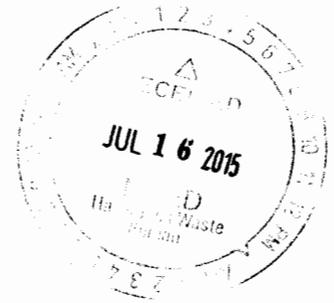




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



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

JUL 16 2015

OFFICE OF
AIR AND RADIATION

Dear Mr. Brown:

The U.S. Environmental Protection Agency conducted a remote Quality Assurance audit of the Department of Energy's (DOE's) Carlsbad Field Office (CBFO), Office of Quality Assurance (OQA) on January 6 –February 12, 2015. The purpose of the audit was to verify implementation of CBFO'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." CBFO 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.

During this audit, the EPA audit team reviewed documents and records provided by CBFO and interviewed applicable CBFO personnel in Carlsbad, New Mexico by phone. 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 3, "Design Control."
- Element 4, "Procurement Document Control."
- Element 5, "Instruction, Procedures and Drawings."
- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 8, "Identification and Control of Items."
- Element 9, "Control of Processes."
- Element 10, "Inspection."
- Element 11, "Test Control."
- Element 12, "Control of Measuring and Test Equipment."
- Element 13, "Handling, Storage, and Shipping."
- Element 14, "Inspection, Test, and Operating Status."
- Element 15, "Control of Nonconforming Items."

Within the scope of this audit, only NQA-1-1989, Element 4, "Procurement Document Control,"

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.



Element 5, "Instruction, Procedures and Drawings," Element 6, "Document Control," and Element 7, "Control of Purchased Items and Services" are applicable to work currently performed by CBFO.

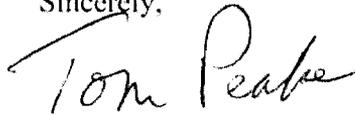
CBFO OQA is also responsible for maintaining the *Quality Assurance Program Document (QAPD)*, U.S. Department of Energy Carlsbad Field Office, DOE/CBFO-94-1012, Revision 11, June 2010. Therefore, the EPA audit team reviewed Revision 11 of the QAPD to evaluate implementation of the requirements in ASME NQA-1-1989 for the 13 elements listed above, using NQA-1-1989 checklists and to ensure that all NQA-1-1989 requirements flow down into the QAPD.

The EPA audit team and CBFO OQA personnel resolved review questions. This included commitments by CBFO OQA to revise the text in the next revision of the QAPD or applicable procedure. Summaries of the questions and resolutions pertaining to the QAPD and to the implementing procedures are included in Attachments A and B of the report, respectively. EPA reviewed a draft of the QAPD, Revision 12, in March 2015 and found that it included all of the changes that EPA had requested from CBFO.

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.

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

Sincerely,



Tom Peake, Director
Center for Waste Management and Regulations

Enclosure

cc: Electronic Distribution
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Site Documents

DOCKET NO: A-98-49; II-A1-120
EPA AIR EDOCKET NO: EPA-HQ-OAR-2001-0012-0453

**EPA REMOTE AUDIT OF THE CARLSBAD FIELD OFFICE
QUALITY ASSURANCE PROGRAM**

JANUARY 6–FEBRUARY 12, 2015

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

JULY 2015

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ATTACHMENTS

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Attachment B	Summary of Comments, Questions and Resolutions Regarding the CBFO Implementing Procedures

ACRONYMS AND ABBREVIATIONS

§	section
ASME	American Society of Mechanical Engineers
CBFO	Carlsbad Field Office
CFR	Code of Federal Regulations
CTAC	Carlsbad Field Office Technical Assistance Contractor
DEAR	Department of Energy Acquisition Regulation
DOE	U.S. Department of Energy
DRR	Document Review Record
EPA	U.S. Environmental Protection Agency
EPA/DC	Environmental Protection Agency Docket Center
FAR	Federal Acquisition Regulation
M&TE	measuring and test equipment
MP	Management Procedure
NQA	nuclear quality assurance
OQA	Office of Quality Assurance
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 (EPA) audit of the Department of Energy's (DOE's) Carlsbad Field Office (CBFO) quality assurance (QA) program. EPA conducted this audit remotely on January 6–February 12, 2015. The purpose of the audit was to verify implementation of CBFO'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." CBFO 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.

