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Governor

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Lieutenant Governor

NEW MEXICO ENVIRONMENT DEPARTMENT

Hazardous Waste Bureau

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RON CURRY
Secretary

SARAH COTTRELL
Deputy Secretary

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

December 9, 2010

Edward Ziemianski, Acting Manager
Carlsbad Field Office
Department of Energy
P.O. Box 3100
Carlsbad, New Mexico 88221-3100

Farok Sharif, President
Washington TRU Solutions LLC
P.O. Box 2078
Carlsbad, New Mexico 88221-5608

RE: NMED APPROVAL OF THE ARGONNE NATIONAL LABORATORY/CENTRAL CHARACTERIZATION PROJECT FINAL AUDIT REPORT, AUDIT A-10-23
WASTE ISOLATION PILOT PLANT
EPA I.D. NUMBER NM4890139088

Dear Messrs. Ziemianski and Sharif:

On October 18, 2010, the New Mexico Environment Department (**NMED**) received the Final Audit Report of the Argonne National Laboratory/Central Characterization Project (**ANL/CCP**) Audit Number A-10-23 (**Audit Report**), from the Department of Energy's Carlsbad Field Office (**CBFO**). CBFO and Washington TRU Solutions LLC (**the Permittees**) were required to submit this Audit Report under the Waste Isolation Pilot Plant (**WIPP**) Hazardous Waste Facility Permit as specified in Permit Condition II.C.2.c. The intended scope of this annual recertification audit was to ensure the continued adequacy, implementation, and effectiveness of the ANL/CCP waste characterization processes for Summary Category Group S5000 debris remote handled (**RH**) waste relative to the requirements of the WIPP Permit. This recertification Audit Report consisted of the following items:

- A narrative report (hardcopy and electronic)
- Completed copies of relevant Permit Attachment B6 checklists (hardcopy and electronic)
- Final ANL/CCP standard operating procedures (hardcopy and electronic)
- Corrective action report

- Objective evidence examined during the audit
  - General information
  - Acceptable knowledge
  - Headspace gas (included under general information)
  - Visual examination

An NMED representative observed the ANL/CCP audit on August 3-5, 2010. NMED has examined the Audit Report for evidence of compliance with the requirements of Permit Conditions II.C.2 (Audit and Surveillance Program) and II.C.1 (Waste Analysis Plan [**WAP**]). The Audit Report indicates there was

- One WAP-related condition adverse to quality requiring the issuance of a CBFO corrective action report that was corrected prior to submittal of the Audit Report; and
- One recommendation identifying an opportunity for improvement.

Attachment 1 contains NMED's general comments based upon observation of the audit and review of the Audit Report. These are provided to guide future audit report preparation and to assist the Permittees in understanding NMED's concerns. NMED requests that the Permittees address the concerns and correct the items listed in Attachment 1 and return them, indicating revisions to any text in the Audit Report and checklists with redline/strikeout annotation. This will ensure the administrative record contains a complete and accurate Audit Report.

During the audit, NMED raised questions regarding conditions adverse to quality (**CAQs**), or deficiencies, that are corrected during the audit and identified as "CDAs." Section 6.2 of the Audit Report, "Deficiencies Corrected During the Audit," describes CDAs as "isolated deficiencies that do not require a root cause determination or actions to preclude recurrence." The section also states that such deficiencies are not significant CAQs and that they are isolated cases "requiring only remedial action and therefore can be corrected during the audit." Following the audit, NMED submitted an observer inquiry form dated August 9, 2010 (Attachment 2) questioning the discretion auditors have regarding the categorization of deficiencies, which stated in part:

> *NMED has become increasingly aware of instances during waste characterization audits where the audit team has requested site personnel to correct [batch data reports] (**BDRs**) that are incomplete or where incorrect information has been recorded. The majority of these corrections have been made to the Site Project Manager (**SPM**) checklist. In many instances, upon further review, the information included within the rest of the BDR is correct, and CBFO has stated that they believe the quality of the data has not been jeopardized. CBFO has stated that they also believe these corrections are not Conditions Adverse to Quality (**CAQ**) and that there is no need for the audit team to record and document the correction... Based upon the controlling documents, clarify your interpretation of what does and does not constitute a CDA, and why corrections to incomplete BDRs are not classified as CAQs. Furthermore, identify in the QAPD and the Permit your authority for discretion regarding the categorization of deficiencies.*

