team did not identify any findings or concerns relative to the NQA-1-1989 Element 18, *Audits*.

8.0 CONCLUSIONS

The EPA audit team reviewed written and electronic records provided by CBFO, interviewed CTAC staff, and gathered objective evidence to support the evaluation of CBFO's QA program

implementation of NQA-1-1989 Element 18. The EPA determined that the CBFO QA program continues to comply with NQA-1-1989 Element 18, *Audits,* and that the program continues to have sufficient independence and authority to verify the quality of items and activities that are important to the long-term isolation of TRU waste.

9.0 REFERENCES

Audit Checklists: Corrective Action; Document Control; Equipment; Grading; Control of Measuring and Test Equipment (M&TE); Organization and QA Program; Procurement; Records; Software; Test Plans; Training

Audit Report, Audit A-17-29, CBFO QAPD Implementation of NQA-1 Criteria; Audit Plan for CBFO Audit A-17-29

Audit Report, Audit A-18-06 of the Sandia National Laboratories Carlsbad Programs Group Quality Assurance Program, dated July 17-19, 2018

Carlsbad Field Office Audit Plan for CBFO Audit A-19-23 of the SNL-CPG Nuclear Waste Management Program, Quality Assurance Program

Carlsbad Field Office Audit Plan for A-19-23, Sandia National Laboratories-Carlsbad Programs Group; Final Audit Report

Carlsbad Field Office Interim Audit Report, Audit A-18-04 of the Advanced Mixed Waste Treatment Project, dated August 27-30, 2018

Carlsbad Field Office Monthly Assessment Schedule, dated February 5, 2019

CAR Report for AMWTP 2018

CBFO MP 3.1, Revision 15

CBFO Organizational chart, dated February 20, 2019

CTAC Organization chart, dated January 14, 2019

Corrective Action Report # 19002 from CBFO Audit A-18-11

Corrective Action Plans for CBFO Corrective Action Report Nos. 19-001, 19-003, 19-004 and 19-005, which resulted from CBFO Audit A-18-11, letter dated November 1, 2018

Final Audit Report, Audit A-19-23 of the SNL-CPG Nuclear Waste Management Program, Quality Assurance Program, dated April 2, 2019

Final Recertification Audit Report, Audit A-18-14 of the Los Alamos National Laboratory Central Characterization Program for TRU Waste Activities at Los Alamos, New Mexico and Carlsbad, New Mexico, dated May 8-10, 2018

Final Audit Recertification Report, Audit A-18-13 of the Oak Ridge National Laboratory Central Characterization Program, dated March 26-28, 2018

List of Open CARs (sorted by CAR number) generated by CTAC staff during audit

MP 3.1, Corrective Action Procedures

Open CARs and Status Report generated by CTAC staff during audit

OP 10.4, Revision 1

OP 10.13, Revision 0, section 5.5, Reporting

OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2; section 5.3, Planning, paragraph 5.3.1

Barton Folder (Internal DOE server)

OP 10.13, Revision 0, section 3.2, Definitions, paragraphs 3.2.3 and 3.2.10; section 5.1, Scheduling; section 5.4, Performance, paragraph 5.4.4

OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraph 5.2.2; section 5.3, Planning, paragraph 5.3.6; section 5.4, Performance

OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2

OP 10.13, Revision 0, section 5.3, Planning, paragraph 5.3.1

OP 10.13, Revision 0, section 5.5, Reporting, paragraph 5.5.2; section 5.6, Audit Response, Follow-Up, and Close-Out, paragraph 5.6.2

OP 10.13, Revision 0, section 5.1, Scheduling

OP 10.13; OP 10.4, Revision 1

QAPD, Revision 13, section 3.2, Independent Assessment, paragraphs A and C

QAPD, Revision 13, section 3.2.2.2, Planning and Preparation for Audits

QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraphs A and B

QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraph A; and section 3.2.2.7, Performing Audits, paragraph A

QAPD, Revision 13, section 3.2.2.8, Reporting Audit Results, paragraphs A and B, section 3.33.10, Audit Records

QAPD, Revision 13, section 3.2.2.7, Performing Audits, paragraph C; section 3.2.2.8, Reporting Audit Results, paragraph A; section 3.2.2.9, Audit Response and Follow Up

