

The audit report will be made available to the public through the Agency's Public docket. Please contact Mike Eagle at (202) 343-9376 if you have questions regarding the enclosed report.

Sincerely,

A handwritten signature in black ink that reads "Tom Peake". The signature is written in a cursive style with a large, sweeping initial "T".

Tom Peake, Director
Center for Waste Management and Regulations

cc: Ava Holland, CBFO
Alton Harris, DOE
Steve Zappe, NMED
WIPP Docket

bcc: WIPP Team

**DOCKET NO: A-98-49
II-A1-108**

EPA AUDITS OF DOE PEER REVIEW OF HISTORICAL INFORMATION

**JUNE 29 – JULY 1, 2010
&
AUGUST 3 – AUGUST 4, 2010**

**U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RADIATION AND INDOOR AIR
CENTER FOR FEDERAL REGULATIONS
1200 PENNSYLVANIA AVE., N.W.
WASHINGTON, DC 20460**

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EXECUTIVE SUMMARY

On June 29 through July 1, 2010, the Environmental Protection Agency (EPA) conducted an audit of a Department of Energy (DOE) Peer Review used to qualify historical information for transuranic (TRU) waste streams SR-BCLDP-004.002 and SR-BCLDP-004.003. This DOE Peer Review was conducted from May 4, 2010 through June 2, 2010. EPA performed a follow-up audit on August 3-4, 2010 to further evaluate the Peer Review. The investigation of activities selected for the EPA audit samples showed that the Peer Review was conducted properly in accordance with the EPA-invoked standard NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories." There was no audit finding of nonconformance with the requirements of NUREG-1297.

During this audit, the EPA also reviewed two DOE's actions related to previous EPA concerns of possible nonconformance generated during a December 2009 audit of DOE's Carlsbad Field Office (CBFO). One concern was elevated to a finding of nonconformance. EPA requires a written response from CBFO in the near future regarding the following finding of nonconformance:

Finding: NQA-1 Element No 16, titled "Corrective Action", states, "Conditions adverse to quality shall be....corrected as soon as possible." The EPA is concerned with the timely closure of corrective action reports issued against CBFO in the areas of document control, records control, and the National TRU Program. The specific Corrective Action Reports (CARs) are: CAR 08-003, *Document Control*; CAR 08-027, *Records Control*; CAR 08-029, *Aged CARS*; and CAR 09-013, *NTP – "What defines a new program?"* EPA reviewed the CARs noted above and determined that none of the CARs had been closed and completed. EPA elevated this concern to a finding and EPA requires a written response from CBFO with regard to the implementation of corrective actions. EPA will further evaluate this finding and its associated corrective actions during an audit in March 2011.

1.0 BACKGROUND

1.1 Regulatory Background

40 CFR Part 194.22(b) states that old information can be qualified with a Peer Review "conducted in a manner that is compatible with NUREG-1297." The requirements of NUREG-1297 are established in DOE's Management Procedure (MP) 10.5, "Peer Review."

1.2 Organizational Background

The mission of the DOE's CBFO is to protect human health by operating the Waste Isolation Pilot Plant (WIPP) for safe disposal of TRU waste. CBFO conducted the Peer Review to qualify historical radiochemistry data that established the radiological properties of Waste Streams SR-BCLDP-004.002 and SR-BCLDP-004.003.

The Carlsbad Technical Assistance Contractor (CTAC) supports CBFO's Quality Assurance

(QA) organization to verify that Peer Reviews are conducted properly.

2.0 PURPOSE AND SCOPE

The purpose of the EPA audit was to verify that the subject Peer Review was conducted in accordance with the applicable requirements of NUREG-1297. The EPA auditors thoroughly reviewed the independence and qualification of the peer panel members. The scope of the EPA audit included all of the activities of the Peer Review.

In addition, the EPA revisited two EPA concerns generated during a December 2009 audit of CBFO to determine if these concerns could be closed.

3.0 DEFINITIONS

Finding: A determination that a specific item or activity does not comply with an applicable EPA requirement. 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 inside the WIPP. *Quality Achievement* is the responsibility of organizations that directly produce such an item or perform such an activity. *Quality Assurance/Verification* is the responsibility of QA organizations that do not produce such an item or perform such an activity.

4.0 EPA AUDIT TEAM MEMBERS

The audit team consisted of one EPA employee and support contractors. All members of the EPA audit team, along with each person's affiliation and function during this audit, are listed in Table 1.

Table 1. EPA Quality Assurance Audit Team Members

Audit Team Member	Audit Responsibility	Affiliation
Mike Eagle	EPA Quality Assurance Audit Team Leader (was present during initial audit)	U.S. EPA ORIA
Patrick Kelly	Lead Quality Assurance Auditor	S. Cohen & Associates, Inc.
Greg Beronja	Quality Assurance Auditor	S. Cohen & Associates, Inc.
Dorothy Gill	Quality Assurance Auditor	S. Cohen & Associates, Inc.

