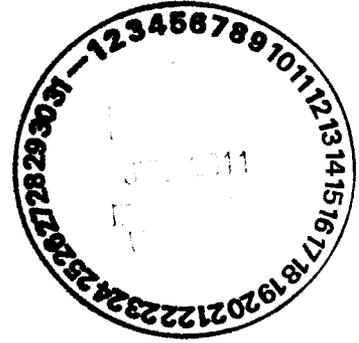




Department of Energy
 Carlsbad Field Office
 P. O. Box 3090
 Carlsbad, New Mexico 88221

JUN 30 2011



Mr. D. K. Ploetz, Manager
 Central Characterization Project
 Retrieval, Characterization and Transportation
 Washington TRU Solutions
 P.O. Box 2078
 Carlsbad, New Mexico 88221-2078

Subject: Evaluation of the CAP for CBFO CAR 11-043, Audit A-11-14, INL/CCP Activities

Dear Mr. Ploetz:

Enclosed are the results of the Carlsbad Field Office (CBFO) evaluation of the Corrective Action Plan (CAP) written in response to CBFO Corrective Action Report (CAR) 11-043 which was identified as a result of Recertification Audit A-11-14 of the Idaho National Laboratory Central Characterization Project (INL/CCP) activities, conducted June 7-9, 2011.

The results of the evaluation are documented on the enclosed CAR Continuation Sheet, which indicates approval. Please provide supporting documentation to CBFO as evidence of completion of the corrective actions as noted in the CAP by July 1, 2011.

If you have any questions regarding this approval, please contact me at (575) 234-7491.

Sincerely,

Dennis S. Miehls
 Senior Quality Assurance Specialist

Enclosure

cc: w/enclosure

R. Unger, CBFO	* ED	R. Joglekar, EPA	ED
J. R. Stroble, CBFO	ED	S. Ghose, EPA	ED
H. Budweg, CBFO	ED	R. Lee, EPA	ED
N. Castaneda, CBFO	ED	J. Kielling, NMED	ED
M. Navarrete, CBFO	ED	S. Holmes, NMED	ED
D. Haar, WTS/CCP	ED	T. Hall, NMED	ED
V. Cannon, WTS/CCP	ED	T. Kesterson, DOE OB WIPP NMED	ED
A. J. Fisher, WTS/CCP	ED	D. Winters, DNFSB	ED
I. Quintana, WTS/CCP	ED	P. Gilbert, LANL-CO	ED
M. Walker, WTS/CCP	ED	G. Lyshik, LANL-CO	ED
Y. Salmon, WTS/CCP	ED	T. Bowden, CTAC	ED
J. Hoff, WTS	ED	J. Walsh, CTAC	ED
M. A. Mullins, WTS	ED	N. Frank, CTAC	ED
J. Wells, DOE-ID	ED	P. Hinojos, CTAC	ED
W. Lattin, DOE-ID	ED	G. White, CTAC	ED
T. Peake, EPA	ED	WIPP Operating Record	ED
M. Eagle, EPA	ED	CBFO QA File	
E. Feltcorn, EPA	ED	CBFO M&RC	

*ED denotes electronic distribution



CBFO Form 3.1-2

CAR CONTINUATION SHEET

1. CAR No: 11-043

2. Activity No: A-11-14

3. Page 1 of 5

Block 16: Acceptance of Proposed Corrective Actions

An evaluation of the corrective actions detailed in the Corrective Action Plan (CAP) for CAR 11-043 has been completed.

The CAP was submitted by URS-WTS letter QA:11:01462 dated June 30, 2011, from D. K. Ploetz, Manager CCP to Mr. Dennis S. Miehs, CBFO, subject, "Corrective Action Plan for Corrective Action Report 11-043, Resulting From Audit A-11-14 of Idaho National Laboratory Central Characterization Project Activities"

Italicized text, taken verbatim from the CAP, is used to show the correlation between the corrective action and the evaluation. Note that the actions in the CAP were informally reviewed by CBFO and found to be acceptable.

REMEDIAL ACTIONS

CCP has taken the following remedial actions in response to the CAR condition:

- a) *CCP has verified that, in accordance with CCP-QP-008, the source documents identified in the INL AK Summary Reports listed in the CAR, along with their associated Attachment 3 forms, are now available in CCP Records.*
- b) *CCP has performed a 100% review for the presence, in CCP Records, of source documents and Attachment 3 forms for 22 issued INL Contact-Handled (CH) AK Summary Reports and 10 issued INL Remote-Handled (RH) AK Summary Reports. The review showed that, at the start of the CCP investigation in response to the CAR:*
 - *Ninety-eight percent (98%) (3455/3526) of the source documents listed in the 22 CH AK Summary Reports were available in CCP Records (with their associated Attachment 3 forms). See the enclosed Table 1 for details. In all cases, the documentation was available: it was just that the documentation had not yet been submitted to CCP Records. As of June 30, 2011, 100% of the source documents and Attachment 3 forms for INL are in CCP Records.*
 - *Ninety-six percent (96%) (2229/2315) of the source documents listed in the 10 RH AK Summary Reports were available in CCP Records (with their associated Attachment 3 forms). See the enclosed Table 1 for details. As with CH, the RH documentation was available: it was just that the documentation had not yet been submitted to CCP Records. As of June 30, 2011, 100% of the source documents and Attachment 3 forms for INL are in CCP Records.*
- c) *As noted in the Extent section of this Corrective Action Plan, CCP has conducted a sample check for the presence, in CCP Records, of AK source documents and Attachment 3 forms for completed AK Summary Reports applicable to waste streams at other CCP Host locations. See the enclosed Table 2 for details.*

Evaluation:

Review of the proposed CAP associated with Remedial Actions submitted by the above referenced letter determined that the remedial actions are acceptable.