QAPD, Revision 13, section 3.2.2.1, Scheduling Audits

Verification and Acceptance of Corrective Actions for CAR 19-002 from CBFO Audit A-18-11, NWP Procurement and Graded Approach Program, dated February 21, 2019

Verification and Acceptance of Corrective Actions for CAR 18-046 from CBFO Audit A-18-17, Argonne National Laboratory, Nuclear Waste Partnership LLC, Central Characterization Program

ATTACHMENT A: ASME NQA-1-1989, ELEMENT 18, CHECKLIST

EPA AUDIT OF CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 18 with Supplement 18S-1, *Audits* EPA AUDITORS: Jerry Ellis, Jr. and Jennifer Mosser DATE: 3/14/19

Basic Requirements

No.	Does the reference document adequately define, describe, address or satisfy the following?	Y, N, I, N/A*	Applicable Procedure and Paragraph; Additional Objective Evidence
1	Are planned and scheduled audits performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness?	Y	QAPD, Revision 13, section 3.2, Independent Assessment, paragraphs A and C OP 10.13, Revision 0, section 3.2, Definitions, paragraphs 3.2.3 and 3.2.10; section 5.1, Scheduling; section 5.4, Performance, paragraph 5.4.4 Carlsbad Field Office Monthly Assessment Schedule, dated February 5, 2019 Carlsbad Field Office Interim Audit Report, Carlsbad Field Office Audit A-18-04 of the Advanced Mixed Waste Treatment Project, dated August 27-30, 2018 Final Recertification Audit Report, Carlsbad Field Office Audit A-18-13 of the Oak Ridge National Laboratory Central Characterization Program, March 26-28, 2018 Audit Report, Carlsbad Field Office Audit A-18-06 of the Sandia National Laboratories Carlsbad Programs Group Quality Assurance Program, July 17-19, 2018 Final Recertification Audit Report, Carlsbad Field Office Audit A-18-14 of the Los Alamos National Laboratory Central Characterization Program for TRU Waste Activities at Los Alamos, New Mexico and Carlsbad, New Mexico, May 8-10, 2018 Final Report, Carlsbad Field Office Audit A-19-23 of the SNL-CPG Nuclear Waste Management Program, Quality Assurance Program, April 2, 2019

No.	Does the reference document adequately define, describe, address or satisfy the following?	Y, N, I, N/A*	Applicable Procedure and Paragraph; Additional Objective Evidence
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?	Y	QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraph A; section 3.2.2.7, Performing Audits, paragraph A OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraph 5.2.2; section 5.3, Planning, paragraph 5.3.6; section 5.4, Performance Carlsbad Field Office Audit Plan for Carlsbad Field Office Audit A-19-23, Sandia National Laboratories-Carlsbad Programs Group Final Recertification Audit Report, Carlsbad Field Office Audit A-18-14 of the Los Alamos National Laboratory Central Characterization Program for TRU Waste Activities at Los Alamos, New Mexico and Carlsbad, New Mexico, May 8-10, 2018 Final Audit Recertification Report, Carlsbad Field Office Audit A-18-13 of the Oak Ridge National Laboratory-Central Characterization Program, March 26-28, 2018
3	Are audit results documented and reported to and reviewed by responsible management? Is follow-up action taken where indicated?	Y	QAPD, Revision 13, section 3.2.2.7, Performing Audits, paragraph C; section 3.2.2.8, Reporting Audit Results, paragraph A; section 3.2.2.9, Audit Response and Follow Up OP 10.13, Revision 0, section 5.5, Reporting, paragraph 5.5.2; section 5.6, Audit Response, Follow-Up, and Close-Out, paragraph 5.6.2 CBFO MP 3.1, Revision 15 List of Open CARs (sorted by CAR number) generated by CTAC staff during audit Open CARs and Status Report generated by CTAC staff during audit

Supplementary Requirements (18S-1)

