



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



MAR 10 2016

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

MAR 10 2016

Dear Mr. Brown:

The U.S. Environmental Protection Agency conducted a quality assurance audit of the Nuclear Waste Partnership (NWP) quality assurance (QA) program. The EPA conducted this audit remotely on August 6–September 24, 2015. The purpose of the audit was to verify implementation of NWP's QA program relative to the requirements of American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1989, "Quality Assurance Program Requirements for Nuclear Facilities."

During this audit, the EPA audit team reviewed documents and procedures provided by NWP and discussed these documents and procedures with applicable NWP personnel via teleconference. The EPA QA auditors evaluated the NWP 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 4, "Procurement Document Control."
- Element 5, "Instruction, Procedures and Drawings."
- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 9, "Control of Processes."
- Element 10, "Inspection."
- Element 12, "Control of Measuring and Test Equipment."
- Element 18, "Audits."

Despite repeated requests for information, NWP was unable to provide sufficient detail regarding the implementing procedures for the EPA to be able to complete all of the audit checklists within the audit period. Therefore, the EPA is limiting the scope of this adequacy determination to incorporation of the NQA-1-1989 elements within the NWP QAPD. The EPA will revisit these NQA-1-1989 elements and reach a conclusion regarding compliance of NWP's implementing procedures with the ASME NQA-1-1989 elements listed above during a future audit.

During the audit, the EPA audit team identified four concerns requiring responses regarding the incorporation of the ASME NQA-1-1989 requirements into the NWP QA Program Document (QAPD). The concerns are discussed in section 7.0 of this report and the issue tracking forms are



included in Attachments A through D. Attachment F summarizes NWP responses to the concerns. As part of the concern resolution, NWP committed to make three revisions to the NWP QAPD. The EPA considers the concerns closed.

Based on this audit, the EPA audit team determined that after revision, the NWP QAPD will adequately incorporate the NQA-1-1989 elements listed above. EPA will verify implementation of the concern resolutions (i.e., revision of the NWP QAPD) during a future audit.

If you have any questions regarding this QA audit report, please contact Lindsey Bender at (202) 343-9479 or bender.lindsey@epa.gov.

Sincerely,



for Tom Peake
Director
Center for Waste Management and Regulations

Enclosure

cc: Electronic Distribution
Todd Shrader, CBFO
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Ricardo Maestas, NMED
Raymond Lee, EPA HQ
Nick Stone, EPA Region 6
Alton Harris, DOE HQ
Site Documents

DOCKET NO: A-98-49; II-A1-123
EPA AIR E-DOCKET NO: EPA-HQ-OAR-2001-0012-0465

**EPA REMOTE AUDIT OF THE NUCLEAR WASTE PARTNERSHIP
QUALITY ASSURANCE PROGRAM**

AUGUST 6–SEPTEMBER 24, 2015

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

MARCH 2016

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Attachment D	EPA Issue No. NWP-QA-2015-04CR
Attachment E	Summary of Questions and Resolutions Regarding the CBFO Implementing Procedures
Attachment F	Summary of Concern Resolutions

ACRONYMS AND ABBREVIATIONS

§	section
ASME	American Society of Mechanical Engineers
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
EPA	U.S. Environmental Protection Agency
EPA/DC	Environmental Protection Agency Docket Center
NQA	nuclear quality assurance
NWP	Nuclear Waste Partnership
QA	quality assurance
QAPD	Quality Assurance Program Document
TRU	transuranic
WIPP	Waste Isolation Pilot Plant
WJC West	William Jefferson Clinton West

1.0 EXECUTIVE SUMMARY

This report presents results of the U.S. Environmental Protection Agency audit of the Nuclear Waste Partnership (NWP) quality assurance (QA) program. EPA conducted this audit remotely on August 6–September 24, 2015. The purpose of the audit was to verify implementation of NWP’s QA program relative to the requirements of American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1989,¹ “Quality Assurance Program Requirements for Nuclear Facilities.” NWP QA 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 standard. NWP is the Department of Energy’s (DOE’s) management and operations contractor for the Waste Isolation Pilot Plant (WIPP). The Central Characterization Program (CCP), a subset of NWP, is responsible for characterization of transuranic (TRU) wastes at most of the DOE TRU waste generator sites.