CBFO Form 3.1-2

CAR CONTINUATION SHEET

1. CAR No: 11-043

2. Activity No: A-11-14

3. Page 2 of 5

INVESTIGATIVE ACTIONS

Extent

The statement of condition in the CAR says that the auditor requested that CCP Records verify that the documents listed on Attachment 4 for selected waste streams were available in hard copy in CCP Records files. CCP-TP-005, Section 4.3.4, does not currently require that all the AK information listed on the Attachment 4 form be submitted to CCP Records. Only the subset of AK information designated as source documents and listed in the AK Summary Report were to be submitted to CCP Records, along with their corresponding Attachment 3 forms. When this criterion is applied to the extensive listings of documents in the statement of condition in the CAR, the actual number of affected documents drops to 24 out of 1,534 source documents (see the enclosed Table 3 for details). As noted elsewhere in this Corrective Action Plan, all of the documents were available, and have been submitted to CCP Records; the only issue is the timing of submittal to CCP Records.

At the time of the CCP investigation after the concern was initially raised during the INL recertification audit, CCP conducted a check in CCP Records for the presence of INL source documents and associated Attachment 3 forms. The review covered 32 CH and RH AKs for INL. The review showed that 97% of the INL documentation that was required to be submitted to CCP Records in accordance with CCP-TP-005 (i.e., actual source documents and associated Attachment 3 forms for completed AK Summary Reports) was available in CCP Records (see the enclosed Table 3 for details). As noted in the Remedial Actions section of this Corrective Action Plan, the set of documentation for all 32 INL AKs is now complete in CCP Records.

Whenever the presence or availability of a source document has been questioned during this or previous audits, AK personnel have always been able to make it available to the auditors. If the document was not already in CCP Records, it was provided to Records at that time. The issue is one of the timing of submittal of AK supporting documentation to CCP Records, after the AK Summary Report has been written and sent to Document Services for review and approval in Q&MIS.

To determine extent of condition beyond INL, CCP performed sample checks of the completeness of AK documentation in CCP Records for approved AK Summary Reports for waste streams at other CCP Host locations. The checks confirmed that 99.5 % (3973/3993) of the required documentation has been submitted to CCP Records, and the remaining documentation was available from AK personnel. See the enclosed Table 2 for details.

Impact

There is no technical impact from the CAR condition. The adequacy of CCP AK Summary Reports was never in question. All of the source documents and Attachment 3 forms are available. The primary issue is the timing of submittal of AK source documents to CCP Records; on past occasions when a single document has not yet been submitted to CCP Records, the AK group provides the document. The situation has been complicated by the lack of clarity and definition in CCP-TP-005, which failed to

CBFO Form 3.1-2

CAR CONTINUATION SHEET

1. CAR No: 11-043

2. Activity No: A-11-14

3. Page 3 of 5

adequately distinguish between Attachment 4 AK information (which demonstrates due diligence) and the subset that are designated as source documents with Attachment 3 forms, and did not explicitly address the acceptability of records in electronic format.

The CAR cites a requirement in the Hazardous Waste Facility Permit (Permit), with which CCP is in compliance. As discussed elsewhere in this Corrective Action Plan, the issue is with the timing of submittal of available AK source documentation to CCP Records. The transfer of source documents from one CCP location to another is strictly an administrative function, controlled entirely by CCP internal procedures, with no violation of the Permit.

CCP-TP-005 does establish additional requirements for the preparation and submittal of Attachment 3 forms, but only for AK Expert personnel, who use them to summarize source document content and limitations on use. The transfer of Attachment 3 forms from one CCP location to another is strictly an administrative function, controlled entirely by CCP internal procedures.

Hazardous Waste Facility Permit, Section C4-3c (as cited in CAR 11-043)

- CCP-TP-005, the procedure for assembling AK information and compiling the auditable record, has been in use since 2001.*
- This procedure ensures that AK information is compiled in an auditable record.*
- AK information is compiled in an auditable record, as defined in C4-2 of the Permit: "'Auditable records' means those records which allow the Permittees to conduct a systematic assessment, analysis, and evaluation of the Permittees compliance with the WAP and this Permit." Since 2001, through the audit process, the Permittees have been able to successfully conduct systematic assessments, analyses, and evaluations of compliance with the WAP and the Permit, in particular those requirements pertaining to AK.*
- Each AK Summary Report includes a reference list of all source documents, which provide the roadmap.*

CBFO audit A-11-14 of CCP/INL was no exception. The audit team was able to complete its audit of CCP AK summary documents, including those identified in the CAR. All source documents were made available to the audit team, allowing them to complete their assessment. The only issue was that some AK documentation had not yet been submitted to CCP Records.

