



UNITED STATES ENVIRONMENTAL PROTECTION AGEN

WASHINGTON, D.C. 20460



DEC 31 2014

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

Dear Mr. Brown:

The U.S. Environmental Protection Agency conducted a quality assurance audit of the Los Alamos National Laboratory-Carlsbad Office (LANL-CO), Waste Isolation Pilot Plant (WIPP) quality assurance (QA) program. EPA conducted this audit remotely from June 10–July 8, 2014, and onsite at LANL-CO from July 22–24, 2014. The purpose of the audit was to verify implementation of LANL-CO'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." LANL-CO, a Department of Energy (DOE) facility, is responsible for providing WIPP transuranic (TRU) waste inventory estimates and laboratory research and program support on actinide-related issues to the DOE Carlsbad Field Office (CBFO) to maintain EPA's certification of the WIPP.

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

- Element 1, "Organization."
- Element 2, "Quality Assurance Program."
- Element 4, "Procurement Document Control."
- Element 5, "Instruction, Procedures and Drawings."
- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 9, "Control of Processes."
- Element 12, "Control of Measuring and Test Equipment."
- Element 16, "Corrective Action."
- Element 17, "QA Records."

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.



Based on this audit, the EPA audit team determined that the LANL-CO WIPP QA program complies 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. The enclosed report (EPA Docket No. A-98-49; II-A1-116; EPA-HQ-OAR-2001-0012-0445) details EPA's evaluation.

EPA identified one concern not requiring a response in LANL-CO's QA program relative to the requirements of ASME NQA-1-1989. NQA-1-1989, Element 16, states that "conditions adverse to quality [(CAQ)] shall be identified promptly and corrected as soon as practical." EPA found that LANL-CO is correcting CAQs in a timely manner; however, LANL-CO procedure LCO-QP16-1, Revision 4-AC1, does not include the NQA-1 requirements that CAQs be identified promptly and corrected as soon as practical. EPA requests that LANL-CO review the language in the applicable section of LCO-QP16-1 and make changes they deem appropriate. The enclosed report supports our determination.

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

Sincerely, Tom Peake

Tom Peake Director Center for Waste Management and Regulations

Enclosure

cc: Electronic Distribution Alton Harris, DOE HQ Joe Franco, CBFO Mike Brown, Manager, CBFO QA Dennis Miehls, CBFO QA Martin Navarrete, CBFO QA Raymond Lee, EPA HQ Nick Stone, EPA Region 6 Trais Kliphuis, NMED Ricardo Maestas, NMED Site Documents

DOCKET NO: A-98-49; II-A1-116 EPA Air eDocket # EPA-HQ-OAR-2001-0012-0445

EPA AUDIT OF THE LOS ALAMOS NATIONAL LABORATORY-CARLSBAD OFFICE QUALITY ASSURANCE PROGRAM

JUNE 10–JULY 8, 2014 JULY 22–24, 2014

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

DECEMBER 2014

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ATTACHMENTS

Attachment A: Concern No. LANL-CO-QA-2014-01C

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ACRONYMS

AC	administrative change
ACRSP	Actinide Chemistry and Repository Science Program
ASME	American Society of Mechanical Engineers
CAQ	condition adverse to quality
CBFO	Carlsbad Field Office
CEMRC	Carlsbad Environmental Monitoring and Research Center
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
FR	finding report
IC	ion chromatography
ICP-MS	inductively coupled plasma mass spectrometry
LANL-CO	Los Alamos National Laboratory-Carlsbad Office
LSC	liquid scintillation counter
NIST	National Institute of Standards and Technology
NQA	nuclear quality assurance
NWP	Nuclear Waste Partnership, LLC
Pu	plutonium
QA	quality assurance
QAPD	Quality Assurance Program Document
QL-1	Quality Level One
RSS	Record Submittal System
RTS	Record Tracking System
S/N	serial number
SNL-CO	Sandia National Laboratory-Carlsbad Office
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 Los Alamos National Laboratory-Carlsbad Office (LANL-CO), Waste Isolation Pilot Plant (WIPP) quality assurance (QA) program. EPA conducted this audit remotely from June 10–July 8, 2014, and onsite at LANL-CO from July 22–24, 2014. The purpose of the audit was to verify implementation of LANL-CO'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." LANL-CO, a Department of Energy (DOE) facility, is responsible for providing WIPP transuranic (TRU) waste inventory estimates and laboratory research and program support on actinide-related issues to the DOE Carlsbad Field Office (CBFO) to maintain EPA's certification of the WIPP.