During this audit, the EPA audit team reviewed documents and procedures provided by NWP and discussed these documents and procedures with applicable NWP personnel via teleconference. EPA QA auditors evaluated the NWP 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 4, “Procurement Document Control.”
- Element 5, “Instruction, Procedures and Drawings.”
- Element 6, “Document Control.”
- Element 7, “Control of Purchased Items and Services.”
- Element 9, “Control of Processes.”
- Element 10, “Inspection.”
- Element 12, “Control of Measuring and Test Equipment.”
- Element 18, “Audits.”

Despite repeated requests for information, NWP was unable to provide sufficient detail regarding the implementing procedures for EPA to be able to complete all of the audit checklists within the audit period. Therefore, EPA is limiting the scope of this adequacy determination to the NWP QA Program Document (QAPD). EPA will revisit these NQA-1-1989 elements and reach a conclusion regarding compliance of NWP’s implementing procedures with the ASME NQA-1-1989 elements listed above during a future audit.

During the audit, the EPA audit team identified four concerns requiring responses regarding the incorporation of the ASME NQA-1-1989 requirements into the NWP QAPD. The concerns are discussed in section 7.0 of this report and the issue tracking forms are included in Attachments A through D. A summary of the letter, email and discussions on how NWP responded to the concerns on November 9 and 23, 2015, and December 14, 2015 is included in Attachments F. As part of the concern resolution, NWP committed to make three revisions to the NWP QAPD. Based on this audit, the EPA audit team determined that after revision, the NWP QAPD will

¹ 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.

adequately incorporate the NQA-1-1989 elements listed above. EPA considers the concerns closed. EPA will verify implementation of the concern resolutions (i.e., revision of the NWP QAPD) during a future audit. Again, the revised scope of this audit determination is limited to incorporation of the NQA-1-1989 elements within the NWP QAPD. EPA will audit inclusion of the NQA-1-1989 elements within the NWP implementing procedures and implementation of NQA-1-1989 within the NWP QA program during future audits.

This report documents these audit activities. This information will be provided through EPA's Electronic Docket (via regulations.gov) and the official Air Docket, in accordance with 40 CFR 194.22 (a)(1). EPA's Air Docket A-98-49 is located at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), William Jefferson Clinton West (WJC West), Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004.

2.0 BACKGROUND

2.1 Regulatory Background

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

1. ASME NQA-1-1989.
2. ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989.
3. 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 EPA with the authority to conduct audits to verify the proper establishment and implementation of QA programs for the WIPP.

2.2 Organizational Background

The Carlsbad Field Office (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 CBFO 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."

NWP is DOE's contractor that manages and operates the WIPP. NWP's CCP contracts with most of the generator sites to perform TRU waste characterization activities at the sites. The NWP QA program supports all NWP activities, including WIPP site operations and CCP waste characterization activities.

NWP performs all activities supporting the WIPP under the NWP Quality Assurance Program

² Quality Assurance Program Document, U.S. Department of Energy Carlsbad Field Office, DOE/CBFO-94-1012, Revision 12, June 12, 2015.

Document (NWP QAPD),³ which incorporates the requirements of NQA-1-1989 and the CBFO QAPD.

3.0 PURPOSE AND SCOPE

The purpose of this remote EPA audit was to verify that the NWP QA program continues to properly implement selected elements of ASME NQA-1-1989. The scope of this remote audit was the evaluation of the incorporation and flow-down of the ASME NQA-1-1989 Element Nos. 4, 5, 6, 7, 9, 10, 12 and 18 into NWP's QAPD and implementing procedures. The revised scope of this audit determination is limited to incorporation of the NQA-1-1989 elements within the NWP QAPD. EPA will audit inclusion of the NQA-1-1989 elements within the NWP implementing procedures and implementation of NQA-1-1989 within the NWP QA program during future audits.

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 AUDIT PARTICIPANTS

The audit team consisted of one EPA employee and three 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
Lindsey Bender	Lead QA Auditor and Audit Team Leader	EPA
Kira Darlow	QA Auditor	SC&A, Inc.
Dorothy Gill	QA Auditor	SC&A, Inc.
Kara Beronja	QA Auditor-in-Training	SC&A, Inc.

Prior to this audit, Lindsey Bender (EPA) evaluated the qualifications of the SC&A, Inc. auditors listed in Table 1. Ms. Bender found that the SC&A, Inc. auditors were qualified based on their:

³ Quality Assurance Program Document, Nuclear Waste Partnership LLC, WP 13-1, Revision 35, November 12, 2014.

