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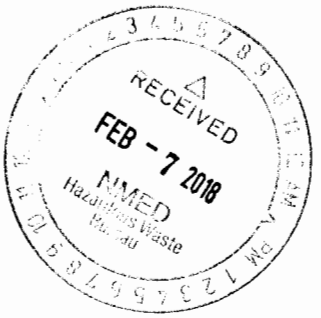



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

FEB 0 7 2018

OFFICE OF
AIR AND RADIATION

Martin Navarrete
Acting Quality Assurance Manager
Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Dear Mr. Navarrete:

The U.S. Environmental Protection Agency is transmitting results of the EPA's audit of the Department of Energy's (DOE's) Carlsbad Field Office (CBFO) quality assurance (QA) program conducted on October 17–19, 2017, at CBFO. 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." CBFO QA is responsible for ensuring that Waste Isolation Pilot Plant (WIPP) operations, including characterization of transuranic (TRU) wastes and Performance Assessments are performed in compliance with the requirements of the NQA-1-1989 standard, as required by EPA regulations at Title 40 of the Code of Federal Regulations (40 CFR) 194.22.

During the audit, the EPA audit team reviewed documents and records provided by CBFO and interviewed CBFO personnel in Carlsbad, New Mexico. The EPA auditors evaluated the CBFO QA program against the NQA-1-1989 elements listed below:

Element 1, "Organization."
Element 2, "Quality Assurance Program."
Element 4, "Procurement Document Control."
Element 7, "Control of Purchased Items and Services."
Element 16, "Corrective Action."
Element 18, "Audits."

During the audit, the EPA audit team identified one concern requiring a response. The concern is that CBFO Operations staff have not responded to Corrective Action Reports (CARs) in a timely manner and needs to do so. CBFO responded to this concern in a letter to EPA on November 22, 2017. In addition, CBFO provided EPA with their corrective action plan. The concern and CBFO's response are discussed in section 6.0 of the audit report. The written response and corrective action plan appropriately addressed EPA's concern. The Agency will monitor the issue to ensure that CBFO adheres to their correction action plan.



The EPA has determined that the CBFO QA program continues to comply with the selected NQA-1-1989 elements and continues to have sufficient independence, authority and resources to verify the quality of items and activities that are important to long-term disposal of TRU waste.

Sincerely,

Tom Peake

Tom Peake, Director
Center for Waste Management and Regulations

Enclosure

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

EPA AIR E-DOCKET NO: EPA-HQ-OAR-2001-0012-0475

# EPA AUDIT OF THE CARLSBAD FIELD OFFICE QUALITY ASSURANCE PROGRAM

## AUDIT NO. AUD-CBFO-OCT-2017

## OCTOBER 17–19, 2017

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

FEBRUARY 2018

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## TABLES



## ATTACHMENTS

## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ASME | American Society of Mechanical Engineers |
| CAR | corrective action report |
| CBFO | Carlsbad Field Office |
| CCP | Central Characterization Program |
| CFR | Code of Federal Regulations |
| CTAC | Carlsbad Field Office Technical Assistance Contractor |
| DOE | U.S. Department of Energy |
| EMCBC | Office of Environmental Management Consolidated Business Center |
| EPA | U.S. Environmental Protection Agency |
| FAR | Federal Acquisition Requirements |
| ICE | Issues Collection and Evaluation |
| NQA | nuclear quality assurance |
| OQA | Office of Quality Assurance |
| QA | quality assurance |
| QAPD | Quality Assurance Program Document |
| QAPP | Quality Assurance Project Plan |
| SRS | Savannah River Site |
| TRU | transuranic |
| WIPP | Waste Isolation Pilot Plant |
| WJC West | William Jefferson Clinton West |

## 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. The EPA conducted this audit on October 17–19, 2017, at CBFO. 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 the NQA-1-1989 requirements.

During this audit, the EPA audit team reviewed documents and records provided by CBFO and interviewed applicable CBFO personnel in Carlsbad, New Mexico. The EPA QA auditors evaluated the CBFO QA program against the NQA-1-1989 elements listed below to ensure compliance with EPA regulations at Title 40 of the Code of Federal Regulations (40 CFR) 194.22:

- Element 1, "Organization."
- Element 2, "Quality Assurance Program."
- Element 4, "Procurement Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 16, "Corrective Action."
- Element 18, "Audits."

Based on this audit, the EPA audit team determined that the CBFO QA program continues to comply with these NQA-1-1989 elements and continues to have sufficient independence, authority and resources to verify the quality of items and activities that are important to long-term isolation of TRU waste.

During the audit, the EPA audit team identified one concern for Element 16 requiring a response. The EPA is concerned that the CBFO corrective action report (CAR) log shows nine CARs issued to CBFO that are overdue: five of the CARs have been overdue for more than one year and four of the CARs that have been overdue between one month and one year. EPA identified that CBFO must respond to open CARs in a more timely manner.

CBFO responded to this concern in a letter to EPA on November 22, 2017. In addition, CBFO provided EPA with their corrective action plan (CAP). The written response and CAP appropriately addressed EPA's concern. The Agency will monitor the issue to ensure that DOE adheres to their CAP. The EPA considers this concern closed and will continue to monitor the issue. The concern and CBFO's response are discussed in section 6.0 of this report.

This document and audit activities will be made available to the public through the EPA's Air Docket A-98-49, located at the Air and Radiation Docket in the EPA Docket Center, WJC West,

[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.

Room 3334, 1301 Constitution Avenue, NW, Washington, D.C., 20460.

## 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.

### 2.2 Organizational Background

CBFO is responsible for management of the WIPP. This responsibility includes oversight of the characterization and emplacement of TRU waste at the WIPP disposal site near Carlsbad, New Mexico. As stated in the Quality Assurance Program Document (QAPD),[2] "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 selected elements of ASME NQA-1-1989. The scope of this EPA 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.

## 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.

[2] U.S. Department of Energy Carlsbad Field Office, Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 13, April 2017

*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 Location

On October 17–19, 2017, the EPA conducted a QA audit of the CBFO QA program in Carlsbad, New Mexico. This included an audit of NQA-1-1989, element 18 audit, during which, the EPA observes CBFO (or CBFO's Technical Assistance Contractor [CTAC]) conducting an audit. Usually, CBFO and CTAC perform the annual recertification audits for the characterization programs at the physical characterization sites. However, CBFO and CTAC conducted the recertification audit for the Savannah River Site-Central Characterization Program (SRS-CCP) at CBFO because SRS-CCP is not characterizing any waste at SRS. CBFO agreed to support the EPA audit during the same week as the SRS-CCP recertification audit, so the EPA conducted the element 18 audit at CBFO concurrently with the audit of the other applicable elements.

### 5.2 Team Members

The audit team consisted of one EPA employee and two EPA support contractors. Table 1 lists all members of the EPA audit team, along with each person's affiliation and function during this audit.

**Table 1. EPA Quality Assurance Audit Team Members**

| Audit Team Member | Audit Responsibility | Affiliation |
|---|---|---|
| Jerry Ellis | EPA QA Audit Team Leader | EPA |
| Kira Darlow | Lead QA Auditor | SC&A, Inc. |
| Patrick Kelly | QA Auditor | SC&A, Inc. |

Table 2 lists all personnel who participated in this audit.

**Table 2. Personnel Participating in Audit Meetings**

| Name | Affiliation and Title/Position | Attended Entrance Meeting | Interviewed | Attended Exit Meeting |
|---|---|---|---|---|
| Dennis S. Miehls | CBFO, Senior QA Specialist | ✓ | ✓ | ✓ |
| Martin Navarrete | CBFO, Senior QA Specialist | ✓ | ✓ | ✓ |
| Michael R. Brown | CBFO, Director CBFO QA | ✓ | ✓ | ✓ |
| Mike Stapleton | CBFO, QA Specialist | ✓ | | ✓ |
| Myles Hall | CBFO, Legal Counsel | ✓ | | |
| Suzanne Hunt | CBFO, Contracting Officer | | ✓ | |
| Todd Shrader | CBFO, Manager | | ✓ | |
| Cindi Castillo | CTAC, QA Auditor/Observer | ✓ | | |

| Name | Affiliation and Title/Position | Attended Entrance Meeting | Interviewed | Attended Exit Meeting |
|---|---|---|---|---|
| Dick Blauvelt* | CTAC, Technical Specialist | | ✓ | |
| Porf Martinez | CTAC, Audits and Assessments Manager | ✓ | | ✓ |
| Priscilla Yanez | CTAC, Lead Auditor | | ✓ | |
| Ricardo Chavez | CTAC, Auditor | | ✓ | |
| Lacey Collis | Portage, Training Coordinator | | ✓ | |
| Kevin Peters* | SRS-CCP, Acceptable Knowledge Expert | | ✓ | |

*Personnel interviewed by phone

## 6.0 PERFORMANCE OF THE AUDIT

As recovery from the February 2014 events within the repository continues, on-going QA oversight of the operations is especially important. During this audit, the EPA evaluated selected aspects of the CBFO QA program to ensure that it has the appropriate independence, authority and resources to oversee all WIPP-related operations.