During this audit, the EPA audit team reviewed documents and records provided by CBFO and discussed these documents and records with applicable CBFO personnel via teleconference. 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 3, "Design Control."
- Element 4, "Procurement Document Control."
- Element 5, "Instruction, Procedures and Drawings."
- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
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- Element 12, "Control of Measuring and Test Equipment."
- Element 13, "Handling, Storage, and Shipping."
- Element 14, "Inspection, Test, and Operating Status."
- Element 15, "Control of Nonconforming Items."

Based on this audit, the EPA audit team determined that the CBFO QA program continues to comply with these NQA-1-1989 elements. EPA did not identify any nonconformances in CBFO's QA program relative to the requirements of ASME NQA-1-1989. 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 Title 40 of the Code of Federal Regulations [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), WJC West, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004.

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.

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

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.”

The CBFO Office of QA (OQA) is responsible for maintaining the QAPD and ensuring that all of the ASME NQA-1-1989 requirements are reflected in the QAPD. All of the organizations and contractors performing work that impacts the long-term isolation of TRU waste at WIPP are required to perform these activities in conformance with the CBFO QAPD.

3.0 PURPOSE AND SCOPE

The purpose of this remote 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 audit was the evaluation of implementation of NQA-1-1989 Element Nos. 3–15. The audit was initially intended to include the implementation activities performed by CBFO QA and the activities performed by the CBFO Technical Assistance Contractor (CTAC) in direct support of the CBFO OQA. However, after starting the audit, EPA determined that the audit scope should be limited to verifying compliance of the CBFO QAPD and select CBFO quality-affecting procedures to compare with the ASME NQA-1-1989 standard.

² Quality Assurance Program Document, U.S. Department of Energy Carlsbad Field Office, DOE/CBFO-94-1012, Revision 11, June 2010.

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	EPA
Kira Darlow	QA Auditor	SC&A, Inc.
Patrick Kelly	QA Auditor	SC&A, Inc.
Karl Lindblad	QA Auditor	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:

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

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
Berry Pace	CTAC, QA Programs Manager	✓	✓	✓
Dennis Miehl	CBFO, Senior QA Specialist	✓	✓	✓
Martin Navarrete	CBFO, Senior QA Specialist	✓	✓	
Michael R. Brown	CBFO, QA Director	✓	✓	✓
Porf Martinez	CTAC, Regulatory Assurance Manager	✓		
Randall Allen	CTAC - Audits & Assessments Manager	✓	✓	✓
Dana C. Bryson	CBFO, Deputy Manager			✓

6.0 PERFORMANCE OF THE AUDIT

The EPA audit team reviewed records provided by CBFO and asked clarifying questions of CBFO personnel during scheduled teleconferences to evaluate implementation of the requirements in ASME NQA-1-1989. CBFO stated, and EPA concurred, that within the scope of this audit, only NQA-1-1989, Element 4, "Procurement Document Control," Element 5, "Instruction, Procedures and Drawings," Element 6, "Document Control," and Element 7, "Control of Purchased Items and Services" are applicable to work currently performed by CBFO. The EPA audit team reviewed documents and procedures provided by CBFO and conducted teleconferences with CBFO personnel to evaluate implementation of the requirements in ASME NQA-1-1989 for these elements, using NQA-1-1989 checklists.

CBFO OQA is also responsible for maintaining the QAPD and ensuring that all NQA-1-1989 requirements flow down into the QAPD. Therefore, the EPA audit team reviewed Revision 11 of the QAPD to evaluate implementation of the requirements in ASME NQA-1-1989 for the 13 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 3, "Design Control."
- Element 4, "Procurement Document Control."
- Element 5, "Instruction, Procedures and Drawings."
- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
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As recovery from the February 2014 events at the repository continues, QA oversight of the operations is especially important. During this audit, EPA evaluated selected aspects of the CBFO QA program to ensure that the upper-tier and implementing procedures continue to comply with the ASME NQA-1-1989 standard.