- Working knowledge and understanding of the NQA standards.
- Training.
- On-the-job training.

Ms. Beronja was an auditor-in-training during this audit; her qualifications as a QA auditor will be addressed in a subsequent EPA QA audit report.

Table 2 lists all personnel who participated in this audit.

Table 2. Personnel Participating in Audit Meetings

Name	Affiliation and Title/Position	Entrance Meeting	Conference Calls	Exit Meeting
Val Cannon	NWP, Assurance Programs Manager	✓	✓	✓
Bill Allen	NWP, QA	✓	✓	✓
Ron Kuhn	NWP, QA Programs Manager	✓	✓	
Cindy Nesser	NWP, QA		✓	✓
Ed Ater	NWP, QA		✓	✓
Berry Pace	CBFO Technical Assistance Contractor (CTAC), QA Programs Manager	✓		
Dennis Miehl	CBFO, Senior QA Specialist	✓		✓
Martin Navarrete	CBFO, Senior QA Specialist	✓	✓	
Michael R. Brown	CBFO, QA Director	✓		✓
Judith Stewart	CTAC, Regulatory Assurance Manager	✓	✓	✓
Jim Schutz	CTAC		✓	

6.0 PERFORMANCE OF THE AUDIT

The EPA audit team reviewed records provided by NWP and asked clarifying questions of NWP personnel during scheduled teleconferences to evaluate implementation of the requirements in select elements of ASME NQA-1-1989. NWP QA is responsible for maintaining the NWP QAPD and ensuring that all NQA-1-1989 requirements flow down into the NWP QAPD. Therefore, the EPA audit team reviewed Revision 35 of the NWP QAPD to evaluate incorporation of the requirements in ASME NQA-1-1989 for the eight elements listed below, using NQA-1-1989 checklists. The checklists will be made available to the public through EPA's Electronic Docket (via regulations.gov) and EPA's Air Docket A-98-49, located at the Air and Radiation Docket in the EPA/DC WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004, as mentioned above.

- Element 4, "Procurement Document Control."
- Element 5, "Instruction, Procedures and Drawings."
- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 9, "Control of Processes."
- Element 10, "Inspection."
- Element 12, "Control of Measuring and Test Equipment."
- Element 18, "Audits."

EPA also attempted to review NWP's implementing procedures for inclusion of the eight NQA-1-1989 elements listed above. However, despite repeated requests for information, NWP was unable to provide sufficient detail regarding the implementing procedures for EPA to be able to complete all of the audit checklists within the audit period. Therefore, EPA is limiting the scope of this adequacy determination to the NWP QAPD. EPA will revisit these NQA-1-1989 elements and reach a conclusion regarding compliance of NWP's implementing procedures with the ASME NQA-1-1989 elements listed above during a future audit.

EPA identified several questions regarding apparent discrepancies between the NWP QAPD and the ASME NQA-1-1989 standard. The EPA audit team and NWP QA personnel had several discussions during the audit to resolve these questions. Resolutions included identification of the required text and reasonable explanations for maintaining the different text (e.g., the different text might be more restrictive than the requirement in the standard). A summary of the questions and resolutions is in Attachment E. There were also a few questions that NWP and EPA could not resolve. EPA identified four concerns requiring responses as a result of this audit (see section 7.0).

7.0 FINDINGS AND CONCERNS

The EPA audit team did not identify any findings relative to the NQA-1-1989 elements discussed above. EPA identified four concerns requiring responses.

EPA Issue No. NWP-QA-2015-01CR (Attachment A): ASME NQA-1-1989, Supplement 7S-1, section 8.1, General, last sentence states: "Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use." NWP indicated that this requirement is implemented in the NWP QAPD in section 2.3.4.1: "The extent of source verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, as well as the supplier's quality of performance... B] Documented evidence of acceptance of source-verified items or services shall be furnished to the party receiving the item, the requisitioner, and the supplier." NWP also stated that "the determination of necessity for documentation to be available at the nuclear facility prior to installation or use begins with the graded approach process." The graded approach as described in section 1.1.8.1 states that it is a "is a systematic determination by which items, services, and processes are analyzed to determine the extent to which the QA requirements of this QAPD are applied to each item, service, or process." Therefore, the QA requirements have to be included in the QAPD before the grading approach can determine whether or not they apply. The text quoted from NWP does not fully address the NQA-1-1989 requirement as it does not provide for the documentary evidence to be available at the nuclear facility and it only addresses documented evidence of source verifications.