The Permittees responded to the observer inquiry on November 30, 2010 (Attachment 3). The response stated that BDRs are critical quality assurance records in the waste characterization process, but that "until a [BDR] is complete and authenticated through approval signature, it is not yet a quality record" and thus not subject to formal documentation and corrective action by means of a Corrective Action Report (**CAR**) or CDA. The response further stated, "Incomplete BDRs, however, are not yet a quality record: they are in process of being developed, have not been reviewed and approved, and errors contained are not CAQs. It has been the practice of the CBFO QA Organization to allow corrections of occasional, isolated errors in incomplete BDRs without documentation since incomplete BDRs are not quality records."

NMED finds the Permittees' response generally to be technically correct but nonresponsive to the original observer inquiry, perhaps due to differing interpretations regarding the phrase, "BDRs that are incomplete." Although the following is clearly understood by both the Permittees and NMED, it bears repeating here for the record: all data and documents reviewed during an audit and provided as objective evidence in an Audit Report are quality records, unless clearly marked as draft, preliminary, or information only. Generally speaking, the audit team evaluates only BDRs that have undergone all levels of QA verification and validation, concluding with the SPM checklist and approval signature. NMED's observer inquiry dealt solely with quality records that are found, following full review and approval by all levels of QA verification and validation, to be either incomplete (i.e., missing information, data, or signatures) or containing incorrect information or data (e.g., wrong BDR numbers). Thus, it is troubling for NMED to read that it is CBFO's practice to allow corrections of occasional, isolated errors in BDRs during audits without documenting these corrections because based on its response to NMED's observer inquiry, CBFO considers these to be "incomplete BDRs" and therefore not quality records. When NMED used the phrase "incomplete BDRs" in the observer inquiry, it meant BDRs that have been determined to meet the requirements for a quality record but are subsequently found to contain quality affecting deficiencies and/or technical inadequacies that are CAQs. The Permittees did not address NMED's underlying concern that the audit team may determine that certain corrections made to quality records during the audit are not CAQs (i.e., deficiencies and technical inadequacies in quality affecting data in completed BDRs) and thus would not be documented in the Audit Report. NMED will continue to question this practice at future audits, and recommends that the Permittees revise their response to the observer inquiry to clarify their position and more completely respond to NMED's concerns.

Despite this unresolved concern, NMED concludes that this Audit Report demonstrates that ANL/CCP has implemented the applicable characterization requirements of the WAP. Therefore, NMED approves the Permittees' Final Audit Report for ANL/CCP Audit A-10-23 for the recertification of S5000 debris RH waste, and amends the previous Audit Report approval for Audit A-09-21 issued by NMED on November 13, 2009 to include all waste forms and processes evaluated by this recertification audit.

This Audit Report approval is of the broad programmatic implementation of waste characterization requirements at the generator/storage site, and does not constitute approval of individual waste characterization procedures, nor condone inappropriate applications of those

procedures. This approval does not relieve the Permittees of their obligation to comply with the requirements of the permit or other applicable laws and regulations.

If you have any questions regarding this matter, please contact Steve Zappe at (505) 476-6051.

Sincerely,

James P. Bearzi
Chief
Hazardous Waste Bureau

JPB:soz

Attachments

cc: Steve Zappe, NMED HWB
Thomas Kesterson, NMED DOEOB
Joseph Klinger, IDNS
John Riekstins, IL EPA
Laurie King, EPA Region 6
Tom Peake, EPA ORIA
Connie Walker, Trinity Engineering
Don Hancock, SRIC
Joni Arends, CCNS
File: Red WIPP '10

Attachment 1

NMED COMMENTS ON THE
ARGONNE NATIONAL LABORATORY/CENTRAL CHARACTERIZATION PROJECT (ANL/CCP) FINAL AUDIT REPORT A-10-23

NMED's review indicated that the body of the Audit Report and the B6 checklists generally appear to address the applicable elements. NMED provides the following comments for the Permittees' consideration.

1. VE BDR RHANLVE 100005 was submitted in the report as objective evidence as both VE1 and GEN1. There is an error with the BDR Number on the Site Project Managers Checklist in the copy submitted as VE1. The Permittees must submit the corrected copy of the BDR as objective evidence VE1.