The EPA audit team reviewed records provided by CBFO, interviewed CBFO personnel to evaluate implementation of the requirements in ASME NQA-1-1989, and gathered objective evidence to support the proper implementation of the following elements:

- Element 1, "Organization."
- Element 2, "Quality Assurance Program."
- Element 4, "Procurement Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 16, "Corrective Action."
- Element 18, "Audits."

During the EPA audit of CBFO's QA program on July 22–24, 2014, the EPA audit team identified two concerns about the CBFO organizational chart (see Attachments A and C in EPA Docket No. A-98-49; II-A1-117 or EPA Air eDocket No. EPA-HQ-OAR-2001-0012-0446). The EPA was concerned about reporting lines for the Office of Quality Assurance (CBFO-QA-2014-02CR) and the listing of unauthorized positions on the organization chart (CBFO-QA-2014-01C). CBFO provided a draft organizational chart after the 2014 audit that addressed the concern documented in Issue No. CBFO-QA-2014-02CR. During the current audit (October 2017), the EPA verified that the organizational chart continues to demonstrate that the Office of Quality Assurance Director has independence and reports directly to the CBFO Manager.

The EPA had no findings or concerns with the implementation of elements 1, 2, 4, 7, and 18. For element 16, the EPA issued Concern No. CBFO-QA-2017-01CR, requiring a response. The EPA's review of CBFO's CAR log identified several open CARs with overdue response dates. The CBFO printout of the open CAR log dated October 16, 2017, shows nine CARs issued to CBFO operations by the CBFO office of quality assurance that are overdue, as follows: five CARs that have been overdue for more than one year and four CARs that have been overdue for between one month and one year. All the organizations responsible for addressing their respective CARs have been sent at least one overdue notification. Given the importance of

corrective action in the overall QA program, CBFO operations must respond to open CARs in a more timely manner.

The CBFO Office of Quality Assurance responded to Concern No. CBFO-QA-2017-01CR on November 22, 2017. In addition, CBFO provided EPA with their corrective action plan. In the response, CBFO stated that they had taken the following actions:

- Entered the EPA concern into their Issues Collection and Evaluation (ICE) system
- Conducted an extent of condition evaluation
- Entered the results of the extent of condition evaluation into the ICE system
- Generated a corrective action plan to resolve the issues

In the corrective action plan, CBFO committed to evaluating applicable procedures, making any necessary revisions and providing training to all CBFO staff on the procedures once they are deemed adequate. The CBFO also committed to reviewing all external assessment reports from the last six months and ensuring that all issues are captured in the ICE system, to moving all identified overdue CARs to the next stage of resolution within 30 days and to improving CBFO management briefing and tracking of CARs and other issues. The CBFO anticipates completing the corrective actions by March 2018. The EPA considers this concern closed and will continue to monitor the issue.

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

## 7.0 FINDINGS AND CONCERNS

The EPA audit team did not identify any findings relative to the NQA-1-1989 elements discussed above. The EPA audit team identified one concern requiring a response. This concern is discussed in section 6.0 above and is included as Attachment A to this report. There are no open issues resulting from this audit.

## 8.0 CONCLUSIONS

The EPA audit team reviewed records and documentation and interviewed personnel to determine the continued compliance of the CBFO QA program with ASME NQA-1-1989. Based on the sample of records, documentation and elements reviewed during this audit, the EPA determined that CBFO continues to comply with the standard.

## 9.0 REFERENCES


A-18-02 Audit Scope, Recertification Audit Scope for the Savannah River Site – Central Characterization Program 2017, September 12, 2017

Audit A-17-02 Interim Report, U.S. Department of Energy Carlsbad Field Office Interim Audit Report of the Savannah River Site Central Characterization Program for Transuranic Waste Characterization and Certification Activities, Carlsbad, New Mexico, Audit Number A-17-02, February 3, 2017

Audit A-18-02 Interim Report, U.S. Department of Energy Carlsbad Field Office Interim Audit Report of the Savannah River Site Central Characterization Program for Transuranic Waste Characterization and Certification Activities, Carlsbad, New Mexico, Audit Number A-18-02, November 8, 2017

Audit Report of the Carlsbad Field Office QAPD Implementation of NQA-1 Criteria, Audit Number A-17-29, August 29–31, 2017

Auditor Qualification Records: Blauvelt, Stegman, Lopez, Chavez, Yanez

C6-1 Checklist, Table C6-1 Waste Analysis Plan (WAP) Checklist, SRS-CCP Recertification Audit A-18-02, provided October 17, 2017

C6-2 Checklist, Table C6-2 Acceptable Knowledge (AK) Checklist, SRS-CCP Recertification Audit A-18-02, provided October 17, 2017

Carlsbad Field Office Audit Plan, A-18-02, September 15, 2017

Carlsbad Field Office Contractor Oversight Plan, DOE/CBFO-04-3299, Revision 4, July 25, 2016

CBFO Monthly Assessment Schedule, dated July 17, 2017, and September 2017

CBFO Organization Chart, dated October 5, 2017

CBFO Semi-Annual CAR Trend Reports, dated February 16, 2017, and August 2, 2017

Corrective Action Plan, Environmental Protection Agency Concern CBFO-QA-2017-01CR, November 20, 2017

CTAC Tentative Assessment Teams, August 31, 2017, and October 12, 2017

DE-EM-0001971, WIPP M&O Contract

DE-SOL-0002555, WIPP M&O Draft Solicitation, April 1, 2011

EPA Concern Nos. CBFO-QA-2014-01C and CBFO-QA-2014-02CR

FAR, Federal Acquisition Requirements, available at: http://farsite.hill.af.mil/, accessed November 6, 2017

FY2016 Fee Determination Scorecard, Contract DE-EM0001971, May 1, 2017

IP-540-15, Review and Approval of Proposed Sales, Procurement, Financial Assistance, and Subcontract Actions, Environmental Management Consolidated Business Center, Revision 1A, May 18, 2012

Lead Auditor Maintenance of Proficiency Record: Yanez

Lead Auditor Qualification and Certification Record: Yanez, Schuetz

Listing of CARs still open as of October 16, 2017

MP 1.2, Grading Activities and Determination of Quality Levels, Revision 5, March 23, 2016

MP 3.1, Corrective Action Reports, Revision 15, September 15, 2017

MP 7.1, Quality Assurance Requirements for Procurement of Services, Revision 4, December 6, 2016

MP 9.1, Management Assessments, Revision 8, April 18, 2016

OP 10.1, Qualification of Audit Personnel and Certification of Lead Auditors, Revision 0, May 31, 2017

OP 10.13, Audits, Revision 0, May 31, 2017

Performance Evaluation and Measurement Plan Annual Fee Plan, 1 October 2015 through 30 September 2016, Contract DE-EM0001971, Revision 2, August 9, 2016

QA Checklists, provided October 17, 2017

QAPD, Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 13, April 2017

Quality Assurance Program Plan for the Waste Isolation Pilot Plant Experimental-Waste Characterization Program, DOE/EM/48063-1, Revision 1, July 15, 1991

Response to Issue CBFO-QA-2017-01CR from Inspection A-CBFO-2017-10, Carlsbad Field Office, November 22, 2017

Source Selection Plan Template, Environmental Management Consolidated Business Center, August 2016

Technical Specialist Qualification Record: Blauvelt, Ricardo, Fitzgerald, Lopez, Schuetz, Chavez

TI-OOC-002, Subcontract Consent Reviews, Environmental Management Consolidated Business Center, Revision 1, August 21, 2008, Attachment B, EMCBC Office of Contracting Subcontract Consent Review Checklist

TI-OOC-004, Developing, Revising, Approving, Submitting and Maintaining Technical Instructions, Environmental Management Consolidated Business Center, Revision 0, October 19, 2015

U.S. Department of Energy Carlsbad Field Office Supervisory Quality Assurance Specialist, GS-1910-15, April 27, 2015

U.S. Department of Energy Environmental Management Carlsbad Field Office Quality Assurance Specialist, GS-1910-14, June 19, 2013

U.S. Department of Energy Environmental Management Carlsbad Field Office Quality Improvement Specialist, GS-1910-12, December 16, 2014

U.S. Department of Energy Environmental Management Carlsbad Field Office Software Quality Assurance Specialist, GS-1910-13, December 30, 2015

