

## HOLTON, BRIAN, NMENV

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**From:** Maestas, Ricardo, NMENV  
**Sent:** Wednesday, January 22, 2020 2:50 PM  
**To:** HOLTON, BRIAN, NMENV  
**Subject:** FW: Scope documents for SQA Audit Feb. 10-13th  
**Attachments:** AUD-LANL-CO-FEB-2020\_Scope.pdf; AUD-SNL-CPG-FEB-2020\_Scope.pdf

**From:** Ellis, Jerry <Ellis.Jerry@epa.gov>  
**Sent:** Wednesday, January 15, 2020 2:38 PM  
**To:** Dennis Miehl (dennis.miehl@cbfo.doe.gov) <dennis.miehl@cbfo.doe.gov>; Maestas, Ricardo, NMENV <Ricardo.Maestas@state.nm.us>  
**Cc:** kdarlow (kdarlow@scainc.com) <kdarlow@scainc.com>; Patrick Kelly <pkelly@scainc.com>; Mosser, Jennifer <Mosser.Jennifer@epa.gov>; Tong, Xinyue <Tong.Xinyue@epa.gov>; Feltcorn, Ed <Feltcorn.Ed@epa.gov>; Peake, Tom <Peake.Tom@epa.gov>; Schultheisz, Daniel <Schultheisz.Daniel@epa.gov>  
**Subject:** [EXT] Scope documents for SQA Audit Feb. 10-13th

Good afternoon Dennis:

Attached are the scopes for the audits that will be conducted in Carlsbad Feb. 10-13, 2020. Please note, the date for requested documents is next Thursday Jan. 23<sup>rd</sup> Let us know where to retrieve them. Thank you.

Scope call for both audits scheduled for:

February 4, 2020

Time: 11-12 MT/1-2pm EST

**Teleconference Info.:** 1-202-991-0477; Participant Code: 7841090#

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RPD Quality Assurance Coordinator  
WIPP Oversight  
U.S. EPA, OAR – Radiation Protection Division  
Phone: 202-564-2766



**Purpose and Scope**  
**EPA Audit of Los Alamos National Laboratory-Carlsbad Operations**  
**Software Quality Assurance Program**  
**Audit No. AUD-LANL-CO-FEB-2020**

<b>Organization Audited:</b>	Los Alamos National Laboratory-Carlsbad Operations (LANL-CO)
<b>Organizations Notified:</b>	Department of Energy - Carlsbad Field Office, New Mexico Environment Department, LANL-CO
<b>Audit Dates:</b>	February 10–13, 2020 <sup>1</sup>
<b>Audit Location:</b>	LANL-CO Quality Assurance Offices in Carlsbad, NM
<b>Inspection Schedule:</b>	To be determined upon discussions with LANL-CO and Sandia National Laboratories-Carlsbad Programs Group Quality Assurance personnel (refer to footnote 1)
<b>EPA Auditors:</b>	Jerry Ellis (EPA Team Lead), Kira Darlow (Lead Auditor, EPA Contractor), Patrick Kelly (Auditor, EPA Contractor), Jennifer Mosser (EPA Observer), Xinyue Tong (EPA Observer)
<b>Audit Purpose:</b>	The purpose of this audit is to verify the proper establishment and implementation of selected elements of the ASME Nuclear Quality Assurance standards (NQA-1-1989 and NQA-2-1989) implemented by LANL-CO with regards to software affecting the long-term isolation of transuranic waste within the Waste Isolation Pilot Plant.
<b>Inspection Scope:</b>	The focus of this audit is to verify implementation of software quality assurance programs according to ASME NQA-1-1989 Element Numbers 1, Organization, 3, Design Control, and 11, Test Control, and ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications. The EPA will review samples of procedures and records from LANL-CO operations and perform interviews with LANL-CO personnel to verify that the LANL-CO quality assurance program complies with these elements

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<sup>1</sup> Audit will be conducted over two days during the period of February 10–13, 2020. The EPA will also conduct a two-day software quality assurance audit of Sandia National Laboratories-Carlsbad Programs Group during the same period.

**Initial Document and Information request. Please provide the following information no later than **January 23, 2020**:**

- Description of how the NQA-1-1989 and NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989, requirements flow down into LANL-CO procedures, including document numbers.
  - For example: The LANL-CO QA and SQA program requirements flow down from the CBFO QAPD into our QA Program Plan (Document No.) and then to our implementing procedures.
- High-level QA document(s), such as a QA Program Plan, referenced in the flow-down description.
- List of software products to which the SQA requirements apply. Please indicate which of these LANL-CO developed in house and which LANL-CO acquired through procurement.
- Current organization chart(s) showing how the QA and SQA programs fit into the overall LANL-CO structure and any QA or SQA positions assigned at other levels of operations, as applicable.
- Procedures or project plans that implement NQA-1-1989 Elements 1, 3, and 11 and NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989, which may include:
  - Software corrective action procedures.
  - Software requirements procedures, including design control and changes to software.
  - Test control procedures, especially as they relate to software.
  - Software verification and validation procedures.
- Other procedures referenced in the procedures provided in response to the above bullet.
- Current list of all procedures relevant to the scope of this audit.
- Any SQA-related program description documents.
- Documents describing interfaces with other organizations (internal and external) responsible for completing quality-affecting activities.
- List of key QA and SQA personnel, plus personnel responsible for implementing the provided procedures. Please indicate each person's role.

If you have any questions, please contact Jerry Ellis at 202-564-2766.