



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

 **ENTERED**

FEB 11 2013

Mr. John E. Kieling, Chief
Hazardous Waste Bureau
New Mexico Environment Department
2905 Rodeo Park Drive East, Building 1
Santa Fe, NM 87505-6303

Subject: Response to Questions from NMED Regarding Conditions Adverse to Quality
Requiring Corrective Action Reports

Dear Mr. Kieling:

I would like to take this opportunity to provide the clarification you requested in your letter of December 13, 2012 regarding the Final Audit Report, Hanford Site/Central Characterization Project, Audit A-12-11. In addition, I would like to provide feedback to you regarding our previous discussions on "issues management" and the revision of Carlsbad Field Office (CBFO) Management Procedure (MP) 10.3, as I believe these subjects are well related.

As stated in your letter, you requested clarification on "why the concern was determined to be an observation and not a deficiency." It was then and is now the CBFO's position that this issue did not arise to the level of a deficiency affecting the quality of the program because we do not believe that there was a "failure to comply with a requirement," but rather a "marginally acceptable" identification of a Nonconformance Report (NCR). As a result, the CBFO categorized this concern as an observation and not a deficiency, and reported it in the audit report as required in section 5.4.3 of MP 10.3.

In response to this request for clarification and as a result of our previous discussions regarding issues management, the CBFO proposes to implement a revision to MP 10.3. The basis for the revision is a result of some potentially conflicting language within the procedure the CBFO believes can be easily clarified with some minor word changes. These word changes will allow the CBFO to implement the requirements of the Hazardous Waste Facility Permit (HWFP), in particular the documentation and reporting of issues/concerns to the New Mexico Environment Department (NMED), while at the same time allowing the CBFO the flexibility to implement the "graded approach" philosophy from NQA-1. That is, not all issues/concerns should be treated equally.

Section 5.4.3 of MP 10.3 provides guidance on the types of concerns that must be reported on Corrective Action Report (CAR) forms. It states:

Those items that affect the quality of the program and/or the data generated by that program, which are required by the Waste Analysis Plan (WAP), will be documented on a CAR and included as part of the final audit report.



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Mr. John E. Kieling

-2-

Unfortunately, other provisions within MP 10.3 tend to indicate all conditions adverse to quality (CAQs) must be documented on a CAR or CDA form. In particular Section 5.4.9 states:

CAQs shall be documented on a CAR (MP 3.1) or a Corrected During the Audit (CDA) Form (see Attachment X, Corrected During the Audit Form).

The CBFO does not believe that this has ever been the intent of either the permit or the procedure. We do realize, however, that we may not have always been consistent in our application. As a result, we propose to revise MP 10.3 to reinforce that not all CAQs require either a CAR or CDA form, but only those CAQs as provided in section 5.4.3 of MP 10.3. All concerns identified during audit activities will continue to be documented, reported, and evaluated for needed corrective measures. Use of a CAR is one of several methods for requesting and tracking corrective actions. The CBFO intends to promote process improvement and apply corrective measures efficiently, effectively, and commensurate with the significance of concerns. Furthermore, the CBFO issues management system is being revised and will include the tracking and trending of all issues identified at certification/recertification audits in order to address issues proactively instead of reacting to issues after they have reached the level of a CAR.

As you know, we will be having our annual refresher training on February 11, 2013, and we look forward to participation from your office. If it is acceptable to you, we would like to discuss specific changes to MP 10.3 at that time.

If you have any questions, please contact Mr. Courtland Fesmire at (575) 234-7548.

Sincerely,


Jose R. Franco, Manager
Carlsbad Field Office

cc:

G. Basabilvazo, CBFO * ED
J. R. Stroble, CBFO ED
C. Fesmire, CBFO ED
G. Hellstrom, CBFO ED
J. Harvill, CTAC ED
R. Allen, CTAC ED

CBFO M&RC

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