No.	Does the reference document adequately define, describe, address or satisfy the following?	Y, N, I, N/A*	Applicable Procedure and Paragraph; Additional Objective Evidence
1	Are internal or external quality assurance audits scheduled to provide coverage and coordination with ongoing quality assurance program activities?	Y	QAPD, Revision 13, section 3.2.2.1, Scheduling Audits OP 10.13, Revision 0, section 5.1, Scheduling Carlsbad Field Office Monthly Assessment Schedule, February 5, 2019
2	Are audit plans developed and documented for each audit?	Y	QAPD, Revision 13, section 3.2.2.2, Planning and Preparation for Audits OP 10.13, Revision 0, section 5.3, Planning, paragraph 5.3.1 Audit Plan for Carlsbad Field Office Audit A-19-23 of the SNL-CPG Nuclear Waste Management Program, Quality Assurance Program

No.	Does the reference document adequately define, describe, address or satisfy the following?	Y, N, I, N/A*	Applicable Procedure and Paragraph; Additional Objective Evidence
3	Does the auditing organization select and assign auditors who are independent of any direct responsibility for performance of the activities that they will audit? Note: 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.	Y	QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraph A OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2 Audit Report, Carlsbad Field Office Audit A-17-29, CBFO QAPD Implementation of NQA-1 Criteria
4	Is the audit team identified prior to the beginning of each audit, with one individual appointed lead auditor?	Y	QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraphs A and B OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2; section 5.3, Planning, paragraph 5.3.1 CBFO Audit Plan for A-19-23, Sandia National Laboratories-Carlsbad Programs Group CBFO Organizational Chart, dated February 20, 2019 CTAC Organization Chart, dated January 14, 2019
5	Are audits performed in accordance with written procedures or checklists?	Y	QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraphs A and B OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2; section 5.3, Planning, paragraph 5.3.1 Checklists for the following categories were provided: Corrective Action; Document Control; Equipment; Grading; Control of Measuring and Test Equipment (M&TE); Organization and QA Program; Procurement; Records; Software; Test Plans; Training
6	Are the elements that have been selected for audits evaluated against specified requirements?	Y	QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraphs A and B OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2; section 5.3, Planning, paragraph 5.3.1
7	Are audit results documented by auditing personnel and reviewed by management having responsibility for the area audited?	Y	OP 10.13, Revision 0; OP 10.4, Revision 1

No.	Does the reference document adequately define, describe, address or satisfy the following?	Y, N, I, N/A*	Applicable Procedure and Paragraph; Additional Objective Evidence
8	Is the audit report signed by the lead auditor prior to issuance?	Y	OP 10.13, Revision 0; OP 10.4 Revision 1 Carlsbad Field Office Interim Audit Report, Audit A-18-04 of the Advanced Mixed Waste Treatment Project, dated August 27-30, 2018 Final Recertification Audit Report (Audit A-18-13) of the Oak Ridge National Laboratory Central Characterization Program, dated March 26-28, 2018 Audit Report (A-18-06) of the Sandia National Laboratories Carlsbad Programs Group Quality Assurance Program, dated July 17-19, 2018 Final Recertification Audit Report (A-18-14) of the Los Alamos National Laboratory Central Characterization Program for TRU Waste Activities at Los Alamos, New Mexico and Carlsbad, New Mexico, dated May 8-10, 2018 Final Audit Report, Carlsbad Field Office Audit A-19-23 of the SNL-CPG Nuclear Waste Management Program, Quality Assurance Program, April 2, 2019
9	Does the audit report include: • Description of the audit scope? • Identification of the auditors? • Identification of persons contacted during audit activities? • Summary of audit results, including a statement on the effectiveness of the quality assurance program elements that were audited? • Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization?	Y	Carlsbad Field Office Interim Audit Report, Audit A-18-04 of the Advanced Mixed Waste Treatment Project, August 27-30, 2018 Final Recertification Audit Report, Carlsbad Field Office Audit A-18-13 of the Oak Ridge National Laboratory-Central Characterization Program, March 26-28, 2018 Audit Report, Carlsbad Field Office Audit A-18-06 of the Sandia National Laboratories Carlsbad Programs Group Quality Assurance Program, July 17-19, 2018 Final Recertification Audit Report, Carlsbad Field Office Audit A-18-14 of the Los Alamos National Laboratory Central Characterization Program for TRU Waste Activities at Los Alamos, New Mexico and Carlsbad, New Mexico, May 8-10, 2018 Final Audit Report, Carlsbad Field Office Audit A-19-23 of the SNL-CPG Nuclear Waste Management Program, Quality Assurance Program, April 2, 2019
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?	Y	MP 3.1 Corrective Action Procedures; CAR Report for AMWTP 2018 Corrective Action Plans for CBFO CAR Nos. 19-001, 19-003, 19-004 and 19-005, which resulted from CBFO Audit A-18-11, letter November 1, 2018 Verification and Acceptance of Corrective Actions for CAR 19-002 from Carlsbad Field Office Audit A-18-11, NWP Procurement and Graded Approach Program, February 21, 2019 Verification and Acceptance of Corrective Actions for CAR 18-046 from Carlsbad Field Office Audit A-18-17, Argonne National Laboratory, Nuclear Waste Partnership LLC, Central Characterization Program