EPA identified several questions regarding apparent discrepancies between the QAPD and procedural language and the ASME NQA-1-1989 standard. The EPA audit team and CBFO OQA personnel had several discussions during the audit to resolve these questions. Resolutions included identification of the required text, reasonable explanations for maintaining the different text (e.g., the different text might be more restrictive than the requirement in the standard) and commitments by CBFO OQA to revise the text in the next revision of the QAPD or applicable procedure. A summary of the questions and resolutions pertaining to the QAPD is included in

Attachment A of this report; a summary of the questions and resolution pertaining to the implementing procedures is included in Attachment B of this report. EPA reviewed a draft of the QAPD, Revision 12, in March 2015 and found that it included all of the changes that EPA had requested from CBFO previously.

EPA determined that the CBFO QA program continues to comply with the NQA-1-1989 elements listed above.

7.0 FINDINGS AND CONCERNS

The EPA audit team did not identify any findings or concerns relative to the NQA-1-1989 elements discussed above. EPA will verify implementation of the revisions noted in Attachments A and B during a future audit.

8.0 CONCLUSIONS

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

9.0 REFERENCES

CBFO MP 4.1, Preparation and Maintenance of CBFO Procedures, Revision 11, May 9, 2013

CBFO MP 4.2, Document Review, Revision 10, November 26, 2014, and Revision 11, January 30, 2015

CBFO MP 4.4, Document Preparation and Control, Revision 10, June 17, 2013

CBFO MP 4.10, The Processing of TRU Waste Site Documents, Revision 3, October 20, 2008

CBFO MP 7.1, Quality Assurance Requirements for Procurement of Services, Revision 3, May 1, 2014

QAPD, Quality Assurance Program Document, U.S. Department of Energy Carlsbad Field Office, DOE/CBFO-94-1012, Revision 11, June 2010, Draft Revision 12, provided March 16, 2015

ATTACHMENT A

SUMMARY OF COMMENTS, QUESTIONS AND RESOLUTIONS REGARDING THE QAPD

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
1	Basic Requirement 3, Design Control, 2 nd sentence	Applicable design inputs shall be...correctly translated into design documents.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.2.2.D. EPA agrees.
2	3S-1, §3, Design Process, end of 1 st paragraph and start of 2 nd paragraph	<u>Appropriate quality standards</u> shall be identified and documented, and their selection reviewed and approved. Changes from <u>specified quality standards</u> , including the reasons for the changes... [underline added]	§2.2.2, paragraph A: <u>Appropriate standards</u> shall be identified and documented, and their selection reviewed and approved. Changes from <u>specified standards</u> , including the reasons for the changes... [underline added]	Please comment on your reasoning for leaving “quality” out of this text in the QAPD.	CBFO provided an explanation. EPA accepts CBFO’s explanation.
3	3S-1, §3, Design Process, 2 nd paragraph	Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.		Please help us find this requirement in the QAPD.	The following will be added as a second sentence at §2.2.2.C. <i>“Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.”</i>
4	3S-1, §3, Design Process, 2 nd paragraph and (b)	The final design...shall (b) identify assemblies and/or components that are part of the item being designed.	§2.2.2, paragraph E, 1 st sentence: Controls for identifying assemblies or components that are part of the item being designed shall be established.	The text in the QAPD does not indicate to us a firm commitment to identify the components in the design documents. Please comment.	The first sentence at §2.2.2.E will be reworded as follows: <i>“Design documents shall identify assemblies and/or components that are part of the item being designed.”</i>
5	3S-1, §3.1, Design Analysis, 1 st paragraph	Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.		Please help us find this requirement in the QAPD.	§2.2.3.A will be reworded as follows: <i>“Design analyses documents shall be planned and controlled.”</i>
6	3S-1, §3.1, Design Analysis, 1 st paragraph	[<u>Design analysis documents</u>] shall be sufficiently detailed as to purpose, method, assumptions...understand the <u>analyses</u> and verify the adequacy	§2.2.2 paragraph D: <u>Design documents</u> shall be sufficiently detailed as to purpose, method, assumptions...understand the <u>documents</u> and verify their	The quoted QAPD section is the closest we can find. Please comment on your reasoning for leaving “analysis” and “analyses” out of the text.	§2.2.2.D will be reworded as follows; <i>“Design analysis documents shall be sufficiently detailed as to</i>