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

- Element 1, "Organization."
- Element 2, "Quality Assurance Program."
- Element 4, "Procurement Document Control."
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- Element 6, "Document Control."
- Element 7, "Control of Purchased Items and Services."
- Element 9, "Control of Processes."
- Element 12, "Control of Measuring and Test Equipment."
- Element 16, "Corrective Action."
- Element 17, "QA Records."

Based on this audit, the EPA audit team determined that the LANL-CO WIPP QA program complies 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.

EPA identified one concern not requiring a response in LANL-CO's QA program relative to the requirements of ASME NQA-1-1989. NQA-1-1989, Element 16, states that "conditions adverse to quality [(CAQ)] shall be identified promptly and corrected as soon as practical." EPA found that LANL-CO is correcting CAQs in a timely manner; however, LANL-CO procedure LCO-QP16-1, Revision 4-AC1, does not include the NQA-1 requirements that CAQs be identified promptly and corrected as soon as practical. EPA requests that LANL-CO review the language in the applicable section of LCO-QP16-1 and make whatever changes they deem appropriate.

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.

This report documents these audit activities. This information will be provided through EPA's Electronic Docket (via regulations.gov) at EPA-HQ-OAR-2001-0012 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), 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

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

LANL-CO provides three categories of quality-affecting work for the DOE CBFO in support of the WIPP: 1) LANL-CO conducts research, testing and experimentation (predominately in the field of actinide chemistry) in support of the CBFO WIPP Repository Investigations Program; 2) LANL-CO provides the WIPP program with the technical expertise to solve challenging waste issues in the packaging, certification, transportation, or emplacement of defense TRU Waste; and 3) LANL-CO manages the WIPP TRU waste inventory for WIPP recertification and provides TRU waste management and strategic planning using a complex-wide container-specific inventory.

LANL-CO performs all activities supporting the WIPP under the CBFO QAPD.

3.0 PURPOSE AND SCOPE

The purpose of this EPA audit was to verify that the LANL-CO WIPP QA program properly implements all applicable elements of ASME NQA-1-1989. The scope of this EPA audit was limited to QA oversight of activities that are important to the long-term isolation of TRU waste

as represented by documentation provided by LANL-CO.

4.0 **DEFINITIONS**

- *Finding:* A determination that a requirement of the NQA standards has not been properly established or implemented. A finding requires a response.
- *Concern:* A judgment that a finding may occur in the future and, depending on the magnitude of the issue, may or may not require a response.
- Quality: The reliability of a specific item or activity that is important to the long-term isolation of TRU waste in the WIPP. "Quality achievement" is the responsibility of operational groups that directly produce such an item or perform such an activity. "Quality assurance/verification" is the responsibility of QA groups that do not produce such an item or perform such an activity.

5.0 EPA AUDIT LOGISTICS

5.1 Audit Schedule

On July 22–24, 2014, EPA conducted QA audits of four DOE programs working on the WIPP project in Carlsbad, New Mexico. For purposes of efficiency, EPA conducted the audits in two parallel tracks with one Lead QA Auditor responsible for each track. Track A included limited-scope audits of the CBFO QA program (see Docket No. A-98-49; II-A1-117; EPA-HQ-OAR-2001-0012-0446) and the Nuclear Waste Partnership (NWP) QA program (see Docket No. A-98-49; II-A1-118; EPA-HQ-OAR-2001-0012-0447). Track B completed audits of the Sandia National Laboratory-Carlsbad Office (SNL-CO) QA program (see Docket No. A-98-49; II-A1-115; EPA-HQ-OAR-2001-0012-0444) and the Los Alamos National Laboratory-Carlsbad Office (LANL-CO) QA program (this report). EPA had begun remote audits of the SNL-CO QA program in May 2014 and the LANL-CO QA program in June 2014. The other members of the EPA audit team participated in all four audits. This report addresses only the results of EPA's audit of the LANL-CO QA program; the docket numbers cited above provide results of the other three EPA QA audits.

5.2 Team Members

The Track B 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.

Audit Team Member	Audit Responsibility	Affiliation
Lindsey Bender	EPA QA Audit Team Leader	EPA
Patrick Kelly	Lead QA Auditor	SC&A, Inc.
Kira Darlow	QA Auditor	SC&A, Inc.
Karl Lindblad	QA Auditor-in-Training	SC&A, Inc.