NWP responded adequately (Attachment F) by committing to revise NWP QAPD section 2.3.4 to include, "Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use. The nuclear facility site may include all WIPP facility locations, including records archive locations and generator sites." EPA considers this concern closed.

EPA Issue No. NWP-QA-2015-02CR (Attachment B): ASME NQA-1-1989, Supplement 7S-1, section 9, Control of Supplier Nonconformances, second paragraph, bulleted list item (c) states: “These methods [for disposition of items and services] shall contain provision for (a) through (e) below... (c) Purchaser disposition of Supplier recommendation.” The applicable section of the NWP QAPD, section 2.3.5, paragraph B, states: “NWP shall evaluate and approve the supplier's recommended disposition.” NWP stated that they very often do not approve the supplier's recommended disposition as initially written and that the procedures allow for NWP personnel to disapprove the recommended disposition. However, the QAPD does not seem to allow for any outcome other than approval of the supplier's recommended disposition. EPA does not have any reason to doubt that NWP personnel have the authority to reject supplier-recommended dispositions according to the implementing procedures. However, the QAPD is the upper-tier document and should also allow for NWP personnel to reject the supplier-recommended disposition. The QAPD does not need to include the exact language as written in NQA-1-1989, but it cannot limit the applicability of NQA-1-1989.

NWP responded adequately (Attachment F) by committing to revise the NWP QAPD, section 2.3.5, paragraph B, to state: “NWP shall evaluate and approve or disapprove the supplier's recommended disposition.” EPA considers this concern closed.

EPA Issue No. NWP-QA-2015-03CR (Attachment C): ASME NQA-1-1989, Supplement 18S-1, section 4, Performance, second sentence, states: “Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity.” The applicable section of the NWP QAPD, section 3.2.2, paragraph A, states: “Independent assessments shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.” NWP explained that they used “shall be scheduled to begin” in place of “shall begin” to meet the requirement to schedule audits. NWP was unable to point to any text in the QAPD that would require NWP to perform work (i.e., audits) as scheduled. EPA does not question NWP's intent to perform the audits as scheduled. However, EPA needs to see documented requirements at the QAPD level to actually conduct the audits instead of just scheduling the audits.

NWP responded adequately (Attachment F) by pointing out language in the NWP QAPD, Sections 3.2 and Section 3.2.5, that is required to implement the NQA-1 requirements for performing audits (the work). Specifically, Section 3.2 first sentence reads: “A process of planned periodic independent assessments shall be established and implemented.” Section 3.2, 2nd paragraph reads: “Independent assessments shall include reviews, inspections, testing, checking, conducting surveillances, and auditing or otherwise determining whether items, processes, or services meet specified requirements.” Section 3.2.5 provides further requirements for Performing Independent Assessments (implementing the work) and provides amplified requirements on the methods to be used and the objective to be achieved. EPA considers this concern closed.

EPA Issue No. NWP-QA-2015-04CR (Attachment D): ASME NQA-1-1989, Supplement 4S-1, section 2.6, Nonconformances, states: “The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.” ASME NQA-1-1989, Supplement 7S-1, section 9, Control of Supplier Nonconformances, states: “The Purchaser

and Supplier shall establish and document methods for disposition of items and services that do not meet procurement documentation requirements.” The applicable section of the NWP QAPD, section 2.3.2.1, paragraph F, states: “When required, purchaser requirements for the supplier to report nonconformances and requirements for NWP approval for the disposition of nonconformances shall be established.” The conditional statement “when required” does not meet the NQA-1 absolute requirement “shall” and does not fully meet the NQA-1 requirements for Supplement 7S-1, section 9.

NWP responded adequately (Attachment F) by committing to revise NWP QAPD, section 2.3.2.1, paragraph F, to remove the “When required” component. EPA considers this concern closed.