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
		of the results without recourse to the originator. [underline added]	adequacy without recourse to the originator. [underline added]		<i>purpose, method, assumptions, designed input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.</i> "
7	3S-1, §3.1, Design Analysis, 1 st paragraph	Calculations shall be identifiable by subject...or by other data such that the calculations are <u>retrievable</u> . [underline added]	§2.2.3, paragraph C: Calculations shall be identifiable by subject...or by other designator such that the calculations are <u>traceable</u> . [underline added]	Please discuss the decision to use "traceable" instead of "retrievable."	CBFO provided an explanation. EPA accepts CBFO's explanation.
8	3S-1, §3.1, Design Analysis, (b)(5)	Identification of any computer calculations, including computer type, computer software name, revision identification, inputs, outputs, <u>evidence of or reference to computer program verification</u> , and the bases (or reference thereto) supporting application of the software to the specific physical problem. [underline added]	§2.2.3, paragraph C.5: Identification of any computer calculations, including computer type, computer software name, revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the software to the specific physical problem.	The underlined text is missing from the QAPD text. Please comment on your reasoning.	CBFO and EPA discussed the missing text and determined that the intent of the requirement is met by §6.2.
9	3S-1, §4.2.1, Design Reviews, (d)	d) Were the design inputs correctly incorporated into the design?		§2.2.6 paragraph A incorporates items (a)–(c) and (e)–(f) from 3S-1 §4.2.1, but skips (d). Please comment.	CBFO identified the requirement in §2.2.6.A.1. EPA agrees.
10	3S-1, §6, Interface Control, 2 nd paragraph	...where necessary, identify incomplete <u>items</u> which require further evaluation, review, or approval. [underline added]	§2.2.4, paragraph D, 2 nd sentence: Where necessary, incomplete <u>designs</u> that require further evaluation, review, or approval shall be identified.	Changing the language from "items" to "designs" seems to EPA to be a narrowing of requirement applicability. Please comment on your reasoning.	§2.2.4.D (last sentence) will be reworded as follows; <i>"Where necessary, incomplete items that require further evaluation, review, or approval shall be identified."</i>
11	3S-1, §6, Interface Control, 2 nd paragraph	Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.2.4. EPA agrees.

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
12	4S-1, §2.5, Documentation Requirements	The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.3.1.B, §2.3.4.C, §2.3.6.C, §2.3.6.E and §2.3.8.B. EPA agrees.
13	4S-1, §3, Procurement Document Review, 2 nd paragraph	Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review <u>prior to contract award</u> . [underline added]	§2.3.5, paragraph B: Procurement document reviews shall be performed and documented <u>prior to the document being issued to the supplier</u> . [underline added]	Please provide the reason for the change of language from “prior to contract award” to “prior to the document being issued to the supplier.”	CBFO provided an explanation. EPA accepts CBFO’s explanation.
14	4S-1, §3, Procurement Document, 3 rd paragraph	Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: (a) Appropriate requirements specified in Section 2 of this Supplement; (b) Determination of any additional or modified design criteria; (c) Analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in DOE and Federal Acquisition Regulation requirements. References to DEAR/FAR will be added in Table I-1 of the QAPD.
15	6S-1, §2, Document	The control system shall be documented and shall	§1.4.2, paragraph A: Documents shall be distributed to affected	The requirement we identified requires that the documents be	§1.4.2.E will be reworded as follows:

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
	Preparation, Review, Approval, and Issuance	provide for...(a) identification of documents...and their specified distribution;	personnel...	distributed, but this does not seem to us to be the same as identifying the specified distribution. Please comment or help us find the correct QAPD reference.	<i>"Controls shall provide for identification of documents to be controlled and their specified distribution."</i>
16	6S-1, §3.2, Minor Changes	Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval <u>as the original documents</u> . [underline added]	Revision 11, §1.4.3, paragraph C: Editorial or minor changes may be made without the same level of review and approval <u>as the original or otherwise changed document</u> . Revision 12, §1.4.3, paragraph C: Editorial or minor changes may be made without the same level of review and approval <u>as technical or other more substantive changes</u> . [underlines added]	Please comment on your decision to revise this text in Revision 12.	The change in Revision 12 was made to address internal comments received. The language from Revision 11 will be reinstated.
17	7S-1, §2, Procurement Planning, 3 rd paragraph (end of sentence)	...and the preparation of applicable procedures prior to the initiation of each individual activity listed below.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.3.1.C. EPA agrees.
18	7S-1, §3.1, Source Evaluation and Selection, paragraph“(a)”	(a) evaluation of the Supplier’s history of providing an identical or similar product which performs satisfactorily in actual use. <u>The Supplier’s history shall reflect current capability</u> . [underline added]	§2.3.2, paragraph C.1: An evaluation of the supplier’s history for providing an identical or similar product that performs satisfactorily in actual use.	Please explain why “The Supplier’s history shall reflect current capability” was excluded from this bullet. If it is located elsewhere in the QAPD, please help us find it.	CBFO and EPA discussed the exclusion and came to an agreement to leave §2.3.2.C.1 unchanged.
19	7S-1, §5, Supplier Performance Evaluation, last paragraph (last sentence)	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.	CBFO identified the requirement in §2.3.7.B. EPA agrees.
20	7S-1 §5, Supplier Performance Evaluation (including §5.1 and §5.2)			Although the QAPD has a specific section for Supplier Performance Evaluation (§2.3.6), many of the NQA requirements for Supplier Performance Evaluation (7S-1, §5, §5.1 and §5.2) are located in the	CBFO and EPA discussed the Supplier Performance Evaluation requirements and came to an agreement that the QAPD text is acceptable as is.

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
				Supplier Performance Evaluation section of the QAPD, specifically, the Source Verification subsection (§2.3.7.1). Please explain why all NQA Supplier Performance Evaluation requirements are not included under the Supplier Performance Evaluation section of the QAPD and are instead included under a subsection of Acceptance of Items or Services	
21	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.	CBFO identified the requirement in §2.3.4.B.3, §2.3.4.C.1, §2.3.4.C.5, §2.3.4.C.6, §2.3.6.C and §2.3.6.E. EPA agrees.
22	7S-1, §7, Control of Changes in Items or Services	The Purchaser and Supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented and are in accordance with this Standard.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.3.3.B and §2.3.5.A. EPA agrees.
23	7S-1, §9, Control of Supplier Non-Conformances, second paragraph (a) and (e)	(a) evaluation of nonconforming items (e) maintenance of records of Supplier-submitted nonconformances		Please help us find these requirements in the QAPD.	CBFO identified the (a) requirement in §2.3.4.C.6 and §2.3.8. EPA agrees. CBFO and EPA discussed the (e) requirement and determined that the requirement is met through compliance with the DEAR/FAR requirements discussed above in row 14.

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
24	8S-1, §2.1, Item Identification	Items <u>of production (batch, lot, component, part)</u> shall be identified from the initial receipt <u>and fabrication of the items up to and including installation and use.</u> [underline added]	§2.1.3, paragraph B: Items shall be identified and traced from the time of receipt, up to and including installation or end use.	Please comment on your decision to leave out the underlined text from the NQA-1 reference.	CBFO provided an explanation. EPA accepts CBFO's explanation.
25	8S-1, §2.1, Item Identification	This identification shall relate an item to an applicable design or other pertinent specifying document.	§2.1.3, paragraph A, 3 rd sentence: Traceability requirements shall be specified in design documents or implementing procedures.	The identified QAPD reference indicates that traceability requirements should flow down from the procedures/design documents, but the NQA-1 requirement goes the other way and indicates that an item's identification should indicate applicable specifying documents. Please comment or help us find the correct QAPD reference.	§2.1.3.A (2 nd and 3 rd Sentences) will be combined and reworded as follows: <i>"The identification of items shall be maintained to ensure appropriate traceability and its relationship to an applicable design or other pertinent specifying document."</i>
26	8S-1, §3.1, Identification and Traceability of Items	...specific identification or traceability requirements (such as identification or traceability of the item to applicable specification <u>and</u> grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records)... [underline added]	§2.1.3, paragraph B.3: ...specific identification or traceability requirements (such as identification or traceability of the item to applicable specification <u>or</u> grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other record(s))... [underline added]	Please comment on your decision to replace "and" with "or."	§2.1.3.B.3 will reworded as follows: <i>"If codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification <u>and/or</u> grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other record(s)), then identification and traceability methods shall be implemented to ensure the special requirements are met."</i>
27	8S-1, §3.3, Maintaining Identification of Stored Items	Provisions shall be made for the control of <u>item identification</u> consistent with the planned duration and conditions of storage, such as: (1) provisions for maintenance or replacement of markings and	§2.1.5, paragraph E: If storage of items is required, methods shall be established for the control of <u>item identification records</u> that are commensurate with the planned duration and conditions of storage. These methods shall provide for,	Please comment on the underlined text changes.	CBFO provided an explanation. EPA accepts CBFO's explanation.

