memorandum

DATE: June 2, 2004

REPLY TO
ATTN OF: CBFO:QA:MLC:GS:04-1512:UFC 2300.00

SUBJECT: Transmittal of Audit Report for Audit A-04-16

TO: R. Paul Detwiler, Acting CBFO Manager

The Carlsbad Field Office (CBFO) performed Audit A-04-16 of the CBFO Quality Assurance Program Document on May 10-13 and 26, 2004. The audit team concluded that the overall status of the CBFO Quality Assurance Program is adequate. The team also concluded that select implementing procedures are satisfactorily implemented and effective, with the exception of the CBFO Management Procedure (MP) 2.1, Personnel Qualification and Training. The implementation and effectiveness of MP 2.1 was determined to be marginal, as further described in Corrective Action Report 04-027, issued under separate cover. The details of the audit as well as conclusions are detailed within the attached audit report.

If you have any questions or comments, please contact me at (505) 234-7442.

M. Lea Chism
Quality Assurance Specialist

Attachment

cc: w/attachment

L. Piper, CBFO
A. Holland, CBFO
F. Huckeba, CBFO
C. F. Wu, CBFO
M. Eagle, EPA
J. Bearzi, NMED
D. Winter, DNFSB
S. Zappe, NMED
P. Rodriguez, CTAC
S. Harrison, CTAC
K. Dunbar, WRES
CBFO QA Record
CBFO M&RC
U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE

AUDIT REPORT OF
SELECT CBFO QA PROGRAM DOCUMENT SECTIONS,
ASSOCIATED IMPLEMENTING PROCEDURES AND
SELECT NQA-1 ELEMENTS

CARLSBAD, NEW MEXICO

AUDIT NUMBER A-04-16

May 10 – 13, 2004
And
May 26, 2004

CBFO QUALITY ASSURANCE PROGRAM

Prepared by: Pete V. Rodriguez, CTAC
Audit Team Leader

Date: 5/26/04

Approved by: Martin Nance
Avila L. Holland, CBFO
Quality Assurance Manager

Date: 6/2/04
1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) Audit A-04-16 was conducted to evaluate the adequacy, implementation, and effectiveness of selected CBFO Quality Assurance Program Document (QAPD) requirements in accordance with criteria 2, 4, 5, 6, 7, 8, 9, 12, 13 and 14 of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance 1 (NQA-1), 1989 edition. Sections 1.1, 1.2, 1.4, 2.1, 2.3, 2.4, and 2.4.6 and the associated implementing procedures of the CBFO QAPD were evaluated during the audit. The audit team also evaluated continued effectiveness of corrective actions resulting from corrective action reports (CARs) generated during the previous assessment. The audit was conducted at the Skeen-Whitlock Building May 10 – 13, and May 26, 2004.

The audit team concluded that overall, the CBFO QAPD and applicable implementing procedures are adequate relative to the flow-down of requirements from NQA-1, criteria 2, 4, 5, 6, 7, 8, 9, 12, 13, and 14. In addition, the audit team concluded that the implementing procedures are satisfactorily implemented and effective, with the exception of CBFO Management Procedure (MP) 2.1, Personnel Qualification and Training. The implementation and effectiveness of MP 2.1 was determined to be unsatisfactory, as further described in section 5.2.1. The audit team also found that corrective actions continue to be effective for selected CARs generated during CBFO Surveillance S-03-08.

The audit team identified one condition adverse to quality resulting in the issuance of a CBFO CAR (04-027) that requires corrective action. This CAR, which is similar to previously issued CAR 03-033, relates to criterion 2, QA Program, and is specific to the requirements for CBFO personnel qualification and training. One isolated deficiency requiring only remedial corrective action was corrected during the audit (CDA). Two Recommendations were offered for management consideration. The CAR, CDA, and Recommendations are described in Section 6.0.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of selected QA processes related to the CBFO QA Program.