Yanez Training and Qualification File

## ATTACHMENT A: CONCERN NO. CBFO-QA-2017-01CR

## EPA INSPECTION ISSUE TRACKING FORM

## ISSUE NO. CBFO-QA-2017-01CR (FINAL)

| | |
|---|---|
| **Inspection No.** AUD-CBFO-OCT-2017 | **Issue Number:** CBFO-QA-2017-01CR<br>**Date:** 10-19-2017 |
| **Inspector:** J. Ellis, K. Darlow, P. Kelly<br>**Attachments?** ☐ YES ☒ NO | **Sample Size:** 9<br>**Population size (if known):** 48 |
| **Description of Issue:** The Department of Energy's Carlsbad Field Office (CBFO) Corrective Action Report (CAR) log shows nine CARs issued to CBFO that are overdue, as follows: five CARS that have been overdue for more than one year and four CARS that have been overdue for between one month and one year. CBFO must respond to open CARs in a more timely manner. | |
| **B. Regulatory Reference:** 40 CFR 194.24(e) | |
| **C. NQA-1-1989 Element(s):** Element 16 | |
| **D. Discussed with:** D. Miehls, M. Navarrete, M. Brown, T. Shrader | |
| **E. Additional Comments:** None | |
| **F. Response Information:**<br>**Written Response Required by CBFO?** ☒ YES ☐ NO<br>**Response Due Date:** November 22, 2017 | |

## ATTACHMENT B: ASME NQA-1-1989, ELEMENT 1, CHECKLIST FOR CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 1 with Supplement 1S-1, *Organization* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Basic Requirements** | | |
| 1. Are the organizational structure, functional responsibilities, levels of authority and lines of communication documented for activities affecting quality? | Y | QAPD, Revision 13, section 1.1, Organization and Quality Assurance Program; section 1.1.1.4, Communication and Interface Responsibilities, paragraph A; Appendix C, CBFO Organization, Responsibilities, and Interfaces; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance; Appendix E, TRU Waste Characterization and Certification Organizational and Individual Responsibilities<br>CBFO Organization Chart, dated 10/5/2017<br>MP 3.1, Revision 15, section 4.0, Responsibilities<br>OP 10.13, Revision 0, section 4.0, Responsibilities<br>CBFO Contractor Oversight Plan, Revision 4 |
| 2. Do persons or organizations responsible for performing quality assurance functions have sufficient authority, access to work areas and organizational freedom to:<br>• Identify quality problems?<br>• Initiate, recommend, or provide solutions to quality problems through designated channels?<br>• Verify implementation of solutions?<br>• Assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency or unsatisfactory condition has occurred? | Y | QAPD, Revision 13, section 1.1.1.3, QA Management, paragraphs A and B; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance<br>CBFO Organization Chart, dated 10/5/2017<br>MP 3.1, Revision 15, Corrective Action Reports<br>OP 10.13, Revision 0, Audits<br>Position Descriptions: Quality Assurance Specialist, Quality Improvement Specialist, Supervisory Quality Assurance Specialist, Software Quality Assurance Specialist |
| 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 effected? | Y | QAPD, Revision 13, section 1.1.1.3, QA Management, paragraphs A and B; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance<br>CBFO Organization Chart, dated 10/5/2017 |
| 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 | QAPD, Revision 13, section 1.1.1.3, QA Management, paragraph A; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance<br>CBFO Organization Chart, dated 10/5/2017 |

NQA-1 ELEMENT: No. 1 with Supplement 1S-1, *Organization* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Supplementary Requirements (1S-1)** | | |
| 1. Are the organizational structure and the responsibility assignments such that:<br>• Quality is achieved and maintained by those who have been assigned responsibility for performing work?<br>• Quality achievement is verified by persons or organizations not directly responsible for performing the work? | Y | QAPD, Revision 13, section 1.1.1, Organization; section 1.1.1.1, Management, paragraph D; section 2.1, Work Processes, paragraph B; Appendix C, CBFO Organization, Responsibilities, and Interfaces; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance<br>CBFO Organization Chart, dated 10/5/2017<br>OP 10.13, Revision 0, Audits |
| 2. Do the individuals or organizations responsible for establishing and executing a quality assurance program delegate any or all of the work to others, and, if so, do the individuals or organizations retain responsibility for the quality assurance program? | Y | QAPD, Revision 13, section 1.1.1, Organization; section 1.1.1.5, Delegation of Work; Appendix C, CBFO Organization, Responsibilities, and Interfaces; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance; Appendix E, TRU Waste Characterization and Certification Organizational and Individual Responsibilities<br>CBFO Organization Chart, dated 10/5/2017<br>MP 3.1, Revision 15, section 4.0, Responsibilities |
| 3. Is responsibility for the control of further processing, delivery, installation or operation of nonconforming items designated in writing? | Y | QAPD, Revision 13, section 1.1.1.3, QA Management, paragraph B; Appendix D, Responsibilities of the Director of the CBFO Office of Quality Assurance<br>CBFO Organization Chart, dated 10/5/2017<br>MP 3.1, Revision 15, section 4.0, Responsibilities |
| 4. Where more than one organization is involved in the execution of quality assurance activities, is the responsibility and authority of each organization clearly established and documented? | Y | QAPD, Revision 13, section 1.1.1.4, Communication and Interface Responsibilities, paragraph B; Appendix C, CBFO Organization, Responsibilities, and Interfaces<br>CBFO Organization Chart, dated 10/5/2017 |
| 5. Are the external interfaces between organizations, as well as the internal interfaces between organizational units, documented? Are interface responsibilities defined and documented? | Y | QAPD, Revision 13, section 1.1.1.4, Communication and Interface Responsibilities, paragraph B; Appendix C, CBFO Organization, Responsibilities, and Interfaces<br>CBFO Organization Chart, dated 10/5/2017 |

*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: The 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 C: ASME NQA-1-1989, ELEMENT 2, CHECKLIST FOR CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Basic Requirements** | | |
| 1. Is a documented quality assurance program planned, implemented and maintained in accordance with NQA-1? | Y | QAPD, Revision 13, section 1.1.2.1, Quality Assurance Program Documents<br>A-17-29, Audit Report |
| 2. Does the quality assurance program identify the activities and items to which it applies? | Y | QAPD, Revision 13, section 1.1.2.2, Applicability of QAPD Requirements |
| 3. Does the quality assurance program provide control over activities affecting quality to an extent consistent with their importance? | Y | QAPD, Revision 13, section 1.1.2.3, Grading Items and Activities and Applying Management Controls<br>MP 1.2, Revision 5, section 1.0, Purpose |
| 4. Was the quality assurance program established at the earliest time consistent with the schedule for accomplishing the activities? | Y | QAPP, DOE/EM/48063-1, Revision 1 |
| 5. Does the quality assurance program provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions, which include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied? | Y | QAPD, Revision 13, section 1.1.2.4, Planning Work |
| 6. Does the quality assurance program provide for any special controls, processes, test equipment, tools and skills to attain the required quality and for verification of quality? | Y | QAPD, Revision 13, section 1.1.1, Organization; section 1.1.2.4, Planning Work; Appendix C, CBFO Organization, Responsibilities, and Interfaces |
| 7. Does the quality assurance program provide for indoctrination and training of personnel performing activities affecting quality? | Y | QAPD, Revision 13, section 1.2.2, Training Requirements, paragraph A |
| 8. Does the management of the organizations implementing the quality assurance program regularly assess the adequacy of that part of the program for which they are responsible and assure its effective implementation? | Y | QAPD, Revision 13, section 1.1.1.1, Management; section 1.1.1.3, QA Management; section 1.3, Quality Improvement; section 1.2.2, Training Requirements; section 3.1, Management Assessment<br>MP 9.1, Revision 8, section 1.0, Purpose |
| **Supplementary Requirements (2S-1)** | | |
| 1. Does the responsible organization designate those activities that require qualified inspection and test personnel and minimum requirements for such personnel? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph A |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program*

EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly

DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 2. Has the responsible organization established written procedures for the qualification of inspection and test personnel to assure that only qualified personnel are permitted to perform inspection and test activities? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph A |
| 3. Do personnel selected for performing inspection and test activities have the experience or training commensurate with the scope, complexity or special nature of the activities? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph C |
| 4. Have provisions been made for the indoctrination of personnel regarding the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph D |
| 5. Has the need for a formal training program been determined? Are training activities, including on-the-job training, conducted to qualify personnel who perform inspections and tests? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph E |
| 6. Are the capabilities of a candidate for certification initially determined by a suitable evaluation of the candidate's education, experience, training and either test results or capability demonstration? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph F |
| 7. Is the job performance of inspection and test personnel reevaluated at periodic intervals not to exceed three years? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph G |
| 8. If it is determined at any time that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, is that person removed from that activity until such time as the required capability has been demonstrated? | Y | QAPD, Revision 13, section 2.4.I, Qualification of Inspection and Test Personnel, paragraph G |
| 9. Is a person reevaluated for a required inspection or test capability if activities have not been performed in his or her qualified area for a period of one year? | Y | QAPD, Revision 13, section 2.4.I, Qualification of Inspection and Test Personnel, paragraph G |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 10. Is the qualification of personnel certified in writing in an appropriate form, including:<br>• Employer's name?<br>• Identification of person being certified?<br>• Activities certified to perform?<br>• Basis used for certification, including:<br>– Education, experience, indoctrination and training?<br>– Test results, where applicable?<br>– Results of capability demonstration?<br>• Results of periodic evaluation?<br>• Results of physical examinations, when required?<br>• Signature of employer's designated representative who is responsible for such certification?<br>• Date of certification and date of certification expiration? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph H |
| 11. Has the responsible organization identified any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph I |
| 12. Does the employer establish and maintain records of personnel qualification? | Y | QAPD, Revision 13, section 2.4.1, Qualification of Inspection and Test Personnel, paragraph J |
| **Supplementary Requirements (2S-2)** | | |
| 1. Does the quality assurance program provide for the qualification of nondestructive examination personnel to the American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, issued June 1980? | Y | QAPD, Revision 13, section 2.4.2, Qualification of Nondestructive Examination Personnel, paragraph A |
| 2. Has the responsible organization established written procedures for the control and administration of nondestructive examination personnel training, examination and certification? | Y | QAPD, Revision 13, section 2.4.2, Qualification of Nondestructive Examination Personnel, paragraph B |
| 3. Does the employer establish and maintain records of personnel qualification? | Y | QAPD, Revision 13, section 2.4.2, Qualification of Nondestructive Examination Personnel, paragraph C |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Supplementary Requirements (2S-3)** | | |
| 1. Has the responsible auditing organization established the qualifications for audit personnel and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs? | Y | QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraph D; section 3.2.2.4, Auditor Qualification; section 3.2.2.5, Technical Specialist Qualification<br>OP 10.1, Revision 0, section 5.1, Technical Specialist Qualification; section 5.2, Auditor Qualification |
| 2. Is the competence of audit personnel developed by one or more of the following methods:<br>• Orientation to provide a working knowledge and understanding of NQA-1 and the auditing organization's procedures for implementing audits and reporting results?<br>• Training programs to provide general and specialized training in audit performance?<br>• On-the-job training, guidance and counseling under the direct supervision of a lead auditor? | Y | QAPD, Revision 13, section 3.2.2.4, Auditor Qualification<br>OP 10.1, Revision 0, section 5.2, Auditor Qualification<br>Auditor Qualification: Blauvelt, Stegman, Lopez, Chavez, Yanez<br>Technical Specialist Qualification: Blauvelt, Ricardo, Fitzgerald, Lopez, Schuetz, Chavez |
| 3. Does a prospective lead auditor have the capability to communicate effectively, both in writing and orally? Has the lead auditor's employer attested to these skills in writing? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph B, Lead Auditor Communication Skills<br>OP 10.1, Revision 0, section 5.3, Lead Auditor Qualification and Certification, paragraph 5.3.6; Form 10.1-3<br>Lead Auditor Qualification: Yanez, Schuetz |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 4. Are prospective lead auditors trained, as necessary, to assure their competence in auditing skills, including training in the following areas:<br>• Knowledge and understanding of NQA-1 and other nuclear-related codes, standards, regulations and regulatory guides?<br>• General structure of quality assurance programs as a whole and applicable elements as defined by NQA-1?<br>• Auditing techniques of examining, questioning, evaluating and reporting; methods of identifying and following up on corrective action items; and closing out audit findings?<br>• Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility?<br>• On-the-job training to include applicable elements of the audit program? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph C, Lead Auditor Training<br>OP 10.1, Revision 0, section 5.3, Lead Auditor Qualification and Certification, paragraph 5.3.1<br>Lead Auditor Qualification: Yanez, Schuetz |
| 5. Is a prospective lead auditor required to have participated in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within one year prior to qualification? | Y | QAPD, Revision 13, section 3.2.2.4, Auditor Qualification, section 3.2.2.6, Lead Auditor Qualification, paragraph A.2, Experience<br>OP 10.1, Revision 0, section 5.3, Lead Auditor Qualification and Certification, paragraph 5.3.4<br>Lead Auditor Qualification: Yanez, Schuetz |
| 6. Is a prospective lead auditor required to pass an examination that evaluates his or her comprehension of and ability to apply the body of knowledge identified under the training requirements (listed under question 4 above)? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph D, Lead Auditor Examination<br>OP 10.1, Revision 0, section 5.3, Lead Auditor Qualification and Certification, paragraph 5.3.3<br>Lead Auditor Qualification: Yanez, Schuetz |
| 7. Do lead auditors maintain their proficiency through one or more of the following:<br>• Regular and active participation in the audit process?<br>• Review and study of codes, standards, procedures, instructions and other documents related to quality assurance program and program auditing?<br>• Participation in training programs? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph F, Lead Auditor Proficiency Maintenance<br>OP 10.1, Revision 0, Form 10.1-4<br>Lead Auditor Maintenance of Proficiency: Yanez |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program*

EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly

DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 8. Does management conduct documented annual assessments of lead auditors to extend their qualification, require retraining or require requalification? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph F, Lead Auditor Proficiency Maintenance<br>OP 10.1, Revision 0, section 5.4, Lead Auditor Annual Maintenance of Proficiency, paragraph 5.4.3<br>Lead Auditor Maintenance of Proficiency: Yanez |
| 9. Are lead auditors who fail to maintain their proficiency for a period of two years or more required to requalify? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph F, Lead Auditor Proficiency Maintenance<br>OP 10.1, Revision 0, section 5.4, Lead Auditor Annual Maintenance of Proficiency, paragraph 5.4.4 |
| 10. Is the employer responsible for training auditors? | Y | QAPD, Revision 13, section 1.1.1.1, Management; section 1.2.2, Training Requirements, paragraph A<br>OP 10.1, Revision 0, section 4.1, CBFO Office of Quality Assurance (OQA) Director or designee [Responsibilities], paragraph 4.1.1 |
| 11. Does the responsible auditing organization select and assign personnel who are independent of any direct responsibility for performance of the activities that they will audit? | Y | QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraph A<br>OP 10.13, Revision 0, section 4.3, Audit Team Leader [Responsibilities], paragraph 4.3.2; section 5.2, Personnel Selection, paragraph 5.2.2<br>CTAC Tentative Assessment Teams, October 12, 2017 |
| 12. Does the lead auditor, prior to commencing the audit, concur that assigned audit personnel collectively have experience or training commensurate with the scope, complexity or special nature of the activities to be audited? | Y | QAPD, Revision 13, section 3.2.2.3, Audit Team Selection, paragraph C<br>OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraph 5.2.2 |
| 13. Is the employer responsible for the development and administration of the examination for a lead auditor? If the employer delegates this activity to an independent certifying agency, does the employer retain responsibility for the conformance of the examination and its administration to the NQA-1-1989 standard? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph D, Lead Auditor Examination<br>OP 10.1, Revision 0, section 4.1, CBFO Office of Quality Assurance (OQA) Director or designee [Responsibilities], paragraph 4.1.6 |
| 14. Does the employer establish and maintain records of personnel qualifications for auditors and lead auditors performing audits? | Y | QAPD, Revision 13, section 1.2.2, Training Requirements, paragraph C<br>OP 10.1, Revision 0, section 4.1, CBFO Office of Quality Assurance (OQA) Director or designee [Responsibilities], paragraph 4.1.7; section 6.0, Records<br>Auditor Qualification: Blauvelt, Stegman, Lopez, Chavez, Yanez<br>Lead Auditor Qualification: Yanez, Schuetz |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program*

EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly

DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 15. Does the employer certify each lead auditor as being qualified to lead audits, including documentation of the following by the certification:<br>• Employer's name?<br>• Lead auditor's name?<br>• Date of certification or recertification?<br>• Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.)?<br>• Signature of employer's designated representative who is responsible for such certification? | Y | QAPD, Revision 13, section 3.2.2.6, Lead Auditor Qualification, paragraph E, Lead Auditor Certification<br>OP 10.1, Revision 0, Form 10.1-4<br>Lead Auditor Qualification and Certification Record: Yanez, Schuetz |
| 16. Are the records for each lead auditor maintained and updated annually? | Y | OP 10.1, Revision 0, section 4.1, CBFO Office of Quality Assurance (OQA) Director or designee [Responsibilities], paragraph 4.1.7; section 5.4, Lead Auditor Maintenance of Proficiency, paragraph 5.4.1; section 6.0, Records<br>Yanez Training and Qualification File |
| **Supplementary Requirements (2S-4)** | | |
| 1. Are personnel identified for indoctrination or training? | Y | QAPD, Revision 13, section 1.2.2, Training Requirements |
| 2. Is the extent of indoctrination and training commensurate with the following:<br>• The scope, complexity and nature of the activity?<br>• The education, experience and proficiency of the person? | Y | QAPD, Revision 13, section 1.2.1, Qualification Requirements, paragraph A |
| 3. Are personnel indoctrinated in the following subjects as they relate to a particular function:<br>• General criteria, including applicable codes, standards and company procedures?<br>• Applicable quality assurance program elements?<br>• Job responsibilities and authority? | Y | QAPD, Revision 13, section 1.2.2, Training Requirements, paragraph B |
| 4. Is training provided, if needed, to:<br>• Achieve initial proficiency?<br>• Maintain proficiency?<br>• Adapt to changes in technology, methods or job responsibilities? | Y | QAPD, Revision 13, section 1.2.2, Training Requirements, paragraph A |