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
		identification <u>records</u> due to damage during handling or aging; (2) protection of identifications on items subject to excessive deterioration due to environmental exposure (3) provisions for updating existing plant records [underlines added]	as applicable: 1. Maintenance or replacement of markings and identification <u>tags</u> damaged during handling or aging 2. Protection of identification markings that are subject to excessive deterioration due to environmental exposure 3. Update of related identification records and documentation [underlines added]		
28	Element 9, general			Please confirm or correct: "work" as described in the QAPD includes the "processes" discussed in NQA-1-1989 Element 9.	CBFO regards the terms "special processes" and "work", synonymous as it relates to Element 9.
29	10S-1, §2.2, Qualification	Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.		Please help us find this requirement in the QAPD.	§2.4.1.E will be reworded as follows: <i>"The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel that perform such inspections and tests. On-the-job training shall also be included in the program, as appropriate, with emphasis on first-hand experience gained through actual performance of inspections and test; the results of which shall be verified for conformance by a qualified person until certification is achieved."</i>
30	10S-1, §6.1, Resolution of Nonconformances	Final inspections shall include <u>a records review</u> of the results <u>and resolution</u> of nonconformances identified by prior inspections. [underlines added]	§2.4.3.4, paragraph A: Final inspections shall include <u>a review of the results and the verification of the resolution</u> of all nonconformances identified by earlier inspections. [underlines added]	Please comment on the different language used.	CBFO provided an explanation. EPA accepts CBFO's explanation.
31	10S-1, §6.1,	The final inspection shall be		Please help us find this	CBFO identified the requirement

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
	Resolution of Nonconformances	planned to arrive at a conclusion regarding conformance of the item to specified requirements.		requirement in the QAPD.	in §2.4.A. EPA agrees.
32	10S-1, §6.2, Inspection Requirements	Completed items shall be inspected for completeness, markings, calibration, <u>adjustments</u> , protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. [underline added]	§2.4.3.4, paragraph B, Finished items shall be inspected for completeness, markings, calibration, protection from damage, or other characteristics, as required to verify the quality and conformance of the item to the applicable requirements.	Please comment on the decision to omit “adjustments” from the QAPD text.	CBFO and EPA discussed the meaning of the term “adjustments” and came to an agreement that the QAPD text is acceptable as is.
33	Basic Requirement 11 Test Control, 2 nd paragraph	Tests required to collect data, such as for siting or design input...		Are such tests described or discussed in the QAPD? Please help us find the correct section.	CBFO identified design qualification testing (§2.2.8) as an example of this type of tests discussed in the QAPD. EPA agrees.
34	11S-1, §2, Test Requirements	Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and <u>operational tests...</u> [underline added]	§2.4.4: Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, and pre-operational tests.	Please comment on the decision to omit “operational tests” from the QAPD text.	§2.4.4 will be worded as follows: <i>“Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests.”</i>
35	11S-1, §3, Test Procedures, 1 st paragraph	Tests procedures shall include or reference <u>test objectives</u> and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, <u>that necessary monitoring is performed</u> , and that suitable environmental conditions are maintained. [underline added]	§2.4.4.1 G: The provisions for ensuring that prerequisites for the given test have been met §2.4.4.1 C: The identification of the M&TE to be used to perform the test to ensure that the equipment being utilized is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function §2.4.4.1 D: Any test prerequisites, including test equipment, instrumentation and software needs, personnel training and qualification, and suitably	QAPD §2.4.4.1 seems to contain all of the other test procedure requirements in this paragraph in NQA-1-1989. Please help us find these requirements in the QAPD.	CBFO and EPA discussed this section and determined that the QAPD text meets all of these requirements as written.