The following criteria were evaluated in accordance with the CBFO QAPD and NQA-1

- Criterion 2 – QA Program, including grading/selection of quality levels and personnel qualification and training
- Criterion 4 – Procurement Document Control
- Criterion 5 – Instructions, Procedures, and Drawings
- Criterion 6 – Document Control
- Criterion 7 – Control of Purchased Items and Services
- Criterion 8 – Identification and Control of Items
- Criterion 9 – Control of Processes
Criterion 12 – Control of Measuring and Test Equipment (M&TE)
Criterion 13 – Handling, Storage, and Shipping
Criterion 14 – Inspection, Test and Operating Status

The evaluation of the CBFO QA documents for adequacy was based on the CBFO QAPD, DOE-CBFO-94-1012, Revision 5, sections 1.1.2.3, 1.2, 1.4, 2.1, 2.3, 2.4, and 2.4.6, and ASME NQA-1, 1989 edition, criteria 2, 4, 5, 6, 7, 8, 9, 12, 13, and 14.

AUDIT TEAM AND OBSERVERS

CBFO AUDIT TEAM

M. Lea Chism CBFO QA Management Representative
Pete Rodriguez Audit Team Leader, CBFO Technical Assistance
Contractor (CTAC)
Tammy Bowden Auditor, CTAC
John Gray Auditor, CTAC
Sandra Harrison Auditor-In-Training, CTAC

OBSERVERS/INSPECTORS

N/A

AUDIT PARTICIPANTS

Individuals contacted during the audit are identified in Attachment 1. A preaudit conference was held in the Skeen-Whitlock Building on May 10, 2004. The audit was concluded with a post-audit conference held in the Skeen-Whitlock Building on May 26, 2004.

SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that overall, the CBFO QA Program is adequate relative to the flow-down of requirements from the ASME NQA-1, 1989 edition, criteria 2, 4, 5, 6, 7, 8, 9, 12, 13, and 14, and the applicable CBFO QAPD sections and CBFO implementing procedures. In addition, the audit team concluded that the implementing procedures are satisfactorily implemented and effective, with the exception of MP 2.1. The audit team also found that corrective actions continue to be effective for CARs previously generated during CBFO Surveillance S-03-08, with the exception of a deficiency similar to that described in CBFO CAR 03-033. CAR 04-027 describes this similar deficiency, which pertains to the qualification and training of “new CBFO employees,” and the CAR also identifies the need for revision to MP 2.1.
5.2 QA Program Audit Details

The evaluation to NQA-1 requirements entailed the review of the CBFO QAPD and implementing procedures and MPs to ensure the flow-down of applicable NQA-1 requirements. The QAPD sections and implementing procedures were found to be adequate in addressing select NQA-1 requirements.

CBFO implementing procedures and QAPD sections included in the audit are identified in Attachment 2. The audit was conducted through interviews with key personnel and review of objective evidence. The results and audit conclusions are contained within this report and are maintained by CBFO as QA records.

5.2.1 Criterion 2 – Quality Assurance Program – Including grading/selection of quality levels and personnel qualification

The audit team evaluated the CBFO process of grading/selection of quality levels through interviews with responsible personnel and review of documentation associated with MP 1.2, Selection of Quality Levels. The audit team verified that the CBFO QA Manager maintains and distributes a QL-1 listing of integrated work activities. It was also verified that the CBFO Manager and assistant managers continuously identify work activities and determine quality levels and document these determinations on Determination of Quality Level Questionnaires (DQLQs). Changes made to work activities are evaluated for quality levels, including instances where subter activities may be added and where supplementary work activities are identified within an area of responsibility. The DQLQs generated by the CBFO are maintained as QA records in accordance with the latest revision of CBFO MP 4.9, Quality Assurance Records. Overall, the CBFO selection of quality levels (grading) is adequate, satisfactorily implemented and effective.