8.0 CONCLUSIONS

The EPA audit team reviewed procedures and documents and interviewed personnel via telephone to determine the continued compliance of the NWP QA program with select elements of ASME NQA-1-1989. EPA determined that after revision, the NWP QAPD will comply with the NQA-1-1989 elements listed above. EPA will revisit these NQA-1-1989 elements and reach a conclusion regarding compliance of NWP’s implementing procedures with the ASME NQA-1-1989 elements listed above during a future audit.

9.0 REFERENCES

NWP QAPD, Quality Assurance Program Document, Nuclear Waste Partnership LLC, WP 13-1, Revision 35, November 12, 2014

CCP-PO-002, CCP Transuranic Waste Certification Plan, Revision 27, May 31, 2013

CCP-QP-002, CCP Training and Qualification Plan, Revision 39, April 14, 2015

CCP-QP-010, CCP Document Preparation, Approval, and Control, Revision 25, November 19, 2014

CCP-QP-015, CCP Procurement, Revision 12, January 31, 2013

CCP-QP-016, CCP Control of Measuring and Testing Equipment, Revision 21, July 29, 2015

CCP-QP-026, CCP Inspection Control, Revision 14, February 13, 2013

CCP-TP-053, CCP Standard Real-Time Radiography (RTR) Inspection Procedure, Revision 15, September 11, 2014

MC 1.2, Internal Audit, Revision 9, November 15, 2012

MP 1.34, NWP Contracts and Procurement Program, Revision 5, December 4, 2012

WP 09-CN3040, Commercial Grade Item Dedication, Revision 3, January 29, 2015

WP 10-AD3028, Calibration and Control of Measurement and Test Equipment, Revision 12, July 31, 2014

WP 10-AD3029, Calibration and Control of Monitoring and Data Collection Equipment, Revision 11, June 27, 2014

WP 10-AD3030, Calibration Label Application and Control, Revision 4, May 16, 2013

WP 10-WC3011, Work Control Process, Revision 34, April 13, 2015

WP 13-QA.03, Quality Assurance Independent Assessment Program, Revision 24, March 25, 2015

WP 13-QA.04, Quality Assurance Department Administrative Program, Revision 21, January 30, 2014

WP 13-QA1003, Quality Assurance Receipt/Source Inspections, Revision 26, July 29, 2013

WP 13-QA1006, Quality Assurance Plant Inspections, Revision 17, August 10, 2015

WP 13-QA3012, Supplier Evaluation/Qualification, Revision 22, February 26, 2015

WP 13-QA3020, Fabrication Oversight, Revision 8, March 6, 2015

WP 15-GM1002, Issues Management Processing of WIPP Forms, Revision 4, June 9, 2015

WP 15-PC3041, Approval/Variation Request Processing, Revision 10, December 2, 2013

WP 15-PC3605, Proposal, Competition, Identification, Selection, Evaluation, and Award, Revision 5, July 17, 2013

WP 15-PC3609, Preparation of Purchase Requisitions, Revision 28, August 27, 2014

WP 15-PS.01, Procedures Program, Revision 0, February 16, 2015

WP 15-PS3002, Controlled Document Processing, Revision 34, February 16, 2015

ATTACHMENT A

**EPA INSPECTION ISSUE TRACKING FORM,
ISSUE NO. NWP-QA-2015-01CR, FINAL**

Inspection No. QA-NWP-2015-1	Issue Number: NWP-QA-2015-01CR Date: September 24, 2015
Inspector: Dorothy Gill, Lindsey Bender Attachments? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Sample Size: 1 Population size (if known): 1
A. Description of Issue:	
<p>ASME NQA-1-1989, Supplement 7S-1, section 8.1, General, last sentence states: "Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use."</p> <p>NWP indicated that this requirement is implemented in the NWP QAPD in section 2.3.4.1: "The extent of source verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, as well as the supplier's quality of performance... B] Documented evidence of acceptance of source-verified items or services shall be furnished to the party receiving the item, the requisitioner, and the supplier." NWP also stated that "the determination of necessity for documentation to be available at the nuclear facility prior to installation or use begins with the graded approach process."</p> <p>The graded approach as described in section 1.1.8.1 states that it is a "is a systematic determination by which items, services, and processes are analyzed to determine the extent to which the QA requirements of this QAPD are applied to each item, service, or process." Therefore, the QA requirements have to be included in the QAPD before the grading approach can determine whether or not they apply. The text quoted from NWP does not fully address the NQA-1-1989 requirement as it does not provide for the documentary evidence to be available at the nuclear facility and it only addresses documented evidence of source verifications.</p>	
B. Regulatory Reference: 40 CFR 194.22(e)	
C. NQA-1-1989 Element(s): 7	
D. Discussed with: V. Cannon, C. Nesser, B. Allen, E. Ater, R. Kuhn	
E. Additional Comments: None	
F. Auditee Response Information:	
<p>Auditee Response Required? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Auditee Response Due Date: 10/29/2015</p>	

