



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. Miehl
 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 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*.