The audit team also evaluated the CBFO process for the qualification and training of personnel. Interviews with responsible personnel and review of documentation associated with MP 2.1, Personnel Qualification and Training, indicate that while this MP adequately addresses the QAPD requirements, the processes described are outdated and no longer used. Examples include the steps of the Individual Development Plan (IDP) and an attached form that is not used due to anticipation of the personal performance development activity being directed and implemented by DOE Savannah River, along with the “POWER” software that is now used to provide available training on line. To date, DOE Savannah River has not provided IDP directions to CBFO; only tracking of individual training requested and completed and associated dates are provided. Also, Attachments I, CAO Qualification Cards, and III, CAO Attendance Sheets, are no longer used. Training activities are entered, tracked, and maintained in the “POWER” software system and qualification cards for QL-1 work are no longer developed in accordance with this procedure and are no longer maintained in the CBFO qualification/training notebook (“Orange Book”). The audit team identified this issue as a significant condition adverse to quality in CAR 04-027. No objective evidence was available to verify conduct of QA program orientation for new CBFO employees. The audit team determined that required orientation of
approximately 15 new employees did not occur. This was also identified and documented as a significant condition adverse to quality in CAR 04-027. MP 2.1 adequately addresses the applicable NQA-1 and QAPD requirements; however, as mentioned earlier, the MP requires revision and updating. The implementation and effectiveness of MP 2.1 was determined to be unsatisfactory due to the significant conditions adverse to quality mentioned above and identified in CAR 04-027.

5.2.2 Criterion 4 – Procurement Document Control

The audit team evaluated the CBFO procurement process through interviews with responsible CBFO personnel involved in the procurement process and review of MP 7.1, QA Requirements for Procurement of Services. Procurement packages were reviewed and found to include all requirements and controls necessary to ensure the performance and quality aspects of the services to be procured. Review of historical Fabrication Oversight and Management Plans provided evidence that the CBFO QA Manager is working with the responsible manager and contracting officer to determine and identify the type and extent of the contract QA controls that are needed. In those cases where QA controls are not required, the correct disclaimer is entered on the procurement document routing sheets. No QL-1 procurements were made in this fiscal year, therefore no objective evidence was available to verify supplier selection or amendments to this type of procurement. Historical procurement records were found to be retained as QA records in accordance with CBFO MP 4.9, Quality Assurance Records.

The audit team verified continued implementation of corrective actions to a previous CAR, CBFO CAR 03-034, Procurement Document Routing Sheet Requirements. Overall, the processes applicable to procurement were determined to be adequate in addressing the CBFO QAPD and NQA-1 requirements. However, implementation and effectiveness were not readily assessable at this time because no occurrences were cited of QL-1 or 2 procurement since the last assessment period. It was also evident that MP 7.1, QA Requirements for Procurement of Services, is under revision in response to a previous CBFO CAR (CAR 02-053).

5.2.3 Criterion 5 – Instructions, Procedures, and Drawings

The audit team evaluated the CBFO implementing procedures established for this criterion. The audit team conducted interviews with responsible personnel and reviewed documentation associated with the implementation of MP 4.1, Preparation and Maintenance of CBFO Procedures, and MP 4.2, Document Review. The documentation reviewed included the MPs cited throughout this report, associated Document Action Requests (DARs), Document Review Records (DRRs), Interim Change Notices (ICNs), and associated correspondence. Procedure content, as well as review and approval signatures, were also verified. The CBFO web page for Internal Requirements Documents was also reviewed. The audit team determined that the CBFO implementing procedures established and documented for this criterion adequately address the CBFO QAPD and NQA-1 requirements, and are satisfactorily implemented and effective. A recommendation was presented for management
consideration, however, concerning the revision of MP 4.2, to recognize either hard copy or electronic DRR submittal (see section 6.4, Recommendation 1).

**Criterion 6 – Document Control**

The audit team evaluated the CBFO document control process, in conjunction with section 5.2.3 above, and conducted interviews with responsible personnel. The team also reviewed MP 4.4, *Document Preparation and Control*. The CBFO program documents and associated control documents examined and reviewed included *CH-Packaging Operations for High Wattage Waste at LANL, RH Packaging Operations Manual*, and the *WIPP Waste Information System User Guide*. The audit team also assessed the MPs cited throughout this report, associated DARs, DRRs, ICNs and associated correspondence. Procedure content, as well as review and approval signatures, were also verified. The CBFO web page for Internal Requirements Documents was also reviewed to verify document control requirements (such as issuance, cancellation, and inactivation).