As addressed in the enclosed Table 3, there was an issue with 24 source documents and their corresponding Attachment 3 forms not being present in CCP Records. The source documents were available. So even though there is a procedural issue, CCP is still in compliance with the Permit. Since there is no Permit violation, this Corrective Action Plan addresses only the issue of records submittal that is governed by CCP internal procedures.

Hazardous Waste Facility Permit, Section C4-3g (as cited in the letter from NMED dated June 29, 2011)

CBFO Form 3.1-2

CAR CONTINUATION SHEET

1. CAR No: 11-043

2. Activity No: A-11-14

3. Page 4 of 5

- *CCP procedure CCP-TP-005, which governs AK, has been in existence and continuous use since 2001.*
- *All of the required AK documents are available at the time of audit. The auditors request and are provided with source documents (typically in electronic form) prior to each audit, along with selected hard copies. During audits, additional source documents are provided, if requested. CCP has always followed this practice.*

AK records are maintained in file in CCP Records in accordance with CCP internal procedures.

- *The CAR was not associated with AK compilation as defined in the Permit under C4-3b. The auditor determined that the AK was adequately and correctly compiled.*
- *The CAR was not associated with hazardous waste characterization.*
- *Subsequent to audit A-11-14, CBFO evaluated the impact of this CAR and determined that no work suspension was required, as documented in Block 11b of CAR 11-043, since CCP is in compliance with the Permit.*

Evaluation:

Review of the proposed CAP associated with Investigative Actions submitted by the above referenced letter determined that the investigative actions are acceptable.

ROOT CAUSE

Root Cause Determination

The root cause is management failure to ensure that CCP-TP-005 adequately distinguished between the totality of AK information assembled for possible use in compiling the AK Summary Report and supporting documentation (e.g., Attachment 3 forms, Attachment 4 forms, and source documents) as the auditable record, and the subset of that information designated as source documents because they were actually used to compile the auditable record. The requirements for AK information are different than the requirements for the source documents listed in AK Summary Reports; the intent of the procedure was that:

- All AK information assembled for possible use in developing AK Summary Reports would be entered on an Attachment 4 form, so that, as a matter of due diligence, there would be a record of the complete set of information that was considered. The Attachment 4 lists all of the information that was collected and considered during the preparation of an AK Summary Report. Only those sources of information that are referenced in the AK Summary Report are considered source documents and submitted to CCP Records.*
- The subset of AK information that was actually used to develop an AK Summary Report would be designated as source documents and would be listed individually in the report.*
- Each source document would be summarized on an Attachment 3 form, describing the contents and any limitations on use.*
- After the AK Summary Report was written and sent to Document Services for review and approval in Q&MIS, the source documents and associated Attachment 3 forms would be transmitted to CCP Records (no specific time frame was called out in CCP-TP-005). In accordance with CCP-QP-008, historical source documentation can be submitted to CCP Records in either hard copy or electronic*

CBFO Form 3.1-2

CAR CONTINUATION SHEET

1. CAR No: 11-043

2. Activity No: A-11-14

3. Page 5 of 5

format.

- e) *It was not intended that the balance of AK information (i.e., the information that was evaluated for possible use, but was not actually used to compile the auditable record) be summarized on an Attachment 3 form or submitted to CCP Records.*

Because CCP-TP-005 did an inadequate job of defining the auditable record, and distinguishing between the separate requirements applicable to assembled AK information versus actual source documents and corresponding Attachment 3 forms, the results have been inconsistent and sometimes not implemented as intended. Lastly, even though acceptable record formats are established in CCP-QP-008, the CCP-TP-005 procedure did not clearly state that AK historical source documentation would be acceptable in either hard copy or electronic format.

Evaluation:

Review of the proposed CAP associated with Root Cause Determination submitted by the above referenced letter determined that the root cause determination is acceptable.

ACTIONS TO PREVENT RECURRENCE

Action to Prevent Recurrence

Based on the results of the Investigative Actions undertaken by CCP, CCP has determined that the following action is appropriate to prevent recurrence of the CAR condition:

- a) *CCP has revised CCP-TP-005 to clarify and better define the AK auditable record, distinguish between AK information and source documents and corresponding submittal requirements to CCP Records, and to explicitly allow documents to be submitted in either hard copy or electronic format (as provided for in CCP-QP-008). The revision establishes the timing criteria for submittal of AK source documents and associated Attachment 3 forms to CCP Records.*
- b) *CCP will brief the AK Experts on the revision to CCP-TP-005.*

Evaluation:

Review of the proposed CAP associated with actions to prevent recurrence submitted by the above referenced letter determined that the proposed actions to prevent recurrence are acceptable.

The evaluation indicates that the corrective actions are adequate. It is recommended that the CAP be accepted.

Evaluation performed by:


Norman C. Frank

6/30/2011
Date