ATTACHMENT B

**EPA INSPECTION ISSUE TRACKING FORM,
ISSUE NO. NWP-QA-2015-02CR, FINAL**

Inspection No. QA-NWP-2015-1	Issue Number: NWP-QA-2015-02CR Date: September 24, 2015
Inspector: Dorothy Gill, Lindsey Bender Attachments? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Sample Size: 1 Population size (if known): 1
A. Description of Issue:	
<p>ASME NQA-1-1989, Supplement 7S-1, section 9, Control of Supplier Nonconformances, second paragraph, bulleted list item (c) states: "These methods [for disposition of items and services] shall contain provision for (a) through (e) below...(c) Purchaser disposition of Supplier recommendation."</p> <p>The applicable section of the NWP QAPD, section 2.3.5, paragraph B, states: "NWP shall evaluate and approve the supplier's recommended disposition."</p> <p>NWP stated that they very often do not approve the supplier's recommended disposition as initially written and that the procedures allow for NWP personnel to disapprove the recommended disposition. However, the QAPD does not seem to allow for any outcome other than approval of the supplier's recommended disposition. EPA does not have any reason to doubt that NWP personnel have the authority to reject supplier-recommended dispositions according to the implementing procedures. However, the QAPD is the upper-tier document and should also allow for NWP personnel to reject the supplier-recommended disposition. The QAPD does not need to include the exact language as written in NQA-1-1989, but it cannot limit the applicability of NQA-1-1989.</p>	
B. Regulatory Reference: 40 CFR 194.22(e)	
C. NQA-1-1989 Element(s): 7	
D. Discussed with: V. Cannon, C. Nesser, B. Allen, E. Ater, R. Kuhn	
E. Additional Comments: None	
F. Auditee Response Information:	
<p>Auditee Response Required? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Auditee Response Due Date: 10/29/2015</p>	

ATTACHMENT C

**EPA INSPECTION ISSUE TRACKING FORM,
ISSUE NO. NWP-QA-2015-03CR, FINAL**

Inspection No. QA-NWP-2015-1	Issue Number: NWP-QA-2015-03CR Date: September 24, 2015
Inspector: Kira Darlow, Lindsey Bender Attachments? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Sample Size: 1 Population size (if known): 1
A. Description of Issue:	
<p>ASME NQA-1-1989, Supplement 18S-1, section 4, Performance, second sentence, states: "Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity."</p> <p>The applicable section of the NWP QAPD, section 3.2.2, paragraph A, states: "Independent assessments shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work."</p> <p>NWP explained that they used "shall be scheduled to begin" in place of "shall begin" to meet the requirement to schedule audits. NWP was unable to point to any text in the QAPD that would require NWP to perform work (i.e., audits) as scheduled. EPA does not question NWP's intent to perform the audits as scheduled. However, EPA needs to see documented requirements at the QAPD level to actually conduct the audits instead of just scheduling the audits.</p>	
B. Regulatory Reference: 40 CFR 194.22(e)	
C. NQA-1-1989 Element(s): 18	
D. Discussed with: V. Cannon, C. Nesser, B. Allen, E. Ater, R. Kuhn	
E. Additional Comments: None	
F. Auditee Response Information:	
<p>Auditee Response Required? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO Auditee Response Due Date: 10/29/2015</p>	