Table 1. EPA Quality Assurance Audit Team Members – Track B

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

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

In addition, Ms. Bender evaluated the qualifications of Mr. Kelly to be a Lead Auditor in oversight of DOE QA audits specific to NQA-1-1989 and found that he is qualified in this capacity based on his:

- Communication skills.
- Technical qualifications.
- Specific understanding of NQA-1.

Mr. Lindblad was an auditor-in-training during this audit; his qualifications as a QA auditor will be addressed in a subsequent EPA QA audit report.

EPA held one Entrance Meeting and one Exit Meeting that included personnel from all four audited organizations, identified in Table 2. Some of these personnel may have been interviewed during one of the other three audits; however, only the personnel interviewed as part of this LANL-CO QA audit are identified in Table 2.

Name	Affiliation and Title/Position	Entrance Meeting	Interview	Exit Meeting
April Heiser	LANL-CO, Records Manager		~	
Berry Pace	CTAC, QA Programs Manager	✓		
Bill Allen	NWP, QA	\checkmark		
Cindi Castillo	CTAC, QA Auditor/Observer	✓		✓
Cliff Stroud	LANL-CO, Deputy Group Leader		\checkmark	
Dana C. Bryson	CBFO, Deputy Manager			~
Danielle Cleveland	LANL-CO		\checkmark	
Dave Guerin	LANL-CO, TRU Waste Inventory/QA		✓	
Dennis Miehls	CBFO, Senior QA Specialist	✓		~
Fran Ito	NWP	✓		
Gene Safley	SNL-CO, QA Lead	\checkmark		
Grace Duran	SNL-CO, Records Lead			~
Jean Francois Lucchini	LANL-CO		✓	
Jim McVay	NWP	✓		
Laurie Smith	LANL-CO, QA Manager	~	✓	~
Martin Navarrete	CBFO, Senior QA Specialist	✓		~
Michael R. Brown	CBFO, QA Director	✓		×
Ned Z. Elkins	LANL-CO, Program Director	✓		
Paul Shoemaker	SNL-CO, Senior Manager			×
Porf Martinez	CTAC, Regulatory Assurance Manager	~		
Priscilla Y. Martinez	CTAC, QA Auditor/Observer	✓		✓
Regina Sides	CBFO, QAD			~
Shelly R. Nielsen	SNL-CO, QA	1		~
Steve Davis	SNL-CO, QA Assessment Task Lead	~		~
Steve Kouba	RES, Manager EPA Compliance Program	1		
Tammy Reynolds	NWP, Deputy Recovery Manager			~
Val Cannon	NWP, QA	1		×

Table 2. Personnel Participating in Audit Meetings

6.0 PERFORMANCE OF THE AUDIT

The EPA audit team reviewed documents and records provided by LANL-CO and interviewed LANL-CO personnel to evaluate implementation of the requirements in ASME NQA-1-1989. LANL-CO stated, and EPA concurred, that the following NQA-1-1989 elements are not applicable to work currently performed by LANL-CO:

- Element 3, "Design Control."
- Element 8, "Identification and Control of Items."
- Element 10, "Inspection."
- Element 11, "Test Control."
- Element 13, "Handling, Storage and Shipping."
- Element 14, "Inspection, Test and Operating Status."
- Element 15, "Control of Nonconforming Items."

• Element 18, "Audits."

The NQA-1-1989 elements listed below are applicable to work currently performed by LANL-CO and were therefore evaluated during this audit.

- Element 1, "Organization."
- Element 2, "Quality Assurance Program."
- 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 12, "Control of Measuring and Test Equipment."
- Element 16, "Corrective Action."
- Element 17, "QA Records."

The EPA audit team reviewed documents and records provided by LANL-CO and interviewed LANL-CO personnel to evaluate implementation of the requirements in ASME NQA-1-1989 for these elements, using NQA-1-1989 checklists. The checklists will be available on line through the EPA's Electronic Docket (via regulations.gov) or in hard copy via the Reading Room/Information Center in the Agency's Air and Radiation docket as described in section 1.0 above. In addition to the 10 elements listed above as evaluated during EPA's audit, EPA also reviewed LANL-CO procedure LCO-QP18-1, Audits, Revision 3. However, LANL-CO is not currently performing any audits; therefore, the EPA audit team did not complete a checklist for Element 18.