NQA-1 ELEMENT: No. 2 with Supplements 2S-1, 2S-2, 2S-3 and 2S-4, *Quality Assurance Program*

EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly

DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 5. Do records of the implementation of indoctrination and training take the form of:<br>• Attendance sheets?<br>• Training logs?<br>• Personnel training records? | N/A | |

*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: The 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 D: ASME NQA-1-1989, ELEMENT 4, CHECKLIST FOR CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 4 with Supplement 4S-1, *Procurement Document Control*

EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly

DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Basic Requirements** | | |
| 1. Are procurement documents required to reference or include design bases or quality requirements? | Y | QAPD, Revision 13, section 2.3.4, Procurement Document Requirements, paragraphs B and C<br>MP 7.1, Revision 4, section 5.1, Procurement Document Requirements, paragraph 5.1.2<br>DE-EM-0001971, section C, Performance Work Statement<br>TI-OOC-002, Revision 1, Attachment B, EMCBC Office of Contracting Subcontract Consent Review Checklist |
| 2. Do procurement documents require suppliers to have a quality assurance (QA) program consistent with the requirements of NQA-1-1989? | Y | QAPD, Revision 13, section 2.3.4, Procurement Document Requirements, paragraph C<br>MP 7.1, Revision 4, section 5.1, Procurement Document Requirements, paragraph 5.1.2<br>DE-EM-0001971, section C, Performance Work Statement, section 3.4, Quality Assurance |
| **Supplementary Requirements (4S-1)** | | |
| 1. Do procurement documents include the following provisions as deemed necessary by the purchaser:<br>• Scope of work?<br>• Technical requirements?<br>• QA program requirements?<br>• Right of access?<br>• Documentation requirements?<br>• Requirement for documenting nonconformances?<br>• Spare and replacement parts? | Y | QAPD, Revision 13, section 2.3.4, Procurement Document Requirements<br>MP 7.1, Revision 4, section 5.1, Procurement Document Requirements, paragraph 5.1.2<br>DE-EM-0001971<br>DE-SOL-0002555 |
| 2. Is the review of procurement documentation documented? | Y | QAPD, Revision 13, section 2.3.5, Procurement Document Review and Approval, paragraph B<br>MP 7.1, Revision 4, section 5.2, Procurement Document Review and Approval; section 6.0, Records<br>TI-OOC-004, Revision 0<br>IP-540-15, Revision 1A |

NQA-1 ELEMENT: No. 4 with Supplement 4S-1, *Procurement Document Control*

EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly

DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 3. Are changes to procurement documents subject to the same degree of control as used in the preparation of the original documents? | Y | QAPD, Revision 13, section 2.3.5, Procurement Document Review and Approval, paragraph A<br>MP 7.1, Revision 4, section 5.1, Procurement Document Requirements, section 5.1.1<br>TI-OOC-004, Revision 0 |

*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: The 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 E: ASME NQA-1-1989, ELEMENT 7, CHECKLIST FOR CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 7 with Supplement 7S-1, *Control of Purchased Items and Services* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Basic Requirements** | | |
| 1. Does the control of purchased items and services provide for:<br>• Source evaluation and selection (as applicable)?<br>• Evaluation of objective evidence of quality furnished by the supplier?<br>• Source inspection or audit?<br>• Examination of items or services upon delivery or completion? | Y | QAPD, Revision 13, section 2.3.2, Supplier Selection; section 2.3.3, section 2.3.7.1, Source Verification; section 2.3.7.2, Receiving Inspection<br>MP 7.1, Revision 4, section 5.3, Administration of Contract, paragraph 5.3.2 |
| **Supplementary Requirements (7S-1)** | | |
| 1. Does procurement planning determine the following:<br>• What is to be accomplished?<br>• Who is to accomplish it?<br>• How it is to be accomplished?<br>• When it is to be accomplished? | Y | QAPD, Revision 13, section 2.3.1, Procurement Planning Requirements<br>FAR, subpart 7.1, Acquisition Plans<br>IP-540-15, Revision 1A |
| 2. Does procurement planning provide for the integration of:<br>• Procurement document preparation, review and change control?<br>• Selection of procurement sources?<br>• Bid evaluation and award?<br>• Purchaser control of supplier performance?<br>• Verification (surveillance, inspection or audit) activities by the purchaser, including notification for hold and witness points?<br>• Control of nonconformances?<br>• Corrective action?<br>• Acceptance of item or service?<br>• Quality assurance records? | Y | QAPD, Revision 13, section 2.3.1, Procurement Planning Requirements, paragraph C<br>MP 7.1, Revision 4, section 5.1, Procurement Document Requirements, section 5.1.1<br>FAR, section 7.105, Contents of Written Acquisition Plans<br>IP-540-15, Revision 1A |

NQA-1 ELEMENT: No. 7 with Supplement 7S-1, *Control of Purchased Items and Services* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 3. Are the measures for evaluation and selection of procurement sources documented? Do they include one or more of the following:<br>• Evaluation of the supplier's history, including current capability, of providing an identical or similar product that performs satisfactorily in actual use?<br>• Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated?<br>• Supplier's technical and quality capability as determined by a direct evaluation of its facilities and personnel and the implementation of its quality assurance program? | Y | QAPD, Revision 13, section 2.3.2, Supplier Selection, paragraphs C and D<br>FAR Subpart 2.101, Definitions, "Source Selection Information"<br>Source Selection Plan Template, August 2016 |
| 4. Are the following items considered in bid evaluations:<br>• Technical considerations?<br>• Quality assurance requirements?<br>• Supplier's personnel?<br>• Supplier's production capability?<br>• Supplier's past performance?<br>• Alternates?<br>• Exceptions? | Y | QAPD, Revision 13, section 2.3.3, Proposal/Bid Evaluation, paragraph A<br>FAR Subpart 2.101, Definitions, "Source Selection Information"<br>Source Selection Plan Template, August 2016 |
| 5. Are the following items considered in a supplier's performance evaluation:<br>• Establishing an understanding between purchaser and supplier of the provisions and specifications of the procurement documents?<br>• Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements?<br>• Reviewing supplier documents that are generated or processed during activities fulfilling procurement requirements?<br>• Identifying and processing necessary change information?<br>• Establishing a method of document information exchange between purchaser and supplier?<br>• Establishing the extent of source surveillance and inspection activities? | Y | QAPD, Revision 13, section 2.3.6, Supplier Performance Evaluation<br>Performance Evaluation and Measurement Plan Annual Fee Plan, Contract DE-EM0001971, August 9, 2016<br>FY2016 Fee Determination Scorecard |

NQA-1 ELEMENT: No. 7 with Supplement 7S-1, *Control of Purchased Items and Services* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 6. Are verification activities of the supplier's quality performance planned, verified and documented by qualified personnel? | Y | QAPD, Revision 13, section 2.3.4, Procurement Document Requirements, paragraph C.4; section 2.3.7.1, Source Verification, paragraph B<br>CBFO Contractor Oversight Plan, Revision 4<br>CBFO Monthly Assessment Schedule, July 2017 and September 2017 |
| 7. Are supplier-generated documents controlled, handled and approved in accordance with established methods? | Y | QAPD, Revision 13, section 2.3.4, Procurement Document Requirements, paragraphs C.1, C.5 and C.6; section 2.3.6, Supplier Performance Evaluation, paragraphs C and E<br>DE-EM-0001971, Section C, Performance Work Statement, paragraph 3.1.3.3; Section H, Special Contract Requirements, subsection H.44, Records Management |
| 8. Are measures established, implemented and documented to control changes to procurement documents? | Y | QAPD, Revision 13, section 2.3.4, Procurement Document Requirements, paragraph C.6; section 2.3.5, Procurement Document Review and Approval, paragraph A; section 2.3.8, Control of Supplier Nonconformances<br>MP 7.1, Revision 4, section 5.1, Procurement Document Requirements, section 5.1.1<br>TI-OOC-004, Revision 0 |
| 9. Are methods established for the acceptance of an item or service being furnished by a supplier? | Y | QAPD, Revision 13, section 2.3.7, Acceptance of Items or Services<br>DE-EM-0001971, Section E, Inspection and Acceptance |
| 10. Is the supplier required to verify that the item or service being furnished complies with the procurement requirements? | Y | QAPD, Revision 13, section 2.3.7, Acceptance of Items or Services, paragraph B<br>DE-EM-0001971, Section E, Inspection and Acceptance |
| 11. Are one or more of the following methods used to accept an item or related services from a supplier:<br>• Supplier certificate of conformance?<br>• Source verification?<br>• Receiving inspection?<br>• Post-installation test?<br>Note: Specific requirements for each of the above are addressed in NQA-1-1989, Supplement 7S-1, paragraph 8.2. | Y | QAPD, Revision 13, section 2.3.7.1, Source Verification; section 2.3.7.2, Receiving Inspection; section 2.3.7.3, Post-installation Testing; section 2.3.7.4, Supplier Certificate of Conformance |