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
			controlled environmental conditions		
36	11S-1, §3, Test Procedures, 2 nd paragraph	Such documents [i.e., the related documents used in lieu of specially prepared written test procedures] shall include adequate instructions to assure the required quality of work.		QAPD §2.4.4.1, paragraph A, contains the allowance to use related documents in lieu of specially written test procedures but does not include the requirement to include adequate instructions to ensure quality of work. Please help us find this requirement in the QAPD.	§2.4.4.1 (last sentence) will be reworded as follows; <i>"If used, the related documents or sections thereof shall be incorporated either directly, or by reference, into the approved test implementing procedure."</i>
37	11S-1, §4, Test Results	Test results shall be documented and evaluated by a <u>responsible authority</u> to assure that test requirements have been satisfied. [underline added]	§2.4.4.3: Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a <u>qualified individual within the responsible organization</u> to ensure that all test requirements have been satisfied.	Please comment on the change in wording.	CBFO provided an explanation. EPA accepts CBFO's explanation.
38	11S-1, §5, Test Records	Test records shall, as a minimum, identify...(f) action taken in connection with any <u>deviations noted</u> [underline added]	§2.4.4.2: Test documentation shall identify...H. The actions taken in connection with any <u>noted nonconformances</u> [underline added]	Please comment on the change in wording.	§2.4.4.2.H will be reworded as follows; <i>"The actions taken in connection with any noted deviations."</i>
39	11S-2, §2, Test Requirements	Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §6.3.1, §6.3.2.B, §6.3.2.C, §6.4.2.B and §6.6.2.4. EPA agrees.
40	11S-2, §2.1, Verification Tests	Depending on the complexity of the computer program being tested, testing may range from a single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules,		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §6.6.2.4.A. EPA agrees.

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
		followed by an overall computer program test. Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.			
41	11S-2, §3, Test Procedures	Test procedures or plans shall specify the following, as applicable: (a) required tests and test sequence (b) required ranges of input parameters (c) identification of the stages at which testing is required (d) criteria for establishing test cases (e) requirements for testing logic branches (f) requirements for hardware integration (g) anticipated output values (h) acceptance criteria (i) reports, records, standard formatting, and conventions		Please help us find this requirement in the QAPD.	Based on discussions with CBFO, EPA identified the requirements in §6.3.2.B, §6.4.2.B, §6.6.2.1, §6.6.2.4.A, §6.6.2.4.B, §6.6.2.4.C, §6.6.2.4.D, §6.7.2.5 and §6.9.2.3.
42	11S-2, §4, Test Results	Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §6.7.2.5. EPA agrees.
43	12S-1, §3.2, Control	The method...of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.4.6.A. EPA agrees.
44	12S-1, §3.2,	If any measuring or test equipment		Please help us find this	CBFO identified the requirement

	NQA-1-1989 Reference	Requirement Text	QAPD Text	EPA Comment	Summary of Response and Disposition
	Control	is consistently found to be out of calibration, it shall be repaired or replaced.		requirement in the QAPD.	in §2.4.6.B. EPA agrees.
45	Basic Requirement 13 Handling, Storage, and Shipping	Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.		Please help us find this requirement in the QAPD.	CBFO identified the requirement in §2.1.3.A. EPA agrees.