The EPA audit team toured the LANL-CO laboratory facilities, which are located at the Carlsbad Environmental Monitoring and Research Center at the New Mexico State University Carlsbad campus, and conducted a limited review of laboratory practices and records. EPA limited the laboratory evaluation to the extent necessary to complete the applicable NQA-1-1989 checklists. EPA did not evaluate the technical adequacy of the laboratory or the usability of the data produced by the laboratory.

As a result of these audit activities, EPA determined that the LANL-CO WIPP QA program complies with these NQA-1-1989 elements and has sufficient independence, authority and resources to verify the quality of items and activities that are important to long-term isolation of TRU waste.

7.0 FINDINGS AND CONCERNS

The EPA audit team did not identify any findings relative to the NQA-1-1989 elements discussed above. The EPA audit team identified one concern not requiring a response related to NQA-1-1989, Element 16.

Concern No. LANL-CO-QA-2014-01C regards LANL-CO procedure LCO-QP16-1, Revision 4-AC1, "Conditions Adverse to Quality." NQA-1-1989, Element 16, states that "[CAQs] shall be identified promptly and corrected as soon as practical." Procedure LCO-QP16-1, Revision 4-AC1, does not include the NQA-1 requirements that CAQs be identified promptly and corrected as soon as practical. Through interviews with LANL-CO personnel and review of corrective action closure dates, EPA found that even though its procedure does not explicitly require timeliness, LANL-CO is correcting CAQs in a timely manner.

EPA is not concerned about the current implementation of the process to address CAQs at LANL; however, EPA requests that LANL-CO review the language in the applicable section of LCO-QP16-1 and make the changes they deem appropriate.

There are no open issues as a result of this audit.

8.0 CONCLUSIONS

The EPA audit team reviewed records documentation and interviewed personnel to determine the compliance of the LANL-CO WIPP QA program with ASME NQA-1-1989. Based on the sample of records reviewed and interviews conducted during this audit, EPA determines that LANL-CO complies with the standard.

9.0 **REFERENCES**

2013 Peer Inspector Training Attendance Record, TRN-1302-01-01-01, January 28, 2013

ACP-EXP-003, Balance Performance Check, Revision 3, January 7, 2011

ACP-EXP-005, Thermometer Calibration and Performance Check, Revision 4, September 18, 2013

ACP-EXP-006, Ultra-Violet, Visible and Near Infra-Red Spectrophotometer Calibration and Performance Check, Revision 4, September 18, 2013

ACP-EXP-011, Inductively Coupled Plasma-Mass Spectrometry, Revision 3-ACI, September 19, 2013

ACP-IMP-003, Test Plans and Task Implementation Plans, Revision 5, September 18, 2013

ACP-IMP-004, Measuring and Test Equipment, Revision 5, September 18, 2013

ACRSP ICP-MS Model 7500, S/N: JP51201393 (also showing S/N: 211306), labeled: "Calibrate Prior to Use", observed July 24, 2014, in CEMRC Laboratory, Room 151

ACRSP Scientific Notebook No. ICP-MS 4, ACP-1312-05-09-01, May 21, 2013

Beckman Multi-Purpose Liquid Scintillation Counter, System ID No. 477965, labeled: "Performance Check-Prior to Use, 1/5/12", observed July 24, 2014, in CEMRC Laboratory, Room 151

Calibration Certificates for PC-0491122, ACP-1405-02-04-08, April 8, 2014

Calibration Standard-Modified (ICP-MSCS-M) for ICP-MS, High Purity Standards Lot No. 1328419, ACP-1406-01-12-97, April 15, 2014

Certificate of Analysis for PC-0429249, ACP-1210-02-04-02, February 29, 2012

Certificate of Analysis for PC-0450072, ACP-1305-01-04-03, October 11, 2012

Demonstration of document review request, demonstrated July 23, 2014

Email from A. Heiser to N. Elkins, et. al., re: Finding Report FR-13-02 Regarding ACRSP data, with Attachment CAQ-1312-01-01.pdf, December 18, 2013

Email from L. Sparks to P. Kelly, re: FR closure times, July 24, 2014

Grading for FY11 and FY12, GRD-1204-01-01-01, April 3, 2012

Grading for FY13, GRD-1301-01-01, January 23, 2013

Grading for FY14, GRD-1312-01-01-01, December 10, 2013

Henry Troemner, LLC requalification, QSL-1306-02-01-01, June 12, 2013

High-Purity Standards requalification, QSL-1210-01-01, September 10, 2012

ICP-MS Iridium Standard, High Purity Standards Lot No. 1307214, ACP-1305-03-12-15, May 7, 2013