NQA-1 ELEMENT: No. 7 with Supplement 7S-1, *Control of Purchased Items and Services* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| 12. Are one or more of the following methods used to accept purchased services:<br>• Technical verification of data produced?<br>• Surveillance and/or audit of the activity?<br>• Review of objective evidence for conformance to the procurement document requirements, such as certifications or stress reports? | Y | QAPD, Revision 13, section 2.3.7.1, Source Verification, paragraph C<br>Performance Evaluation and Measurement Plan Annual Fee Plan, Contract DE-EM0001971, August 9, 2016<br>DE-EM-0001971, Section E, Inspection and Acceptance |
| 13. Do the purchaser and supplier have documented methods for disposition of items and services that do not meet procurement document requirements? | Y | QAPD, Revision 13, Table I-1, QA Program Source Documents; section 2.3.1, Procurement Planning Requirements, paragraph C.6; section 2.3.8, Control of Supplier Nonconformances<br>DE-EM-0001971, Section E, Inspection and Acceptance |
| 14. Do the methods in question 13 contain provisions for:<br>• Evaluation of nonconforming items?<br>• Submittal of a nonconformance notice to the purchaser by the supplier as directed by the purchaser? (See note below.) Does this submittal include the supplier-recommended disposition (e.g., use-as-is or repair) and technical justification?<br>• Purchaser's disposition of the supplier's recommendation?<br>• Verification of the implementation of the disposition?<br>• Maintenance of records of supplier-submitted nonconformances?<br>Note: Specific requirements for nonconformances to the procurement requirements or purchaser-approved documents are addressed in NQA-1-1989, Supplement 7S-1, paragraph 9(b). | Y | QAPD, Revision 13, Table I-1, QA Program Source Documents; section 2.3.I, Procurement Planning Requirements, paragraph C.6; section 2.3.8, Control of Supplier Nonconformances |

*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: The 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 F: ASME NQA-1-1989, ELEMENT 16, CHECKLIST FOR CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 16, *Corrective Action* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Basic Requirements** | | |
| 1. Are conditions adverse to quality identified promptly and corrected as soon as practical?[3] | Y | QAPD, Revision 13, section 1.1.1.2, Employees; section 1.3, Quality Improvement; section 1.3.3.3, Remediation of Conditions Adverse to Quality; section 1.3.3.7, Corrective Action Follow-up<br>MP 3.1, Revision 15, Corrective Action Reports, Attachments I–IV<br>CAR Trend Reports, February 16, 2017, and August 2, 2017<br>List of Open CARs as of October 16, 2017<br>Corrective action plan for EPA Concern CBFO-QA-2017-01CR |
| 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 | QAPD, Revision 13, section 1.3.3.5, Corrective Action Plans<br>MP 3.1, Revision 15, section 5.1, Corrective Action Report Initiation, paragraph 5.1.8; Attachments I–IV |
| 3. Are the identification, cause and corrective action for significant conditions adverse to quality documented and reported to appropriate levels of management? | Y | QAPD, Revision 13, section 1.3.3.3, Remediation of Conditions Adverse to Quality, paragraph B; section 1.3.3.4, Significant Conditions Adverse to Quality, paragraph B<br>List of Open CARs as of October 16, 2017 |
| 4. Is follow-up action taken to verify implementation of corrective action? | Y | QAPD, Revision 13, section 1.3.3.7, Corrective Action Follow-up<br>MP 3.1, Revision 15, section 5.6, Verification of Corrective Action Completion<br>List of Open CARs as of October 16, 2017 |
| **Supplementary Requirement – None** | | |

*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: The 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.

3 The CBFO Office of Quality Assurance identifies conditions adverse to quality for the CBFO Operations staff to correct.

## ATTACHMENT G: ASME NQA-1-1989, ELEMENT 18, CHECKLIST FOR CBFO OFFICE OF QUALITY ASSURANCE

NQA-1 ELEMENT: No. 18 with Supplement 18S-1, *Audits* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced document adequately define, describe, address or satisfy the following:** | **Y, N, I, N/A*** | **Applicable Procedure and Paragraph; Additional Objective Evidence** |
|---|---|---|
| **Basic Requirements** | | |
| 1. Are planned and scheduled audits performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness? | Y | QAPD, Revision 13, section 3.2, Independent Assessment, paragraphs A and C<br>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<br>Carlsbad Field Office Monthly Assessment Schedule, July 2017 and September 2017<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report |
| 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<br>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<br>Carlsbad Field Office Audit Plan, A-18-02<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report<br>Checklists: C6-1, C6-2, QA |
| 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<br>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<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report<br>List of Open CARs as of October 16, 2017 |
| **Supplementary Requirements (18S-1)** | | |
| 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<br>OP 10.13, Revision 0, section 5.1, Scheduling<br>Carlsbad Field Office Monthly Assessment Schedule, July 2017 and September 2017 |
| 2. Are audit plans developed and documented for each audit? | Y | QAPD, Revision 13, section 3.2.2.2, Planning and Preparation for Audits<br>OP 10.13, Revision 0, section 5.3, Planning, paragraph 5.3.1<br>Carlsbad Field Office Audit Plan, A-18-02 |

NQA-1 ELEMENT: No. 18 with Supplement 18S-1, *Audits* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced 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?<br><br>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<br>OP 10.13, Revision 0, section 5.2, Personnel Selection, paragraphs 5.2.1 and 5.2.2<br>Carlsbad Field Office Audit Plan, A-18-02<br>CTAC Tentative Assessment Teams, October 12, 2017 |
| 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<br>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<br>Carlsbad Field Office Audit Plan, A-18-02<br>CTAC Tentative Assessment Teams, August 31, 2017, and October 12, 2017 |
| 5. Are audits performed in accordance with written procedures or checklists? | Y | QAPD, Revision 13, section 3.2.2.7, Performing Audits, paragraph A<br>OP 10.13, Revision 0, section 5.3, Planning, paragraph 5.3.6; section 5.4, Performance<br>Carlsbad Field Office Audit Plan, A-18-02<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report<br>Checklists: C6-1, C6-2, QA |
| 6. Are the elements that have been selected for audits evaluated against specified requirements? | Y | QAPD, Revision 13, section 3.2.2.7, Performing Audits, paragraph B<br>OP 10.13, Revision 0, section 5.3, Planning, paragraphs 5.3.1 and 5.3.6<br>Carlsbad Field Office Audit Plan, A-18-02<br>Checklists: C6-1, C6-2, QA<br>A-18-02 Audit Scope |
| 7. Are audit results documented by auditing personnel and reviewed by management having responsibility for the area audited? | Y | QAPD, Revision 13, section 3.2.2.7, Performing Audits, paragraph C; section 3.2.2.8, Reporting Audit Results, paragraph A<br>OP 10.13, Revision 0, section 4.3, Audit Team Leader [Responsibilities], paragraph 4.3.10; section 4.4, Audit Team [Responsibilities], paragraphs 4.4.4–4.4.6; section 5.5, Reporting, paragraph 5.5.2<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report |

NQA-1 ELEMENT: No. 18 with Supplement 18S-1, *Audits* EPA AUDITORS: J. Ellis, K. Darlow, P. Kelly DATE: October 2017

| **Does the referenced 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 | QAPD, Revision 13, section 3.2.2.8, Reporting Audit Results, paragraph A<br>OP 10.13, Revision 0, section 5.5, Reporting, paragraph 5.5.1<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report |
| 9. Does the audit report include:<br>• Description of the audit scope?<br>• Identification of the auditors?<br>• Identification of persons contacted during audit activities?<br>• Summary of audit results, including a statement on the effectiveness of the quality assurance program elements that were audited?<br>• Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization? | Y | QAPD, Revision 13, section 3.2.2.8, Reporting Audit Results, paragraph A<br>OP 10.13, Revision 0, Attachment V, Audit Report Format (Example)<br>Audit A-17-02 Interim Report<br>Audit A-18-02 Interim Report |
| 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 | QAPD, Revision 13, section 3.2.2.9, Audit Response and Follow Up<br>OP 10.13, Revision 0, section 5.6, Audit Response, Follow-up, and Close-Out, paragraph 5.6.2<br>List of Open CARs as of October 16, 2017 |
| 11. Is follow-up action taken to verify that corrective action is accomplished as scheduled? | Y | QAPD, Revision 13, section 3.2.2.9, Audit Response and Follow Up<br>OP 10.13, Revision 0, section 5.6, Audit Response, Follow-up, and Close-Out, paragraph 5.6.2<br>MP 3.1, Revision 15, section 5.6, Verification of Corrective Action Completion<br>List of Open CARs as of October 16, 2017 |
| 12. Do audit records include audit plans, audit reports, written replies and the record of completion of corrective action? | Y | QAPD, Revision 13, section 3.2.2.10, Audit Records<br>OP 10.13, Revision 0, section 6.0, Records, paragraph 6.1<br>MP 3.1, Revision 15, section 6.0, Records, paragraph 6.1 |