No.	Does the reference document adequately define, describe, address or satisfy the following?	Y, N, I, N/A*	Applicable Procedure and Paragraph; Additional Objective Evidence
11	Is follow-up action taken to verify that corrective action is accomplished as scheduled?	Y	MP 3.1 Corrective Action Procedures Corrective Action Report No. 19002 from Carlsbad Field Office Audit A-18-11
12	Do audit records include audit plans, audit reports, written replies and the record of completion of corrective action?	Y	QAPD, Revision 13, section 3.2.2.8, Reporting Audit Results, paragraphs A and B, section 3.33.10 Audit Records OP 10.13, Revision 0, section 5.5, Reporting EPA auditors observed audit records in the Barton Folder (Internal DOE server) which showed audit plans, reports, responses to CARs and CAR closure documentation

*Y: The referenced documents adequately define, describe, address or satisfy the NQA-1-1989 requirement.
N: The referenced documents do not adequately define, describe, address or satisfy the NQA-1-1989 requirement.
I: EPA requires additional information to determine if the referenced documents adequately define, describe, address or satisfy the NQA-1-1989 requirement.
N/A: The specific NQA-1-1989 requirement is not applicable to the subject QA program.

ATTACHMENT B: DESCRIPTIONS OF NQA-1 BASIC REQUIREMENTS (ELEMENTS)[2]

As stated in the introduction to the ASME NQA-1-1989 standard, the requirements of the standard apply to activities which could affect the quality of structures, systems, and components of nuclear facilities. Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning. "Entity," in the context of this summary, refers to the organization responsible for implementing the ASME NQA-1-1989 standard.

The summaries included in this attachment are for general information only and are not intended to supersede the language of ASME NQA-1-1989.

Element 1, *Organization*, requires that the entity document the following for activities affecting Organizational structure

- Functional responsibilities
- Levels of authority
- Lines of communication

The entity shall establish the organizational structure and responsibilities such that:

- Senior management establishes overall expectations for effective QA program implementation and is responsible for obtaining desired end result.
- Quality is achieved and maintained by those performing work.
- Quality achievement is verified by those not directly responsible for performing work.
- Persons responsible for assuring implementation of the QA program have required authority and organization freedom, including sufficient independence from cost and schedule considerations.

Element 2, *QA Program*, requires that the QA program be planned, implemented and maintained, and that management shall regularly assess the adequacy and effective implementation of the QA program. The QA program shall:

- Identify the activities and items to which it applies.
- Provide control over activities affecting quality consistent with their importance (i.e., follow a graded approach to apply varying degrees of control and verification to items and services to ensure compliance with requirements).
- Provide for planning and accomplishment of activities affecting quality under suitably controlled conditions.

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[2] Adapted from: History, Evolution and Content of NQA-1, Ron Schrotke, Member, ASME NQA-1 Main Committee and ASME Board of Nuclear Codes and Standards, presented on May 14, 2015, to DOE Quality Assurance Framework: Application to DOE Nuclear Projects, Emphasis on ASME NQA-1, Training Workshop.

- Provide for indoctrination and training of personnel, as necessary, including inspection and test personnel, nondestructive examination personnel and QA program audit personnel.

Element 3, *Design Control*, requires that designs, including design inputs, design documents, design interfaces and design changes be defined, controlled and verified. Design adequacy shall be verified by qualified persons that were not part of the original design work.