   As noted in the approval letter above, NMED is concerned that the Audit Team allowed CCP to correct BDR RHANLVE 100005 (a quality record) during the audit but did not include the correction in the Audit Report as a CDA. NMED staff expressed this concern during the audit, yet the audit team concluded that the error was not a CAQ. The Permittees must provide further justification for not including this correction in the Audit Report as a CDA.

2. Question 296 of the B6 Checklist cites CCP-QO-002, Sections 4.1.2 and 4.3.7. Section 4.2 and "Note" above 4.2 better answers the second part of this question.

Attachment 2

Observer Inquiry Form

Observer: Ricardo Maestas/SOZ **Date: August 9, 2010** **Tracking No. _____**

Discussion of Request:

NMED has become increasingly aware of instances during waste characterization audits where the audit team has requested site personnel to correct BDRs that are incomplete or where incorrect information has been recorded. The majority of these corrections have been made to the Site Project Manager (SPM) checklist. In many instances, upon further review, the information included within the rest of the BDR is correct, and CBFO has stated that they believe the quality of the data has not been jeopardized. CBFO has stated that they also believe these corrections are not Conditions Adverse to Quality (CAQ) and that there is no need for the audit team to record and document the correction.

The CBFO QAPD, Rev. 11, page A-7, defines RCRA Related Deficiency as: "*A deficiency that is a violation of the requirements of the WIPP Hazardous Waste Facility Permit.*"

Permit Attachment B3, Section B3-10b(1), requires an SPM signature release to... "*Verify that data are within established data assessment criteria and meet all applicable QAOs (Sections B3-2 through B3-9)*" (last bullet).

Permit Attachment B3, Section B3-4a, states:

> *Completeness*
> *A video and audio media recording of the radiography examination and a validated radiography data form will be obtained for 100 percent of the waste containers subject to radiography. All video and audio media recordings and radiography data forms will be subject to validation as indicated in Section B3-10.*

Since the Permit requires "radiography data forms [to] be subject to validation as indicated in Section B3-10," an error in an SPM checklist of a BDR is a "RCRA Related Deficiency" as defined in the QAPD.

Permit Attachment B6, Section B6-4, states: "*Deficiencies and observations will be documented and included as part of the final audit report. Those items that have been resolved during the audit (isolated deficiencies that do not require a root cause determination or actions to preclude recurrence), will be verified prior to the end of the audit, and the resolution will be described in the audit report.*"

NMED interprets this to mean that corrections to BDRs made during the audit are documented in the audit report, because these corrections, as minor as they are, are indeed CAQs because the auditors cannot use the documents "as is" for their objective evidence.

CBFO MP 10.3 Section 5.4.3 states, "Conditions adverse to quality and observations will be documented and included as part of the audit report (isolated deficiencies that do

not require a root cause determination, actions to preclude recurrence, or non-editorial procedure revisions) will be verified prior to the end of the audit, and resolutions will be described in the audit report." Furthermore Section 5.4.9 states "CAQs shall be documented on a CAR or Corrected During the Audit Form." These deficiencies are not been documented and therefore cannot be trended over time to see if any changes in training or other actions need to be taken.

Based upon the controlling documents, clarify your interpretation of what does and does not constitute a CDA, and why corrections to incomplete BDRs are not classified as CAQs. Furthermore, identify in the QAPD and the Permit your authority for discretion regarding the categorization of deficiencies.

ATL Response: _____

_____

_____

_____

_____

_____

_____

Observer: Accept Response _____ **Do Not Accept Response** _____

(Provide Reason)

_____

_____

_____

_____

Inquiry Closed: _____ _____

ATL **Date**

Attachment 3

Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221

NOV 30 2010

Mr. Steve Zappe, Project Leader
Hazardous Materials Bureau
New Mexico Environment Department
2905 Rodeo Park Drive East, Building 1
Santa Fe, New Mexico 87505-6303

Subject: CBFO Response to NMED Observer Inquiry Form

Dear Mr. Zappe:

This letter transmits the Department of Energy (DOE) Carlsbad Field Office (CBFO) response to the New Mexico Environment Department (NMED) Observer Inquiry submitted by Ricardo Maestas on August 9, 2010 and subsequent clarification email sent by you on September 30, 2010.

Should you have any questions concerning this response, please contact me at (575) 234-7491.