ATTACHMENT D

**EPA INSPECTION ISSUE TRACKING FORM,
ISSUE NO. NWP-QA-2015-04CR, FINAL**

Inspection No. QA-NWP-2015-1	Issue Number: NWP-QA-2015-04CR Date: September 24, 2015
Inspector: Dorothy Gill, Lindsey Bender Attachments? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Sample Size: 1 Population size (if known): 1
A. Description of Issue:	
<p>ASME NQA-1-1989, Supplement 4S-1, section 2.6, Nonconformances, states: "The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances."</p> <p>ASME NQA-1-1989, Supplement 7S-1, section 9, Control of Supplier Nonconformances, states: "The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement documentation requirements."</p> <p>The applicable section of the NWP QAPD, section 2.3.2.1, paragraph F, states: "When required, purchaser requirements for the supplier to report nonconformances and requirements for NWP approval for the disposition of nonconformances shall be established."</p> <p>The conditional statement "when required" does not meet the NQA-1 absolute requirement "shall" and does not fully meet the NQA-1 requirements for Supplement 7S-1, section 9.</p>	
B. Regulatory Reference: 40 CFR 194.22(e)	
C. NQA-1-1989 Element(s): 4 and 7	
D. Discussed with: V. Cannon, C. Nesser, B. Allen, E. Ater, R. Kuhn	
E. Additional Comments: None	
F. Auditee Response Information:	
<p>Auditee Response Required? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Auditee Response Due Date: 10/29/2015</p>	

ATTACHMENT E

SUMMARY OF QUESTIONS AND RESOLUTIONS REGARDING THE NWP QAPD

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
1	7S-1, 3.1 Source Evaluation and Selection, 1st paragraph	The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.	Section 2.3.1.2, 1st paragraph: Supplier selection shall be based on an evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements.	Please comment on your reasoning for leaving out the "prior to award of contract" text.	NWP identified the requirement in §2.3.1.2 and §2.3.1.3 A and B. EPA agrees.
2	7S-1, 5 Supplier Performance Evaluation, last paragraph	These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for verification of quality achievement.		Please help us find this requirement in the QAPD.	NWP identified the requirement in §2.3. EPA agrees.
3	7S-1, 6 Control of Supplier Generated Documents	Supplier generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to assure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.		Please help us find this requirement in the QAPD.	NWP identified the requirement in §2.3.2.1 E. EPA agrees.
4	7S-1, 8.1 General, last sentence	Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use.		Please help us find this requirement in the QAPD.	See EPA Issue No. NWP-QA-2015-01CR

5	7S-1, 9 Control of Supplier Non-Conformances, second paragraph (a)	(a) evaluation of nonconforming items		Please help us find this requirement in the QAPD.	NWP identified the requirement in §2.3.5 B. EPA agrees.
6	7S-1, 9 Control of Supplier Non-Conformances, second paragraph (c)	Purchaser disposition of Supplier recommendation	Section 2.3.5.B: NWP shall evaluate and approve the supplier's recommended disposition	Please comment on your reasoning for not allowing for the possibility of the purchaser NOT accepting/approving the supplier's recommended disposition or help us find the requirement in the QAPD.	See EPA Issue No. NWP-QA-2015-02CR
7	Element 9, general			Please confirm or correct: "work" and "work processes" as used in the QAPD are interchangeable as they relate to the requirements of NQA-1-1989, Element 9.	NWP provided an explanation. EPA accepts NWP's explanation.
8	10S-1, 5.1 Inspection, first paragraph and 5.2.2	5.1: Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. 5.2.2: Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the concluded process or construction.	Section 2.4.2.3.A: Items in process shall be inspected as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be conducted when control is deemed inadequate using only one method.	Please comment on your reasoning for leaving out the construction-related language (i.e., "or under construction" in A and "or construction" in C).	NWP provided an explanation. EPA accepts NWP's explanation.
9	18S-1, 2 Scheduling, 1st sentence	Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities.		Please help us find this requirement in the QAPD.	NWP identified the requirement in §3, §3.2 and §4.1. EPA agrees.