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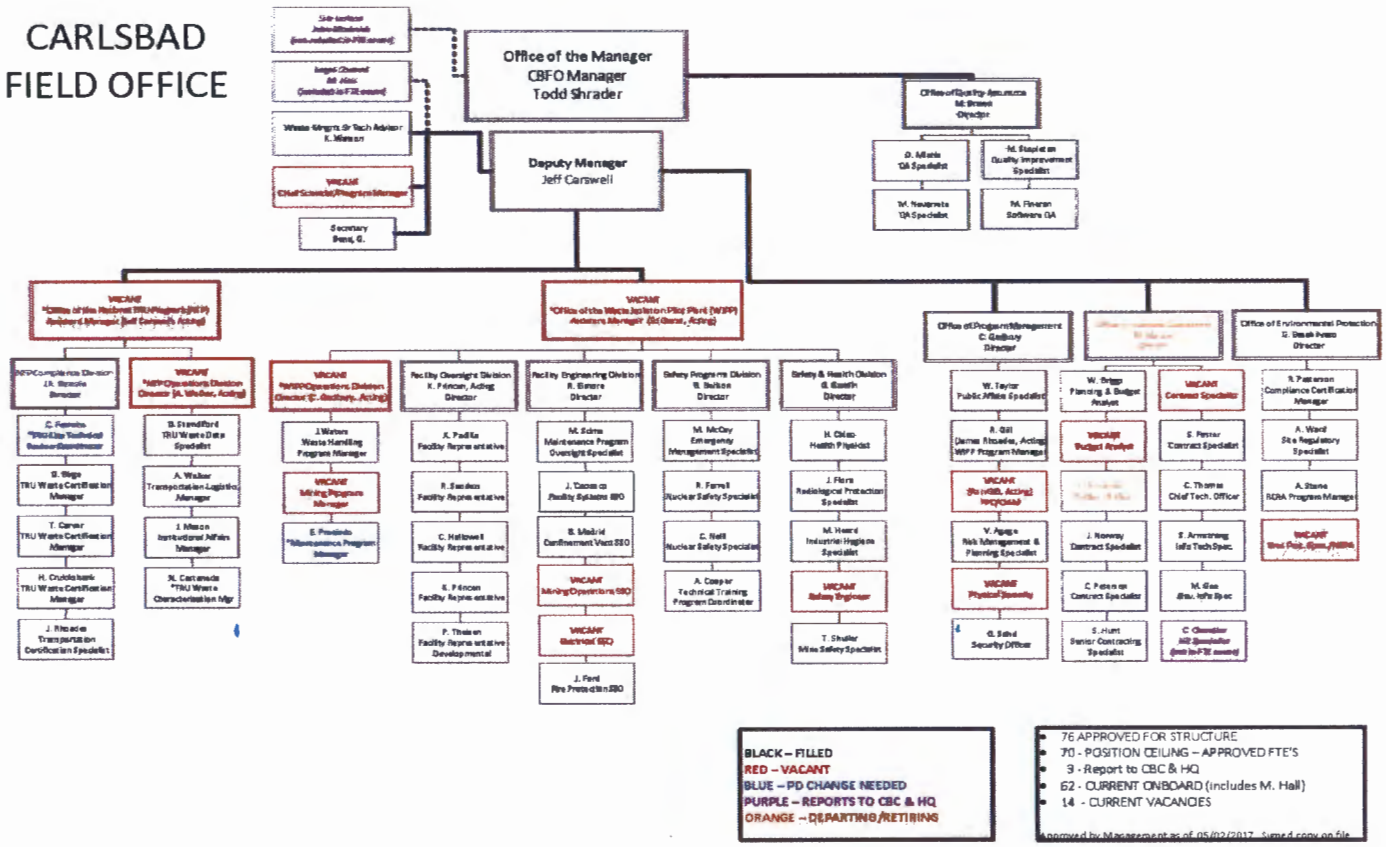
## ATTACHMENT H: CBFO ORGANIZATIONAL CHART



## ATTACHMENT I: AUDIT SCOPE

**Environmental Protection Agency Quality Assurance Audit:**
**Carlsbad Field Office's Quality Assurance Program**

**Organization Audited:** Department of Energy (DOE) Carlsbad Field Office (CBFO) Office of Quality Assurance (OQA)

**Organizations Notified:** DOE CBFO QA Organization, EPA Region 6, New Mexico Environmental Department, DOE HQ

**Audit Dates:** October 17–19, 2017

**Audit Location:** CBFO Quality Assurance Offices at the Skeen-Whitlock Building, Carlsbad, New Mexico

**Audit Purpose:** The purpose of this audit is to verify the proper establishment and implementation of selected aspects of the ASME Nuclear Quality Assurance (NQA-1-1989) for the CBFO Quality Assurance (QA) program, with regards to activities affecting the long-term isolation of transuranic waste within the Waste Isolation Pilot Plant (WIPP).

**Audit Scope:** The scope of this audit is the evaluation of the implementation of NQA-1-1989 Element Nos. 1, 2, 4, 7, 16 and 18. The audit will include the implementation activities performed by CBFO QA, as well as the activities performed by the CBFO Technical Assistance Contractor (CTAC) in direct support of the CBFO OQA.

**EPA Audit Team:**

- Jerry Ellis, U.S. EPA Audit Lead
- Kira Darlow, Lead QA Auditor (SC&A)
- Patrick Kelly, QA Auditor (SC&A)

**Proposed Audit Schedule:**

**Tuesday, October 17**

8:00 a.m.–8:30 a.m. Arrive at Skeen-Whitlock building and complete access requirements

8:30 a.m.–9:00 a.m. Audit Opening Meeting

9:00 a.m.–12:00 p.m. Observe SRS-CCP Recertification Audit (A-18-02) pre-audit conference in Conference Room T-224 and interview Audit Team Leader

## ATTACHMENT I: AUDIT SCOPE

**Environmental Protection Agency Quality Assurance Audit:**
**Carlsbad Field Office's Quality Assurance Program**

**Organization Audited:** Department of Energy (DOE) Carlsbad Field Office (CBFO) Office of Quality Assurance (OQA)

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**EPA Audit Team:**

- Jerry Ellis, U.S. EPA Audit Lead
- Kira Darlow, Lead QA Auditor (SC&A)
- Patrick Kelly, QA Auditor (SC&A)

**Proposed Audit Schedule:**

**Tuesday, October 17**

8:00 a.m.–8:30 a.m. Arrive at Skeen-Whitlock building and complete access requirements

8:30 a.m.–9:00 a.m. Audit Opening Meeting

9:00 a.m.–12:00 p.m. Observe SRS-CCP Recertification Audit (A-18-02) pre-audit conference in Conference Room T-224 and interview Audit Team Leader

12:00 p.m.–1:00 pm Lunch

1:00 p.m.–3:30 p.m. Observe SRS-CCP Recertification Audit subject matter interviews and review auditor qualifications

3:30 p.m.–4:00 p.m. EPA Audit Team Caucus

**Wednesday, October 18**

8:00 a.m.–8:30 a.m. Management Briefing (if requested)

8:30 a.m.–12:00 p.m. CBFO NQA-1 Elements 1 and 2, Organization and QA Program: personnel interviews*

12:00 p.m.–1:00 p.m. Lunch

1:00 p.m.–3:30 p.m. CBFO NQA-1 Elements 4 and 7, Procurement Document Control and Control of Purchased Items and Services, especially pertaining to services: personnel interviews*

3:30 p.m.–4:00 p.m. EPA Audit Team Caucus

**Thursday, October 19**

8:00 a.m.–8:30 a.m. Management Briefing (if requested)

8:30 a.m.–11:00 a.m. CBFO NQA-1 Element 16, Corrective Action: personnel interviews*

11:00 a.m.–12:00 p.m. Follow-up with CBFO as needed to resolve outstanding questions

12:00 p.m.–1:00 p.m. Lunch

1:00 p.m.–2:00 p.m. EPA Audit Team Caucus

2:00 p.m.–3:00 p.m. Observe SRS-CCP Recertification Audit post-audit conference in Conference Room T-224

3:00 p.m.–3:30 p.m. EPA Audit Team Caucus

3:30 p.m.–4:00 p.m. Audit Closing Meeting. EPA will provide a written list of concerns or findings at this meeting.

* Face-to-face interview are preferred, but interviews may be conducted by telephone if interviewees are not available onsite.