Sincerely,

Dennis S. Miehls
Acting Director of Quality Assurance

Enclosure

cc: w/enclosure

R. Maestas, NMED	*ED
E. Ziemianski, CBFO	ED
O. Vincent, CBFO	ED
G. Hellstrom, CBFO	ED
A. Holland, CBFO	ED
J. R. Stroble, CBFO	ED
G. Basabilvazo, CBFO	ED
M. Navarrete, CBFO	ED
C. Riggs, CTAC	ED
G. Knox, CTAC	ED

WIPP Operating Record, MS: 452-09
CBFO QA File
CBFO M&RC
*ED denotes electronic distribution

CBFO:QA:DSM:MAG:10-1829:UFC 2300.00

CBFO Response to NMED Observer Inquiry dated August 9, 2010

In an Observer Inquiry Form dated August 9, 2010, the New Mexico Environment Department (NMED) requested the following: "Based upon the controlling documents, clarify your interpretation of what does and does not constitute a CDA, and why corrections to incomplete BDRs are not classified as CAQs. Furthermore, identify in the QAPD and the Permit your authority for discretion regarding the categorization of deficiencies."

Batch Data Reports (BDRs) are a critical quality assurance record in the waste certification process and are subject to the full records management controls described in DOE/CBFO-94-1012, *Quality Assurance Program Document.* Quality Assurance Program Document (QAPD) Section 1.5.2.D, *Generating QA Records,* states: "Documents shall be considered valid QA records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated. ... This authentication represents a certification as to the content of the record by those individuals with knowledge of the related facts, whether by direct personnel knowledge or through the direct reports of others...." In practical terms, this means that until a document is complete and authenticated through approval signature, it is not yet a quality record. The QAPD Appendix A also defines Condition Adverse to Quality (CAQ) as "an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies."

The Carlsbad Field Office (CBFO) Management Procedure (MP) 10.3, paragraph 5.4.9 states, "CAQs shall be documented on a CAR or Corrected During the Audit (CDA) Form ...." Because of concern about the potential for lack of thoroughness and appropriateness of corrective actions for CDAs, the CBFO Quality Assurance (QA) Manager has limited the use of CDAs. CAQs may only be documented as CDAs if the CAQ is isolated, corrective actions are remedial in nature, and procedures and processes are not affected.

Deficiencies and technical inadequacies in quality affecting data in completed BDRs are considered to be CAQs and as such are subject to formal documentation and corrective action by means of a Corrective Action Report (CAR). Incomplete BDRs, however, are not yet a quality record: they are in process of being developed, have not been reviewed and approved, and errors contained are not CAQs. It has been the practice of the CBFO QA Organization to allow corrections of occasional, isolated errors in incomplete BDRs without documentation since incomplete BDRs are not quality records. However, during the audit, the auditors also consider whether there is a pattern of multiple or repeated errors that may indicate a problem with the processes that generate the BDRs. If such a pattern is recognized, then a CAQ likely exists and a CAR will be written.

The Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit (HWFP), Attachment B6, page B6-4 dated April 1, 2010 which was in effect at the time of the inquiry, requires that "When a deficiency is identified by the audit team, the audit team member who identified the deficiency prepares the CAR. The Permittees review the CAR, determine validity (assure that a requirement has in fact been violated), classify the significance of the deficiency, assign a response due date, and issue the CAR to the site or Permittee approved laboratory." The CBFO QA Manager and QA staff have the responsibility for determining the validity of CAQs identified during audits. Given that under the QA program controls on quality records, an incomplete BDR is not yet a quality record, occasional and isolated errors in the document do not constitute a CAQ. It has not been CBFO policy to have the auditors prepare draft CARs for this type of isolated condition since they are fully cognizant of the CBFO QA program requirements for quality records.

Regarding authority for discretion in the categorization of deficiencies, Appendix D of the QAPD defines the responsibilities of the CBFO QA Manager. It states in part:

"The CBFO QA Manager has the following additional authorities and responsibilities: ...
- Developing, establishing, and interpreting CBFO QA policy and ensuring effective implementation"

The requirements of the QAPD regarding quality records and identification of CAQs are consistent with nuclear industry quality assurance practices and are compliant with the requirements of ASME NQA-1-1989 *Quality Assurance Program Requirements for Nuclear Facilities* and ASME NQA-3-1989 *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*.