Element 4, *Procurement Document Control*, requires that procurement documents include applicable design bases and other technical and quality requirements, including any requirements for the supplier's quality assurance program to be consistent with ASME NQA-1-1989. Procurement documents and changes to these documents shall be reviewed for completeness and adequacy prior to issuance to the supplier.

Element 5, *Instructions, Procedures and Drawings*, requires that activities affecting quality be performed in accordance with documented instructions, procedures or drawings, as appropriate to the activity. The instructions, procedures or drawings shall include quantitative or qualitative acceptance criteria for determining successful completion of the activity.

Element 6, *Document Control*, requires that documents, including those identified in Element 5, that specify quality requirements or prescribe activities affecting quality be controlled. The document control system includes identification of documents to which it applies; assignment of responsibility for preparing, reviewing, approving, and issuing documents; and review of documents, including changes to the documents, prior to issuance.

Element 7, *Control of Purchased Items and Services*, requires that procurement of items and services be controlled to assure conformance with specified criteria. Requirements are specified to achieve control of procurement planning, source evaluation and selection, bid evaluation, supplier performance evaluation, supplier generated documents, changes in items or services, acceptance of items or services, supplier nonconformances, and commercial grade items and services.

Element 8, *Identification and Control of Items*, requires that controls be established to assure only correct and accepted items are used or installed and that identification be maintained on items or documents traceable to the items.

Element 9, *Control of Special Processes*, applies to processes that require a high degree of skill and cannot be verified after completion (e.g., heat treating, welding, etc.). These processes shall be performed by qualified personnel using specified instructions, procedures, drawings, checklists, process travelers or other appropriate means that also specify the acceptance criteria.

Element 10, *Inspection*, requires inspections be performed to verify conformance of an item or activity to specified requirements or continued acceptability of items in service. Inspection personnel shall be independent of the work being inspected and the inspection results shall be documented.

Element 11, *Test Control*, requires that tests to be performed to verify conformance of an item or computer program to specified requirements and demonstrate satisfactory performance shall be

planned and executed according to specified methods and evaluated against specified criteria. Test results shall be documented.

Element 12, *Control of Measuring and Test Equipment*, requires that tools, gauges, instruments and other measuring and test equipment used for activities affecting quality be controlled, calibrated at specific periods, adjusted and maintained to required accuracy limits.

Element 13, *Handling, Storage and Shipping*, requires that handling, storage, cleaning, packaging, shipping and preservation of items be conducted in accordance with established documents or procedures to prevent damage and loss and to minimize deterioration.

Element 14, *Inspection, Test, and Operating Status*, requires that the status of inspection and test activities be identified either on the items or in documents traceable to items where it is necessary to ensure that required inspections and tests are performed and only those items that passed the required inspections or tests are installed, used and operated.

Element 15, *Control of Nonconforming Items*, requires that items not conforming to specified requirements be controlled to prevent inadvertent installation or use. Nonconforming items shall be identified and segregated when practical. The nonconformances shall be documented and evaluated. Disposition of the nonconforming items shall be documented, and the affected organizations notified.

Element 16, *Corrective Action*, requires that conditions adverse to quality be identified promptly and corrected as soon as practical. Additional requirements apply to significant conditions adverse to quality:

- The cause of the condition shall be determined.
- Corrective action shall be taken to preclude recurrence.
- The identification, cause and corrective action shall be documented and reported to appropriate levels of management.
- Completion of corrective actions shall be verified.

Element 17, *Quality Assurance Records*, requires that records providing evidence of quality be specified, prepared and maintained. Records shall be protected against loss, damage or deterioration and shall be legible, identifiable and retrievable. The records control system shall specify requirements and responsibilities for record generation, transmittal, distribution, retention, maintenance and disposition.

Element 18, *Audits*, requires that audits be performed to verify compliance with all aspects of the QA program and determine the effectiveness of the QA program. Audits shall be planned and performed in accordance with written procedures or checklists. The audit team shall be independent of the activities being audited and shall include at least one lead auditor appointed to lead the audit; the lead auditor shall select and assure qualification of the rest of the audit team. Audit results shall be documented and reported to and reviewed by responsible management; responsible management shall respond to adverse audit findings as appropriate and the auditing organization shall follow up to verify completion of corrective action.