5.0 PERFORMANCE OF THE AUDIT

5.1 Peer Review

5.1.1 Review of Documents and Records

Prior to the start of the audit, the EPA audit team reviewed applicable documents and the records generated during the subject peer review, including:

- NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories, 1988
- Remote-Handled TRU Waste Characterization Program Implementation Plan, October 2003
- CBFO MP 10.5, Peer Review
- Peer Review Plan, Savannah River Site Historical Radiochemistry Data, Peer Review Plan
- Letter, dated April 22, 2010 from the panel manager to the CTAC Environmental Compliance & Safety Support Manager, requesting his participation in panel selection
- SRS Peer review Selection Committee Meeting Minutes, conference call April 27, 2010
- Peer review Panel Selection Justification/Decision Form
- Determination of Peer Review Panel Member Independence Form
- Peer Review Panel Member Verification of Education/Employment Form
- Resumes of the two peer panel members and the review panel manager
- Peer Review Panel Member Selection Justification/Decision Form
- Peer Review Panel Orientation Form and training material
- May 4 & 5, 2010, meeting minutes and training material
- Observer Inquiry Forms generated during the review process
- Peer Review Report
- CTAC audit report

The EPA audit team verified the correct flow down of requirements from NUREG 1297 to CBFO's peer review procedure MP 10.5. EPA verified implementation of the peer review process by reviewing the records listed above and by interviewing selected personnel. Initially, the panel member résumés that had been provided for review were incomplete. The EPA audit team generated Concern No. 3 to address this issue.

5.1.2 Personnel Interviews

The EPA audit team conducted interviews with the panel manager (on two occasions), each panel member (on two occasions), and the CTAC auditor who performed an audit of the Peer Review process.

5.1.2.1 Peer Panel Manager

The panel manager was interviewed by the EPA team by telephone. The panel manager was contracted with Navarro Research and Engineering, Inc., to perform this peer review and worked

closely with the CTAC Environmental Compliance and Safety Support Manager to select panel members in accordance with MP 10.5. The manager stated that he had performed over twenty peer reviews and was very familiar with the process. The scope of the peer review was provided to the manager and he made panel member recommendations based on his previous knowledge of potential panel member experts. Qualifications of the selected panel members were verified telephonically by CTAC QA support personnel and each panel member completed the required determination of independence form.

The panel review manager and the CTAC Environmental Compliance and Safety Support Manager generated a written plan for the peer review which included the scope and purpose of the review. The panel members attended an orientation meeting the day before the actual panel meeting. The panel manager stated that his responsibilities included facilitation of the review process, processing Observer Inquiries, and guiding panel caucuses to ensure that the panel members received the information needed for them to reach a technically sound decision.

The panel manager contacted the panel members throughout the process, culminating in issuance of a peer panel review report. This report was written by the panel manager and members, but only signed by the panel members.

The panel manager stated that he felt that the entire process was performed in a short timeframe, but did not feel this negatively impacted the quality of the peer review conclusions.

5.1.2.2 Peer Panel Review Members

The panel for this review consisted of two PhD-level chemists, each with over 25 years of experience. The EPA team interviewed the panel members separately by telephone. Both panel members stated that the peer review schedule was aggressive and the scope was initially not well defined. EPA generated Concern No. 2 to address this issue. However, both chemists felt that, by the end of the peer review meeting in Albuquerque (held at the start of May, 2010), they had a clear understanding of what data and information was to be used to make their conclusions. During the peer-review, the panel members were told that EPA had already approved the subject data. Peer-review is one method DOE can use to qualify data prior to EPA approval of the data. During the peer-review of historical information of waste streams discussed on page 1, a DOE representative incorrectly told the peer-reviews that EPA had already approved the subject data, thus potentially improperly influencing DOE's peer-review qualification process that is supposed to take place before an EPA approval. When this concern was presented to the two panel members that heard the incorrect statement, both members stated to the audit team that the erroneous information given to them did not influence their own decision making for the qualification of the data.

When questioned about their experience with radiochemical data, both panel members stated that they were not experts in this area. EPA generated Concern No. 1 to address this issue. During the follow-up audit, EPA determined that one of the panel members had sufficient experience to evaluate the radiochemical data. Both members had extensive experience in laboratory QA programs and protocols. Review of the panel members' résumés (complete and updated résumés were provided during the audits) confirmed these statements.