With respect to the document control processes as described in MP 4.4, which has been established strictly for CBFO program documents and not MPs, the following recommendation was presented for management consideration: re-assess and consider revision to MP 4.4 to better describe the current process used by CBFO to prepare and control “CBFO program documents.” The current process entails control of these documents through the CBFO web page, Document Services (management and operation contractor (M&O) Washington TRU Solutions (WTS)), and/or the Quality and Manufacturing Integrated System (Q&MIS) system, which is also an M&O system. The audit team recommends development of a unified and consistent document control system (see section 6.4, Recommendation 2).

The audit team determined that the CBFO implementing procedures established and documented for this criterion adequately address the CBFO QAPD and NQA-1 requirements, and are satisfactorily implemented and effective.

**Criterion 7 – Control of Purchased Items and Services**

The audit team evaluated the control of purchased items and services. The audit team conducted interviews with CBFO personnel responsible for the control of purchased items and services and QA. MP 7.1, *QA Requirements for Procurement of Services*, was also reviewed. CBFO acceptance of contract terms and conditions, acceptance of suppliers’ QA programs, or verification that all contractual, technical, and QA requirements have been met upon completion or termination of a QL-1 procurement was not feasible, as CBFO has not initiated a QL-1 procurement since the last assessment. The CBFO meets the intent of NQA-1, criterion 7, through QAPD section 2.3, and through contracts for this service to be performed by the Waste Isolation Pilot Plant (WIPP) M&O contractor. The requirement to establish appropriate controls to ensure use of only correct and acceptable items was found to be implemented and addressed in the historical fabrication oversight and management plans for packaging contracts. The processes applicable to control of purchased items and services were
determined to be adequate. Implementation and effectiveness, however, were not applicable to the CBFO organization at this time, as it does not directly perform this function or activity.

5.2.6 Criterion 8 – Identification and Control of Items

The audit team evaluated the process of identification and control of items through review of the requirements of CBFO QAPD section 2.1.3. The CBFO is not performing the functions or activities associated with this criterion and therefore no MPs have been developed.

The audit team determined that the process for the identification and control of items is adequately addressed within the CBFO QAPD and meets NQA-1 requirements. Implementation and effectiveness of this criterion, however, is not applicable as the CBFO does not currently perform the functions or activities associated with identifying and controlling items.

5.2.7 Criterion 9 – Control of Processes

The audit team evaluated the control of processes as implemented and applicable to the activities performed by the CBFO. One of these processes is described in MP 4.10, *Processing of TRU Waste Site Documents*. The audit team interviewed CBFO personnel responsible for evaluating site documents related to site processes and waste characterization. The audit team determined that CBFO receives site documents and adequately distributes, reviews, and comments with respect to adequacy of site documentation and processes compared to the CBFO QAPD, the Hazardous Waste Facility Permit (HWFP), Waste Analysis Plan (WAP), and/or Contact-Handled TRU Waste Acceptance Criteria (WAC), as applicable. Technical and QA comments are communicated to sites, issues are resolved, and approval of site documents is granted in accordance with CBFO procedures. Documentation of review, comment, and resolution is performed adequately and in accordance with CBFO procedures.

The audit team also evaluated the process used by CBFO to certify generator sites to perform waste certification and shipping activities as described in MP 5.2, *TRU Waste Site Certification/Recertification*. The audit team verified that the CBFO QA and National TRU Program (NTP) departments determine readiness for site audits, schedule audit activities, and assign audit resources in accordance with the procedure. The audit team also determined that sites are notified of deficiencies and that deficiencies are resolved prior to recommendation of certification. The NTP Assistant Manager and QA Manager recommend certification to the CBFO Manager in accordance with procedure and after resolution of CBFO comments. The NTP Assistant Manager and QA Manager generate and maintain certification documentation and make appropriate notification of certification and/or recertification status to regulators and internal CBFO departments.