10	18S-1, 4 Performance, 2nd sentence	Auditing <u>shall begin</u> as early in the life of the activity as practical and <u>shall be continued</u> at intervals consistent with the schedule for accomplishing the activity.	Section 3.2.2.A: Independent assessments <u>shall be scheduled to begin</u> as early in the life of the work as practical and <u>shall be scheduled to continue</u> at intervals consistent with the schedule for accomplishing the work.	Please comment on your reasoning for adding “be scheduled to” to each of the underlined sections of text.	See EPA Issue No. NWP-QA-2015-03CR
11	18S-1, 6 Response	Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.		Please help us find the requirement to make notifications “in writing” in the QAPD.	NWP identified the requirement in §3.2.7 and §1.3.4.1 B. EPA agrees.
12	4S-1, 2.6 Nonconformances	The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.	QAPD, section 2.3.2.1, F states “When required, purchaser requirements for the supplier to report nonconformances and requirements for NWP approval for the disposition of nonconformances shall be established.”	Please help us find this requirement in the QAPD. The conditional statement (“when required”) does not meet the NQA-1 absolute requirement (“shall”).	See EPA Issue No. NWP-QA-2015-04CR
13	7S-1, section 5, 2nd paragraph	Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.	Section 2.3 of the QAPD does not address starting activities as soon as practical	Please help us find this requirement in the QAPD.	NWP identified the requirement in §2.3.1.1. EPA agrees.
14	7S-1, section 5.2, 2nd paragraph	The Purchaser shall assure that his documentation is evaluated to determine the Supplier's quality assurance program effectiveness.		Please help us find this requirement in the QAPD.	NWP identified the requirement in §2.3.1.2 A, B and C. EPA agrees.

Attachment F: Summary of Concern Resolutions

NWP-QA-2015-01CR

ASME NQA-1-1989, Supplement 7S-1, section 8.1, General, last sentences states: “Where required by code, regulation or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to in stallion or use.”

Response: November 9, letter, November 23, email and discussion

Although the term “nuclear facility” is not specifically cited in the NWP QAPD, other terms such as “NWP”, the “site”, “the party” receiving the items, the “requisitioner”, and the purchaser” are all terms used to identify/infer organizationally or individually those entities comprising the WIPP nuclear facility. These terms are used throughout the four forms of NQA-1 allowable methods for acceptance of items and services and used throughout Section 2.3.4. These allowable methods also provide language for ensuring that the documentary evidence of conformance is available at the WIPP nuclear facility prior to installation or use.

EPA did not agree with this response and discussed this with NWP.

Second Response: December 14, 2015, email and discussion and email, accepted by EPA. Per our discussion, the following is the proposed change to our previously submitted corrective action plan to address EPA Issue Number NWP-QA-2015-01CR. Text to be added is shown in red.

2.3.4 Methods of Acceptance of Items and Services

Prior to offering an item or service for acceptance, the supplier shall verify that the item or service complies with the procurement requirements.

Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use. The nuclear facility site may include all WIPP facility locations, including records archive locations and generator sites.

NWP shall accept items and services by one or a combination of the following methods.

NWP-QA-2015-02CR

ASME NQA-1-1989, Supplement 7S-1, Section 9, Control of Supplier Nonconformances, second paragraph, bulleted list item (c) states: “These methods [for disposition of items and services] shall contain provision for (a) through (e) below...(c) Purchaser disposition of Supplier recommendation.”

Response: November 9, letter, November 23, email and discussion

The NWP QAPD, Section 2.3.5.B will be reworded as follow to add the term “disapprove” for a NWP disapproval of a supplier recommended disposition to a NCR.

“NWP shall evaluate and approve or **disapprove** the supplier’s recommended disposition.”

NWP-QA-2015-03CR

ASME NQA-1-1989, Supplement 18S-1, section 4, Performance, second sentence, states: “Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity.”

Response: November 9, letter, November 23, email and discussion

The NWP QAPD Section 3.2 provides the language required to implement the NQA-1 requirement for performing audits (the work). Specifically, Section 3.2 first sentence reads: "A process of planned periodic independent assessments shall be established and implemented." Section 3.2, 2nd paragraph reads: "Independent assessments shall include reviews, inspections, testing, checking, conducting surveillances, and auditing or otherwise determining whether items, processes, or services meet specified requirements." Section 3.2.5 provides further requirements for Performing Independent Assessments (implementing the work) and provides amplified requirements on the methods to be used and the objective to be achieved.

NWP-QA-2015-04CR

ASME NQA-1-1989, Supplement 4S-1, section 2.6, Nonconformances, states; "The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances."

ASME-1-1989, Supplement 7S-1, section 9, Control of Supplier Nonconformances, states: "The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement documentation requirements."

Response: November 9, letter, November 23, email and discussion

The NWP QAPD, Section 2.3.2.1.F will be reworded as follows to delete "When Required," to ensure NWP procurement documents always include the Purchaser's requirements for reporting and approving disposition of nonconformances.

"Purchaser requirements for the supplier to report nonconformances and requirements for NWP's approval of the disposition of nonconformances shall be established."