**Initial Document and Information Request:**

- CBFO procedures that implement NQA-1-1989, Elements 1, 2, 4, 7, 16 and 18, including:
  - Training and qualification procedures, including procedures that address general training and qualification and training and qualification of audit, inspection and test, and nondestructive examination personnel, as applicable
  - QA grading procedures

  - Corrective action procedures
  - Audit and surveillance procedures
  - Procurement procedures
- List of internal audits and surveillances performed by CBFO/CTAC QA from 2014–present, indicating the status of the final report
- Current CBFO assessment schedule
- List of Quality Level-1(QL-1) procurement activities for 2014–present
- List of non-conformances subject to corrective action for the past 12 months
- List of corrective actions still open for more than 12 months
- Corrective action trend reports
- Any program description documents
- Documents describing interfaces with other organizations (internal and external) responsible for completing QA activities
- Key position descriptions
- Audit plan and checklists or criteria that will be used for CBFO Audit A-18-02
- Qualification and training documentation for auditors, lead auditor, and technical specialists identified in the audit plan for CBFO Audit A-18-02
- Report for CBFO Audit A-18-02 (when available)
- Written replies from SRS-CCP regarding audit report for CBFO Audit A-18-02, if necessary
- Record of completion of corrective action associated with CBFO Audit A-18-02, if necessary

ATTACHMENT J: DESCRIPTIONS OF NQA-1 BASIC REQUIREMENTS (ELEMENTS)

NQA-1 Element 1, *Organization,* is properly established in Section QAPD-2.1.1, titled "Organization", of Appendix QAPD. CBFO's organization is structured so that operational organizations performing the work are responsible for achieving quality. CBFO's QA Organization has the authority and organizational freedom to properly verify the achievement of quality. CBFO's requirement for *Organization* is established, and the organizational structure is defined. The responsibilities and authority of the CBFO QA Manager are described.

NQA-1 Element 2, *Quality Assurance Program*, is properly established in Table QAPD-1, titled "QA Program Documents", and in Sections QAPD-2.1.2 through QAPD-2.1.2.4. The referenced table lists the source documents used for planning and maintaining the QAPD, and the NQA standards are listed. Section QAPD-2.1.2 identifies items and activities to which the QAPD applies. CBFO is required to plan work, provide for personnel training and qualification. And, for compliance with NQA-3-1989, CBFO will provide for management assessments.

NQA-1 Element 3, *Design Control*, is properly established in Section QAPD-3.2, titled "Design Control." CBFO's QA Organization requires that design work, including changes, incorporates appropriate controls and requirements such as general design criteria, design bases, and control of inputs. Design interfaces must be identified and controlled. The adequacy of design products must be verified by individuals or groups independent from those who performed the work. Verification must be completed before approval and implementation of the design. The control of design activities also includes design reviews and qualification testing.

NQA-1 Element 4, *Procurement Document Control,* is properly established in Section QAPD-3.3.4, titled "Procurement Document Requirements." CBFO's QA Organization requires that procurement documents address the scope of work, technical requirements, design bases, appropriate codes, standards, regulations, procedures, instructions, tests, inspections, hold points, acceptance criteria, and documentation requirements. Procurement documents must be reviewed to verify that the documents include appropriate provisions for ensuring that items and services meet the prescribed requirements. These procurement documents must be reviewed by QA personnel. The reviewers are required to have access to pertinent information and an adequate understanding of the requirements and scope of the procurement.

NQA-1 Element 5, *Instructions, Procedures, and Drawings*, is properly established in Section QAPD-3.1.2, titled "Implementing Procedures." CBFO's QA Organization requires that activities affecting quality are prescribed by and performed in accordance with the appropriate established, documented, and approved instructions, procedures, or drawings. Instructions, procedures, and drawings must be developed, reviewed, and approved by technically competent personnel. Each of the program participants must develop implementing documents that address the quality activities applicable to his or her QA program requirements and work scope.

NQA-1 Element 6, *Document Control,* is properly established in Section QAPD-2.4, titled "Documents." CBFO's QA Organization requires that documents that specify quality requirements or prescribe activities affecting quality, such as instructions, procedures, drawings, test plans, and management plans, are controlled to assure that the correct documents are being employed. Controlled documents must be reviewed by competent personnel, using specified criteria for adequacy, correctness, and completeness before approval and issuance. Review comment documentation must be maintained by the originating organization. Responsibilities for document preparation must be specified and the documents must be controlled during the preparation, review, approval, issuance, use, and revision processes.

NQA-1 Element 7, *Control of Purchased Items and Services*, is properly established in Section QAPD Sections 3.3.2, 3.3.6, and 3.3.7. CBFO's QA Organization requires that controls must be established to ensure that procured items and services meet performance specifications. Prospective suppliers must be evaluated and selected on the basis of documented criteria. Procurement controls must be in place to ensure that approved suppliers continue to provide acceptable items and services.

NQA-1 Element 8, *Identification and Control of Items*, is properly established in Section QAPD-3.1.3, titled "Item Identification and Control." CBFO's QA Organization requires that processes must be used to identify, control, and maintain items from receipt through installation and end-use. Item identification must ensure the appropriate traceability as specified in design documents, codes, standards, specifications, and implementing procedures. An identification marking must be placed on the item or in documents traceable to the item. Acceptable methods and materials for characteristics and markings must be prescribed, and the authority for applying and removing status indicators and markings must also be specified.

NQA-1 Element 9, *Control of Processes*, is properly established in Section QAPD-3.1.4, titled "Special Processes." CBFO's QA Organization requires that work processes must be performed in accordance with established, approved, and documented technical standards and administrative controls. Work must be planned, authorized, and performed under controlled conditions using approved instructions, procedures, drawings, or other appropriate means. Implementing procedures must be developed, reviewed, and approved by qualified and competent personnel. Personnel performing work must be responsible for complying with appropriate instructions.

NQA-1 Element 10, *Inspections*, is properly established in Section QAPD-3.4.1, QAPD-3.4.3.6, and QAPD-3.4. CBFO's QA Organization requires inspections to determine acceptance or rejection of an item or activity. Inspection documentation required of program participants includes:

- approved implementing procedures;
- identification of the items and processes to be inspected, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, and any hold points;
- the acceptance of items and processes by qualified and authorized persons;
- identification of any measuring and test equipment used, including the equipment.

NQA-1 Element 11, *Test Control*, is properly established in Sections QAPD-3.4 and QAPD-7.6.2.4. (Software testing is established in Section 7.0 of the Appendix QAPD and will be addressed below under the establishment of NQA-2a-1990) CBFO's QA Organization requires tests to determine the capability of an item to meet specified requirements by subjecting the item to a set of defined operating conditions. Test planning is required and includes:

- identification of the procedures and related requirements documents used to control and perform the test (for example, test plans);
- identification of the item to be tested, test requirements, and acceptance criteria;
- identification of the measuring and test equipment (M&TE) including the type, range, accuracy, and tolerance;

- test prerequisites and provisions to ensure that all test requirements and objectives have been met;
- any designated hold points; and
- recording methods used to collect and record the data.

NQA-1 Element 12, *Control of Measuring and Test Equipment*, is properly established in Section QAPD-3.4.6. CBFO's QA Organization requires the use of control systems for measuring and test equipment to ensure that suspect and out-of-tolerance equipment are not used.

NQA-1 Element 13, *Handling, Storage, and Shipping*, is properly established in Section QAPD-3.1.5. Handling, storage, cleaning, packaging, shipping, and preservation of items must be controlled to prevent damage or loss and to minimize deterioration.

NQA-1 Element 14, *Inspection, Test, and Operating Status*, is properly established in Section QAPD-3.1.3. Status indicators must be employed to help prevent inadvertent installation, use, or operation of items that have not passed the required inspections or tests. Only authorized persons can apply and remove status indicators on items, as appropriate. The specific status indicators, their use, and the authority to apply or remove them are delineated in applicable QA plans or implementing procedures

NQA-1 Element 15, *Control of Nonconforming Items*, is properly established in *Section QAPD-2.3,* titled "Nonconformances", and in Section QAPD-2.3.2.2, titled "Identifying Nonconforming Items and Data." Items that do not conform to specified requirements must be controlled to prevent their installation, use, or operation before correction. Nonconforming items can be identified at any time by anyone

NQA-1 Element 16, *Corrective Action*, is properly established in Sections QAPD-2.3.3, 2.3.3.4, 2.3.3.5, and 2.3.3.7. "Corrective actions" are measures that are taken to rectify a condition that is adverse to quality and, where necessary, to preclude recurrence. Conditions adverse to quality must be evaluated, the appropriate corrective actions must be defined and implemented, and the completion and effectiveness of the corrective action must be verified. If the condition adverse to quality is determined to be significant, corrective action is identified, investigative action is taken, the root cause is determined, and appropriate actions are taken to preclude recurrence. A significant condition adverse to quality includes a condition, which if uncorrected, could have a bad effect on waste isolation. When appropriate, further work on the item, activity, or process must be halted until the appropriate actions have been taken and verified.

NQA-1 Element 17, *Quality Assurance Records*, is properly established in Section QAPD-2.5, titled "Records." CBFO's QA Organization requires that records must be specified, prepared, reviewed, approved, maintained, and disposed of in accordance with the CBFO QAPD. Records provide evidence of quality achievement and evidence that the QA program has been properly implemented. The records management system is documented in appropriate QA plans and implementing procedures. The generation, classification, indexing, and retention of QA records are controlled in accordance with appropriate plans and records-related procedures.

NQA-1 Element 18, *Audits*, is properly established in Section QAPD-4.2.2, titled "Audits." Audits verify that all of the WIPP's QA programs comply with the requirement of the NQA standards. The management and control of audits are documented in QA plans or implementing procedures.