An additional process evaluated by the audit team included the process of establishing standards for all correspondence generated by the CBFO, as described in MP 5.3,
Correspondence Standards. The audit team examined the documentation and objective evidence associated with the implementation of this procedure. One concern was identified regarding two incomplete entries in the Office of Program Support (OPS) Outgoing Correspondence Log. CBFO MP 5.3 section 4.6 states in part that "Secretaries will maintain the outgoing correspondence logs, ensure that each letter has the correct number and file code . . ." Corrected entries and updating of the log were verified during the audit. This was reported as CDA No. 1.

The control of processes as implemented by CBFO and described above, was determined to be adequate, satisfactorily implemented, and effective. Note: The term "Special Processes" as referred to in NQA-1 criterion 9, is not applicable to CBFO.

Criterion 12 – Control of Measuring and Test Equipment

The audit team evaluated the M&TE process through review of the requirements of the CBFO QAPD section 2.4.6. The team established that CBFO is not performing the functions or activities associated with this criterion and therefore no MPs have been developed.

The audit team determined that the process for M&TE is adequately addressed in the CBFO QAPD and is in accordance with NQA-1. However, implementation and effectiveness of this criterion is not applicable because the CBFO currently performs no functions or activities associated with M&TE.

Criterion 13 – Handling Storage and Shipping

The audit team evaluated the handling, storage, and shipping requirements described in QAPD section 2.1.5. The audit team concluded that this section adequately addresses the NQA-1 requirements relative to criterion 13. The team also concluded that since CBFO does not perform the functions or activities associated with this criterion, development of MPs for this criterion is not necessary. Consequently, implementation and effectiveness is not applicable.

5.2.10 Criterion 14 – Inspection, Test and Operating Status

The audit team evaluated the CBFO requirements for inspection, test, and operating status as described in QAPD section 2.4. The team established that CBFO is not performing the functions or activities associated with this criterion and therefore no MPs have been developed.

The audit team concluded that the process for this criterion is adequately addressed in the CBFO QAPD and is in accordance with NQA-1 requirements. Implementation and effectiveness of this criterion, however, is not applicable as the CBFO does not currently perform the functions or activities associated with inspection, test and operating status.
6.0 **CARs, CDAs, OBSERVATIONS, RECOMMENDATIONS, AND EXEMPLARY PRACTICES**

**Corrective Action Reports**

CAR 04-027 was initiated as a result of Audit A-04-16 and has been transmitted to CBFO under separate cover. A brief description of the CAR is provided below.

**CBFO CAR 04-027**

The CBFO QA Team Leader is not providing initial QA program orientation, QA, or MP training of all CBFO personnel. No required follow-on training has occurred based on changes to the CBFO QAPD and/or the CBFO MPs in the last fiscal year. According to the CBFO Training Administrator, approximately 15 new CBFO employees have not received QA program orientation as required by MP 2.1.

MP 2.1 is not being fully implemented. The processes described in this procedure and the forms associated with these processes are not currently being implemented. ICN #2 deleted the portion of step 5.1.1 that established the requirement that qualification cards for CBFO individuals performing QL-1 activities be completed prior to their performance of these quality-affecting activities. The procedure references maintenance of IDP sheets and qualification cards in qualification/training notebooks (Orange Books), but these notebooks are no longer used and there is no objective evidence of current qualification cards or IDP sheets.

**Deficiencies Corrected During the Audit (CDA)**

One deficiency, requiring remedial action only, was identified during the audit. The deficiency was corrected and verified prior to completion of the audit. The CDA is identified below and in the completed checklists, and is documented on CDA forms.

**CDA No. 1**

Two entries in the OPS Outgoing Correspondence Log were incomplete. The audit team verified that the log was updated and determined that the deficiency was corrected during the audit.

**Observations**

None

**6.4 Recommendations**

The following recommendations are presented for CBFO management consideration.

1. A requirement in CBFO MP 4.2, *Document Review*, section 5.2.1, states in part that a DRR shall be attached to any document sent out for review. Not all DRRs are submitted via hard copy with the document – some are sent electronically.
Consequently, objective evidence is not always readily available to substantiate the requirement. It is therefore recommended that the procedure be revised to reflect the actual practice of either hard copy or electronic DRR submittal.