5.1.2.3 CTAC Auditor

EPA also evaluated a CBFO QA audit, A-10-22, of this peer review to verify that the audit was conducted in accordance with NQA-1 Element 18, Audits. The EPA interviewed the CTAC auditor who performed the audit; the auditor stated that he began with a document review to ensure proper and complete flow-down of requirements from NUREG 1297 and then observed the peer review process. The auditor stated that he had sufficient independence to perform his task. A checklist was used by the auditor to guide his audit and a report was generated at the end of the process. EPA did not identify any concerns or findings during the interview with the auditor.

5.1.3 Peer Review Concerns

Concern No. 1: NUREG 1297, Section IV, Section 3.a states, "...each peer reviewer should have recognized and verifiable technical credentials in the technical area he or she has been selected to cover. The technical qualifications of each peer, and hence of the peer review group as a whole, should relate to the importance of the subject matter to be reviewed." However, the EPA is concerned that the peer panel members may not have recognized and verifiable technical credentials in gamma and alpha spectrometry, i.e., the technical area selected for review, despite the fact that both peer panel members have PhDs in chemistry. Accordingly, the qualifications of the peer review group as a whole may not relate to the importance of the subject matter to be reviewed. The EPA conducted a follow-up audit on August 3 through August 4, 2010, to further investigate this concern, including further interviews of personnel involved in the peer review.

DOE's Initial Response: The National TRU Programs (NTP) Manager stated that this schedule was reasonable and that he would support the follow-up audit, subject to the availability of requested personnel. The EPA accepted DOE's response.

Concern Resolution: The EPA accepted DOE's response and conducted the follow-up audit on August 3-4, 2010, as planned. At the follow-up audit, the EPA audit team obtained further information through interviews with the peer panel members and review of updated panel member résumés. This information adequately addressed EPA's initial concern regarding the qualifications of the panel members.

Status of Concern: EPA considers this concern to be closed.

Concern No. 2: NUREG 1297, Section 4, *Peer Review Process*, states, "For any given peer review, procedures should require a planning document that describes the work to be reviewed." Consistent with this requirement, CBFO Procedure MP 10.5, Attachment 1, A.6.1 requires that peer review plans contain "the scope and a description of the work to be reviewed." EPA has a minor concern that the description of the work to be reviewed initially provided in the Peer Review Plan was vague.

EPA did not require a response to this minor concern and the EPA audit team evaluated it further

during the follow-up audit on August 3-4, 2010. While EPA acknowledges there is room for improvement in the scope definition, EPA is satisfied that this concern did not adversely affect the peer review. However, EPA may further evaluate this area during subsequent audits of peer review.

Concern No. 3: EPA's review of the documentation associated with the Peer Review determined that complete résumés were not provided in the data package.

DOE's Response: DOE agreed that the résumés were incomplete and committed to locating complete résumés and providing them to EPA prior to the end of the audit.

Concern Resolution: DOE located the complete résumés and included these in the data package during the audit.

Status of Concern: EPA considers this concern to be closed.

EPA intends to conduct audits additional future peer reviews to verify continued compliance. These audits will include an assessment of peer independence and qualifications. DOE has no peer reviews currently planned; they have agreed to provide EPA with reasonable notice of future peer review plans.

5.2 Follow-Up of Previous Audit

The EPA team reviewed two DOE's actions related to previous EPA concerns of possible nonconformance generated during a December 2009 audit of DOE's Carlsbad Field Office (CBFO). One concern was elevated to a finding of nonconformance. EPA requires a written response from CBFO regarding the following finding of nonconformance:

Concern No.1: NQA-1 Element No 16, Corrective Action, states, "Conditions adverse to quality shall be....corrected as soon as possible." The EPA is concerned with the timely closure of corrective action reports issued against CBFO in the areas of document control, records control, and the National TRU Program. The specific CARs are: CAR 08-003, *Document Control*; CAR 08-027, *Records Control*; CAR 08-029, *Aged CARs*; and CAR 09-013, *NTP – "What defines a new program?"* This is a repeat concern. A response to this concern is not required. EPA will conduct a follow-up audit of CBFO in the month of March, 2011 to verify the proper execution of the following NQA-1 Elements: No. 6, *Document Control*; No. 16, *Corrective Action*; and No. 17, *Quality Assurance Records*.

Status of Concern: EPA reviewed the CARs noted above in the concern above and determined that none of the CARs had been closed and completed. EPA elevated this concern to a finding and EPA requires a written response from CBFO with regard to the implementation of corrective actions. EPA will further evaluate this finding and its associated corrective actions during future audit.

Concern No. 2: The EPA requires the establishment of applicable NQA-1 requirements in the QA plans of all organizations performing activities important to waste isolation. The EPA is concerned that the LANL-CO QA plan may be modified to incorporate the requirements of another QA standard and thus possibly compromise the implementation of the NQA-1 standard at LANL-CO. A response to this concern is not required. The EPA will review any future changes to the LANL-CO QA plan.

