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JAN 11 2011

Mr. Steve Zappe, Project Leader
Hazardous Materials Bureau
New Mexico Environment Department
2905 E. Rodeo Park Drive, Bldg. 1
Santa Fe, NM 87505-6110

Subject: Transmittal of Responses, Revised B6 Checklist, and Revised Batch Data Report Addressing NMED Comments Associated with CBFO Audit A-10-23

Dear Mr. Zappe:

Enclosed are the subject documents associated with Carlsbad Field Office (CBFO) Audit A-10-23 of the Argonne National Laboratory Central Characterization Project. The comments were transmitted to CBFO by letter dated December 9, 2010.

Should you have any questions, please contact Martin P. Navarrete, CBFO Acting Director of the Office of Quality Assurance, at (575) 234-7483.

Sincerely,

Edward Ziemianski
Acting Manager

Enclosure

cc: w/o enclosure

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WIPP Operating Record, MS: 452-09
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CBFO:OQA:DSM:MAG:11-0413:UFC 2300.00

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RESPONSE TO NMED COMMENTS ON THE ANL/CCP FINAL AUDIT REPORT A-10-23

The NMED letter dated December 9, 2010, for Final Audit Report A-10-23 included two comments related to the associated B6 checklists and submitted Objective Evidence reviewed during the audit (shown here in italics). The actions taken to address the comments are provided in the following responses.

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.*

   Response: A copy of VE BDR RHANLVE 100005, with a correct SPM Checklist, is provided for replacement in the VE1 objective evidence package.

   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

   Response: During the review of BDR RHANLVE 100005 by the audit team, it was discovered that the BDR number on the SPM checklist was incorrect ('10005' instead of '100005'). This BDR number is for the purpose of linking the SPM checklist to the BDR package and did not impact or affect any information on the checklist or in the BDR (i.e., the correction was to an item that was not quality-affecting). Per CCP-TP-001, the SPM has the final approval of all BDRs and no other reviews are performed before submittal of the BDR to records. The audit team investigated the impact of the deficiency (a missing leading zero in the BDR identifier) upon discovery, determining that it was not a quality-affecting issue and required only an editorial change. The audit team requested the auditee correct the BDR number, which is allowed per CCP-QP-008, Revision 17, *CCP Records Management,* section 4.7.1.[A.2] NOTE, and this was done during the audit. CBFO has established that only isolated quality-affecting CAQs corrected during the audit are required to be documented on CDA forms and included in the audit report. As the concern was determined not to be a CAQ (i.e., not quality-affecting, but editorial) by the audit team, the ATL, and the CBFO audit lead, it was not documented on a CDA form or included in the audit report.

2. *Question 296 of the B6 Checklist cites CCP-QP-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.*

   Response: The B6-6 checklist has been revised to include Section 4.2 and 4.2 'Note'. A copy of the revised checklist is provided as evidence of the correction.

As requested on page 3, 2nd paragraph, of the NMED A-10-23 Audit Approval letter, CBFO is submitting a revised response to the NMED Observer Inquiry, dated August 9, 2010.

Revised response to Observer Inquiry

CBFO MP 10.3 Rev. 7, section 3.2.7 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." It needs to be stated that while CAQs are failures, malfunctions, deficiencies, defective items, nonconformances and technical inadequacies, not all failures, malfunctions, deficiencies, defective items, nonconformances and technical inadequacies are CAQs. To that point, CBFO management defines failures, malfunctions, deficiencies, defective items, nonconformances and technical inadequacies as CAQs only when those conditions impact the integrity of the data demonstrating compliance to the Permit or CBFO QA program requirements. CBFO does not consider editorial errors as CAQs.

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 the conditions adverse to quality are consistent with nuclear industry quality assurance practices and with the requirements of ASME NQA-1-1989, *Quality Assurance Program Requirements for Nuclear Facilities,* and ASME NQA-3-1989, *Quality Assurance Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories.*