ICP-MS Thorium Standard, High Purity Standards Lot No. 1234128, ACP-1305-03-12-16, May 7, 2013

Interference Check Solution A (ICP-MS-ICS 3, solution A) Standard for ICP-MS, High Purity Standards Lot No. 1405548, ACP-1406-01-12-95, April 15, 2014

INV-SP-03, Requests for Quality Level 1 Inventory Information, Revision 11, May 14, 2014

Key Position Descriptions, provided June 2, 2014

LANL-CO Finding Report FR-13-01, CAQ-1305-01-01-01

LANL-CO Finding Report FR-13-02, CAQ-1312-01-01-01

LANL-CO Material/Service Acceptance and Quality Level Determination for Procurement Request CEMRC 01/10/2012 to Eckert & Ziegler Analytics for LSC Calibration Standards (C-14; H-3 and Background), ACP-1205-03-04-01, March 27, 2012

LANL-CO Organization Chart for EPA Audit, provided June 2, 2014

LANL-CO Qualified Supplier List, Updated April 24, 2014

LCO-ACP-01, LANL-CO/CEMRC Interface Document, Revision 4, April 5, 2012

LCO-MP18-1, Management Assessments, Revision 4, October 29, 2012

LCO-MP7-1, Procurement, Revision 7-AC1, September 20, 2013

LCO-QP16-1, Conditions Adverse to Quality, Revision 4-AC1, September 12, 2013

LCO-QP17-1, Record Management, Revision 12, September 3, 2013

LCO-QP18-1, Audits, Revision 3, July 12, 2011

LCO-QP18-2, Qualification of Audit Personnel, Revision 3, September 24, 2013

LCO-QP2-1, Establishing Quality Controls, Revision 5, September 24, 2013

LCO-QP2-2, Quality Assurance Requirements for Quality Level One Activities, Revision 5, September 24, 2013

LCO-QP2-3, Qualification and Training, Revision 5, May 16, 2014

LCO-QP6-1, Controlled Document Development, Change, and Revision, Revision 11, September 3, 2013

LCO-QP6-2, Controlled Document Review and Approval, Revision 11, September 3, 2013

LCO-QP6-3, Document Control and Distribution, Revision 11, September 3, 2013

LCO-QP9-1, Analyses, Revision 5, December 19, 2013

LCO-QPD-04, LANL-CO Document and Record Management Plan, Revision 8, September 3, 2013

LCO-QPD-06, LANL-CO Organization and Interface, Revision 2, May 14, 2014

Lead Auditor Maintenance of Proficiency for L. Sparks, TRN-1310-02-01-01, September 25, 2013

Lead Auditor Qualification for L. Sparks, TRN-0510-01-01-01, October 7, 2005

List of Measuring and Test Equipment, provided June 2, 2014

List of Qualified Audit Personnel, provided 6/2/2014

LSC Standard Set B, Eckert & Ziegler Lot Nos. 90474, 90475, 90476, ACP-1205-04-12-07, March 21, 2012

M&TE Data Sheet for Digital Hygro/Thermometer with Timer, DHT34 Control Company, S/N: 122454202, ACP-1301-02-12-35, October 10, 2012

M&TE Data Sheet for Inductively Coupled Plasma-Mass Spectrometer, S/N: JP51201393; M&TE Data Sheet for Software, ACP-0706-03-12-48, May 10, 2007

M&TE Data Sheet for Pu-242 Standard Reference Material, NIST, Lot No. 721-Pu242, ACP-1104-01-12-16, March 10, 2011

Management Assessment MA-12-01, MAR-1203-01-01-01, March 15, 2012

Management Assessment MA-12-02, MAR-1205-02-01-01, May 30, 2012

Management Assessment MA-12-03, MAR-1210-01-01, October 25, 2012

Management Assessment MA-12-04, MAR-1209-01-01-01, September 10, 2012

Management Assessment MA-12-05, MAR-1208-01-01-01, August 23, 2012

Management Assessment MA-12-06, MAR-1303-02-01-01, March 25, 2013

Management Assessment MA-13-01, MAR-1303-01-01-01, March 14, 2013

Management Assessment MA-13-02, MAR-1310-01-01, October 29, 2013

Management Assessment MA-13-03, MAR-1305-01-01-01, May 6, 2013

Management Assessment MA-13-04, MAR-1404-01-01-01, April 7, 2014

Management Assessment MA-14-01, MAR-1403-01-01-01, March 12, 2014

Material Acceptance Form for PC-0429249, ACP-1210-02-04-02, September 4, 2012

Material Acceptance Form for PC-0450072, ACP-1305-01-04-03, March 20, 2013

Material Acceptance Form for PC-0491122, ACP-1405-02-04-08, April 23, 2014

Memo to the Quality Assurance File, QAM-13-04, March 25, 2013

Mettler Toledo requalification, QSL-1208-01-01-01, July 25, 2012

Posted records access list, observed July 23, 2014

Procurement Request PC-0429249 to Fisher for Sodium Chloride for QL1 work, ACP-1210-02-04-02, August 27, 2012