Status of Concern: EPA reviewed the status of this concern with regard to the proper establishment of the NQA-1 requirements in the LANL QA Plan. EPA is satisfied with the responses given during the review, but the concern remains open and EPA will continue to monitor this concern during future audits.

5.3 Identification of Follow-Up Activities

EPA intends to conduct audits of future peer reviews held to verify continued compliance. These audits will include an assessment of peer independence and qualifications. NTP has no peer reviews currently planned, however they have agreed to provide EPA with reasonable notice of future peer reviews.

6.0 CONCLUSIONS

EPA determined that the peer review, conducted to qualify historical radiochemical data analyzed by Battelle Columbus Laboratories and used by the Savannah River Site to establish radiological properties of RH TRU waste streams SR-BCLDP-004.002 and SR-BCLDP-004.003, was conducted in accordance with the requirements of NUREG 1297.

EPA will continue to monitor progress of corrective action for the two concerns identified during the December, 2009 audit and expects DOE to respond to Concern No. 1 which has now been elevated to a finding.

ATTACHMENT A

PERSONNEL PARTICIPATING IN AUDIT MEETINGS

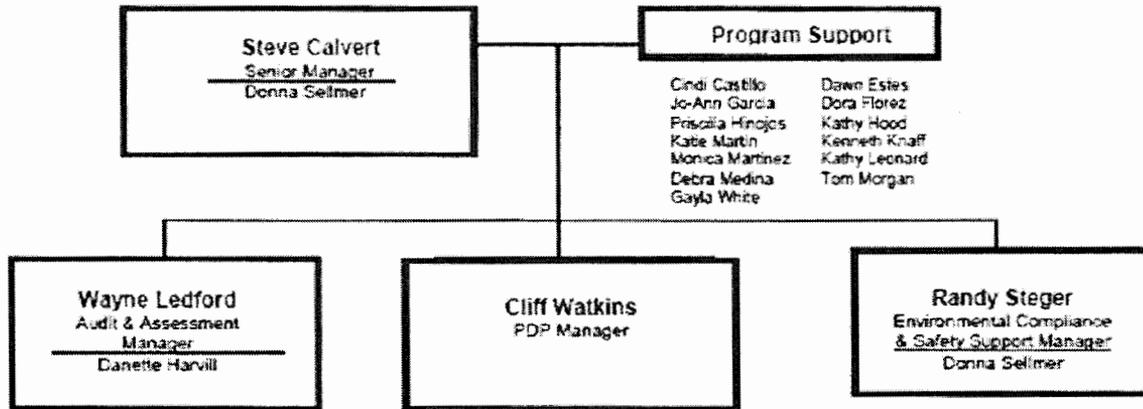
NAME	AFFILIATION	ENTRANCE MEETING	EXIT MEETING
Mike Eagle	EPA, Audit Team Leader	X	X
Greg Beronja	EPA/SC&A	X	X
Patrick Kelly	EPA/SC&A	X	X
Dorothy Gill	EPA/SC&A	X	X
Ava Holland	CBFO QA Manager	X	X
Casey Gadbury	CBFO	X	X
Dennis Miehl	CBFO QA Specialist	X	X
Berry Pace	CTAC Auditor		X
Court Fesmire	CBFO	X	X
Roger Nelson	CBFO		X

ATTACHMENT B

**AUDIT INFORMATION – CARLSBAD TECHNICAL ASSISTANCE CONTRACTOR
WAYNE LEDFORD, CTAC AUDIT AND ASSESSMENT MANAGER**



**Carlsbad Field Office
Technical Assistance Contractor**



Dick Blauvelt
Tammy Bowden
Earl Bradford – C
Rhet Bradford – C
Rick Castillo
Norman Frank
Regina Garcia
Paul Gomez
Dave Kimbro
Harley Kirschenmann – PT
Greg Knox
Mavis Lin – PT
Forf Martinez
Prissy Martinez
Jim Oliver

Berry Pace
Allison Pangle
Willie Price – PT
Tommy Putnam
Jim Schuetz
Vern Stoggett
David Stuenkel – C
B. J. Verret
Jack Walsh – PT
Nick Wade – PT
Jimmy Wilburn – PT

Terry McKibbin – C
Berta Oates – PT

Lokesh Chaturvedi – C
Allie Crawford
Joe Field
Terry Foppe – C
Dave Ganaway
Vivian Hail – C
Harold Johnson – PT
Jon Gusley
Charleen Roberts – C
Jeff Woody – C

*PT – Part Time Support
C – Sub Contractor Support*