2. With respect to the document control processes described in MP 4.4, which has been established strictly for CBFO program documents, and not MPs – it is recommended that MP 4.4 be reassessed and considered for revision. The current process, as described in MP 4.4 for the control of “CBFO program documents,” entails control through the CBFO web page, Document Services (M&O/WTS), and/or the QMIS system, which is also an M&O system. Consequently, it is recommended that a unified and consistent system be established.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: CBFO Implementing Documents
<table>
<thead>
<tr>
<th>NAME</th>
<th>ORGANIZATION</th>
<th>PREAUDIT MEETING</th>
<th>CONTACTED DURING AUDIT</th>
<th>POST AUDIT MEETING</th>
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<tbody>
<tr>
<td>Brisbin, Kathy</td>
<td>OPA, OLA, OPS Dept. Secretary</td>
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<td>Brown, Michael</td>
<td>CBFO – Transportation Packaging Manager</td>
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<td>Chism, Lea</td>
<td>CBFO – QA Specialist</td>
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<td>Colt, Stanley</td>
<td>CBFO – Contracting Officer</td>
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<td>Crockett, Patti</td>
<td>CBFO – Program Analyst</td>
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<td>Holland, Ava</td>
<td>CBFO – QA Manager</td>
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<td>Huckeba, Freida</td>
<td>CBFO – Acting AM</td>
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<td>Knerr, Reinhard</td>
<td>CBFO – NTP Waste Certification Lead</td>
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<td>McCallister, Russell</td>
<td>CBFO – Assistant NTP Waste Certification Lead</td>
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<td>Milligan, Meg</td>
<td>CBFO – Chief Information Officer</td>
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<td>Ramirez, Clndi</td>
<td>L&amp;M – Document Services</td>
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<td>Sena, Gloria</td>
<td>CBFO – QA Dept. Secretary</td>
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<td>Simmons, Craig</td>
<td>L&amp;M – Document Services</td>
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<td>Waldram, Veronica</td>
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<td>Wolf, Judy</td>
<td>NTP, ODR, OEC Dept. Secretary</td>
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<td>Wu, Chuan-Fu</td>
<td>CBFO – Senior Technical Advisor</td>
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<td>Activities</td>
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<tr>
<td>Criterion 2 – QA Program (Grading/Selection of Quality Levels and Personnel Qualification and Training)</td>
<td>MP 1.2, Selection Of Quality Levels&lt;br&gt;QAPD Section 1.1.2.3&lt;br&gt;MP 2.1, Personnel Qualification and Training&lt;br&gt;QAPD Section 1.2</td>
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<td>MP 7.1, QA Requirements for Procurement of Services&lt;br&gt;QAPD Section 2.3</td>
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<td>Criterion 5 – Instructions, Procedures, and Drawings</td>
<td>MP 4.1, Preparation and Maintenance of CBFO Procedures&lt;br&gt;MP 4.4, Document Preparation and Control&lt;br&gt;QAPD Sections 1.4 and 2.1.2</td>
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<td>Criterion 7 - Control of Purchased Items and Services</td>
<td>MP 7.1, QA Requirements for Procurement of Services&lt;br&gt;QAPD Sections 2.3 and 2.3.7</td>
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<td>Criterion 8 - Identification and Control of Items</td>
<td>MPs – N/A&lt;br&gt;CBOQ QAPD Section 2.1.3</td>
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<td>Criterion 9 – Control of Processes</td>
<td>MP 4.10, Processing of TRU Waste Site Documents&lt;br&gt;MP 5.2, TRU Waste Site Certification/Recertification&lt;br&gt;MP 5.3, Correspondence Standards&lt;br&gt;CBOQ QAPD Section 2.1.4</td>
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<td>Criterion 13 - Handling, Storage, and Shipping</td>
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<td>Criterion 14 – Inspection, Test and Operating Status</td>
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