Procurement Request PC-0450072 to High Purity Standards for Multi-Element IC Standard and Oxalate Standard for IC and LANL-CO Material/Service Quality Level Determination Form, ACP-1305-01-04-03, March 11, 2013

Procurement Request PC-0455212 to High Purity Standards for Multiple Standards for ICP-MS and IC Analysis and LANL-CO Material/Service Quality Level Determination Form, ACP-1309-02-04-01, April 23, 2013

Procurement Request PC-0491122 to Troemner for ACRSP Weights No. B and No. C Recertification, ACP-1405-02-04-08, March 12, 2014

QA Index of Quality Assurance Controlled Documents, May 16, 2014

QA-DL-01, LANL-CO QA Distribution and Required Reading List, TRN-1406-01-01-01, Revision 11, June 4, 2014

QAPD, Quality Assurance Program Document, DOE/CBFO-94-1012, Revision 11, June 2010

Quality Assurance Project Leader Qualification for L. Sparks, TRN-0502-05-01-01, February 21, 2005

Records filing demonstration, July 23, 2014

Review Package for INV-SP-03, Revision 10

Review Package for INV-SP-03, Revision 11

Review Package for LCO-QP2-1, Revisions 0 and 5

Review Package for LCO-QPD-04, Revision 7

Review Package for LCO-QPD-04, Revision 8

RSS and RTS demonstration, July 23, 2014

Supplier Evaluation of Bruker AXS, Inc., QSL-1403-01-01, March 25, 2014

Supplier Evaluation of Michell Instruments, Inc., QSL-1312-01-01, December 12, 2013

Tour of laboratory offices, July 24, 2014

Tour of record storage room, July 23, 2014

Training records for B. Ams, D. Guerin D, A. Heiser, D. Reed, C. Stroud

Varian Cary 5000 UV/VIS/NIR Spectrometer S/N: ELO6113131, labeled: "Frequency of Performance Check-Monthly" and Maintenance Log, observed July 24, 2014, in CEMRC Laboratory, Room 151

Visual confirmation of expiration date labels, ICP-MS Standard Solutions or dilutions thereof stored in fume hood, on open laboratory bench or in laboratory glove box, observed July 24, 2014, in CEMRC Laboratory, Room 151

Visual confirmation of markings on equipment, Liquid Scintillation System, Beckman LS6500, System ID 474965, observed July 24, 2014, in CEMRC Laboratory, Room 151

Working Document Cover Sheet, Liquid Scintillation System, Beckman LS6500, ACP-0502-11-12-04, October 11, 2004

ATTACHMENT A

EPA INSPECTION ISSUE TRACKING FORM

CONCERN NO. LANL-CO-QA-2014-01C, FINAL

Inspection No. QA-LANL-CO-2014-1	Concern Number: LANL-CO-QA-2014-01C		
	Date: July 23, 2014		
Inspector: Kira Darlow, Patrick Kelly	Sample Size: 1		
Attachments? 🗌 YES 🛛 NO	Population size (if known): 1		

Description of Issue: NQA-1-1989, Element 16, states that "conditions adverse to quality [(CAQ)] shall be identified promptly and corrected as soon as practical." EPA found that in practice, LANL-CO is correcting CAQs in a timely manner. However, procedure LCO-QP16-1, Revision 4-AC1, does not include the NQA-1 requirements that CAQs be identified promptly and corrected as soon as practical.

EPA requests that LANL-CO review the language in the applicable section of LCO-QP16-1 and make whatever changes they deem appropriate.

B. Regulatory Reference: 40 CFR 194.22(e)

C. NQA-1-1989 Element(s): 16

D. Discussed with: Laurie Smith and David Guerin

E. Additional Comments: None

F. Site Response Information:

Site Response Required? YES NO Site Response Due Date: Not Applicable