ATTACHMENT B

SUMMARY OF COMMENTS, QUESTIONS AND RESOLUTIONS REGARDING THE CBFO IMPLEMENTING PROCEDURES

	EPA Comment	Summary of Response and Disposition
1	We did not find a part of the Document Control procedures that covers the requirement from 6S-1, §3.1: The organization reviewing major changes to documents shall have access to pertinent background data or information upon which to base their approval.	CBFO provided an explanation. EPA accepts CBFO's explanation.
2	CBFO MP 4.1, Revision 11, §5.9, covers posting the new version of the procedure on the Intranet but does not mention removing the old version. Is this step documented elsewhere? While theoretically people should know to check for multiple versions and to only use the newest revision, removing the obsolete version would provide a greater level of document control.	CBFO agreed to consider including guidance for removing the old version in the next revision of MP 4.1.
3	Editorial comment: CBFO MP 4.10, Revision 3, Scope: "This document supersedes Management Procedure (MP) 4.10, Revision 1." We think this should say "Revision 2."	CBFO agreed to correct this in the next revision.
4	CBFO MP 4.1, Revision 11, §5.3.1, paragraph D addresses primary and secondary headings, but there are also tertiary headings (i.e., "5.3.1 General Requirements") that appear to follow the same rules as the secondary headings, but are not defined.	CBFO agreed to consider including guidance for tertiary (third-level headings) in the next revision of MP 4.1.
5	"Document Review/Approval Matrix" is defined in both CBFO MP 4.4, Revision 11, and CBFO MP 4.2, Revision 10. However, the definitions (see below) do not match exactly. They do not appear to contradict each other, but it would be cleaner if they matched.	CBFO revised the "Document Review/Approval Matrix" definition in MP 4.2, Revision 11. EPA reviewed the revised procedure and concurs with the change.
6	CBFO MP 4.2, Revision 10, Paragraph 5.4.3 mentions the concurrence sheet used for CBFO correspondence. ("The concurrence sheet used for CBFO correspondence will substitute for a DRR.") Should this paragraph or the references section mention CBFO MP 5.3?	CBFO agreed to add a reference or specific language to provide a "link" to MP 5.3.
7	CBFO MP 4.2, Revision 10, Paragraph 6.2: "Such packages must be identified as QA records by the preparer. Records packages for program documents will be forwarded to Document Services by the Government Information Specialist for <i>records retention</i> only." Please explain this requirement. We do not understand the term <i>records retention</i> in this context.	CBFO provided an explanation. EPA accepts CBFO's explanation.
8	CBFO MP 4.2, Revision 10, Paragraph 6.3: The text introducing the list of records in 6.3.1–6.3.6 implies that this list is specific to the record packages for internal CBFO procedures. CBFO MP 4.1, Revision 11, also defines a record package for internal CBFO procedures, but the lists do not match.	CBFO addressed this in MP 4.2, Revision 11. EPA reviewed the revised procedure and concurs with the change.
9	Editorial comment: CBFO MP 5.2, Revision 3, Paragraph 5.3.4: The lettered bullets restart with A after C, i.e., A, B, C, A, B, C, D, E, F, G, H.	CBFO agreed to correct the lettered sequence in the next revision of MP 5.2.
10	CBFO-MP-7.1, Revision 3, §5.1, Acquisition Planning, paragraph 5.1.3 does not include two of the NQA-1-1989 requirements from the corresponding section of Element 7S-1. Please help us find these requirements in the implementing procedures.	CBFO and EPA discussed the apparently missing requirements and determined that they are not applicable to current CBFO activities and therefore do not need to be included in the implementing procedures.

	EPA Comment	Summary of Response and Disposition
11	EPA could not identify the Element 7S-1 §5 requirements in the implementing procedures. Please help us find these requirements in the implementing procedures.	CBFO and EPA discussed the NQA-1-1989 requirement and determined that the intent of the requirement is met through compliance with the DOE and Federal Acquisition Requirements, which are identified in MP 7.1 as references.
12	EPA could not identify the NQA-1-1989 Element 7S-1 requirement to control, handle and approve supplier-generated documents in accordance with established methods within the implementing procedure. Please help us find this requirement in the implementing procedures.	CBFO and EPA discussed the apparently missing requirement and determined that it is met through a combination of MP 7.1, §5.2.2.D, and the DOE and Federal Acquisition Requirements, which are identified in MP 7.1 as references.
13	EPA could not identify the NQA-1-1989 Element 7S-1 requirement for the purchaser and supplier to have documented methods for disposition of items and services that do not meet procurement document requirements within the implementing procedure. Please help us find this requirement in the implementing procedures.	CBFO and EPA discussed the apparently missing requirement and determined that the "items" component does not apply to work performed by CBFO and that the "services" component is covered by the DOE and Federal Acquisition Requirements, which are identified in MP 7.1 as references. Any records generated by these activities are managed in accordance with CBFO records management procedures, as required in MP 7.1, §6.0.