DATE: FEB 10 2016
REPLY TO ATTN OF: CBFO:OQA:MPN:BA:16-1255:UFC 2300.00
SUBJECT: Evaluation of the Proposed CAP for CBFO CAR 16-007

To: Mr. Benjamine B. Roberts, DOE-ID

The Carlsbad Field Office (CBFO) has evaluated Revision 1 of the Corrective Action Plan (CAP) provided by the Idaho Treatment Group for Corrective Action Report (CAR) 16-007. The results of the evaluation are provided in the attached CAR Continuation Sheet.

The results of the evaluation indicates that the remedial actions, investigative actions and proposed actions to preclude recurrence satisfactorily address the condition adverse to quality documented in CAR 16-007, and provides adequate measures to prevent recurrence. Therefore, the CAP for CAR 16-007 is approved.

Please provide your closure documentation by February 29, 2016 as indicated on your Revision 1 CAP, dated January 26, 2016.

If you have any questions or comments, please contact me at (575) 234-7483.

Attachment

cc: w/attachment
M. Brown, CBFO *ED
J.R. Stroble, CBFO ED
D. Miehls, CBFO ED
N. Castaneda, CBFO ED
G. Birge, CBFO ED
T. Carver, CBFO ED
S. Ross, EM-43 ED
J. Zimmerman, DOE-ID ED
M. Wilcox, DOE-ID ED
T. Jenkins, DOE-ID ED
A. Bergman, DOE-ID ED
B. Blyth, DOE-ID ED
D. Haar, AMWTP ED
G. Byram, AMWTP ED
G. Tedford, AMWTP ED
A. Morse, AMWTP ED
J. Kieling, NMED ED
R. Maestas, NMED ED
C. Smith, NMED ED
V. Daub, CTAC ED
R. Allen, CTAC ED
P. Martinez, CTAC ED
B. Pace, CTAC ED
C. Castillo, CTAC ED
R. Vawter, CTAC ED
P. Hinojos, CTAC ED
G. White, CTAC ED
Site Documents ED
CBFO QA File ED
CBFO M&RC ED

*ED denotes electronic distribution
An evaluation was performed of the Corrective Action Plan (CAP), Rev 1, developed to address Carlsbad Field Office (CBFO) Corrective Action Report (CAR) 16-007. The CAP was submitted via Idaho Treatment Group (ITG) letter C-2016-0041, dated January 26, 2016, from Mr. David J. Richardson, President and AMWTP Manager, ITG, to Mr. Martin Navarrete, Senior Quality Assurance Specialist, CBFO Quality Assurance.

Italicized text, taken verbatim from the CAP, is used to reflect the correlation between the actions required by the CAR and the method used for evaluation.

REQUIREMENT INVOLVED:
CBFO QAPD, Rev. 12, Section 1.1.2.3 A states: "The graded approach is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with the following factors:
1. The importance of an item or activity with respect to safety, waste isolation, security and regulatory compliance
2. The importance of the data to be generated
3. The need to demonstrate compliance with specific regulatory design and QA requirements
4. The impact on the results of performance assessments and engineering analyses
5. The magnitude of a hazard or the consequence of failure
6. The life-cycle stage of a facility or item
7. The programmatic mission of a facility
8. The particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls of processes)
9. The relative importance of radiological and non-radiological hazards":

CONDITION ADVERSE TO QUALITY:
The graded approach factors of "the importance of the data to be generated" and "the consequence of failure" are not listed in MP-Q&SI-5.6, Graded Approach, Rev. 4 when determining level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements.

REMEDIAL ACTIONS
MP-Q&SI-5.6, Graded Approach, was under revision at time of audit. DCR 21162 will be revised to include "the importance of the data to be generated" and "the consequence of failure" in MP-Q&SI-5.6.

Evaluation:
The draft of the changes to the current procedure AMWTP MP-Q&SI-5.6 was provided and deemed acceptable. MP-Q&SI, Rev. 5A (draft), Section 1.2.1 includes "Importance of data generated" and "The magnitude of a hazard or the consequences of failure", when grading items and activities.
INVESTIGATIVE ACTIONS

In March 2006, MP-Q&SI-5.6 was reviewed by CBFO. CBFO procedure comment stated: “Does not show the requirements for importance of the data to be generated...” Response provided to CBFO stated “Definition of Class II equipment aligns with the process analysis flowchart in Appendix A which identifies WIPP requirements as a key factor to be evaluated.” MP-Q&SI-5.6 was subsequently approved by CBFO in March 2006.

To ensure compliance, CBFO Quality Assurance Program Document (QAPD), Rev. 12 was evaluated to determine if similar information associated with graded approach was not addressed in MP-Q&SI-5.6, Graded Approach. It was determined that no additional changes were required.

Evaluation:
MP-Q&SI-5.6, Rev. 4, along with CBFO Document Review Record for MP-Q&SI-5.6 Rev. 2A, Graded Approach, dated 3-23-2006 were reviewed. The flowchart in Appendix A of Q&SI-5.6 identifies the consideration of importance to safety and consequences of failure when qualifying Class 2 equipment. Class 2 equipment is defined in MP-Q&SI-5.6 as equipment controlled or designated by the DSA as “other items important to safety.” CBFO approved the AMWTP responses to CBFO comments. Actions are deemed acceptable.

*This document is on AMWTP's WIPP Procedure List and will require review/concurrence by DOE-ID and then formal review/approval by CBFO prior to closure of this CAR.

ROOT CAUSE DETERMINATION

CAR 16-007 did not require a root cause determination.

Evaluation:
Not applicable.

ACTIONS TO PRECLUDE RECURRENCE

1. Since 2006, when CBFO approved this procedure, rigor within AMWTP Document Control process, including multi-disciplined reviewers and enhanced review process, has increased significantly which ensures issues similar to MP-Q&SI-5.6 do not occur.

Evaluation:
The proposed corrective actions to preclude recurrence, as described, are deemed appropriate to address the condition adverse to quality addressed in the CAR.
**CAR CONTINUATION SHEET**

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**ACCEPTANCE**

The evaluation of the results of the CAP indicate that the investigative actions and the proposed corrective actions to preclude recurrence satisfactorily address the condition adverse to quality documented in CAR 16-007. Therefore, it is recommended that the CAP for CAR 16-007 be approved.

Evaluation Performed By: Harley Kirschenmann, CTAC Auditor

[Signature]

Date: 2/9/2016