

United States Government

 ENTERED  
Department of Energy

# memorandum

Carlsbad Field Office  
Carlsbad, New Mexico 88221JUL 2001  
RECEIVED

DATE: July 26, 2001

REPLY TO  
ATTN OF: CBFO:QA:MLC:VW:01-1188:UFC:2300

SUBJECT: Evaluation of Corrective Action Responses for (CARs); 01-048, 01-049, 01-051, 01-054, 01-057, 01-059 and 01-063 Identified During CBFO Surveillance S-01-19

TO: Farok Sharif, WTS/CCP

The Carlsbad Field Office (CBFO) has evaluated the corrective action response for the subject CARs. The results of the evaluation indicate that responses for the subject CARs (01-048, 01-049, 01-051, 01-054, 01-057, 01-059 and 01-063) are unacceptable. The evaluation results are documented in the attached CAR Continuation Sheets.

You are requested to revise the CAR responses accordingly and resubmit them for review and acceptance.

If you have any questions or comments, please contact me at (505) 234 -7423.

  
for Samuel A. Vega  
Quality Assurance Manager

## Attachments

cc: w/attachments  
K. Watson, CBFO  
L. Chism, CBFO  
B. Bennington, CBFO  
M. Eagle, EPA  
S. Monroe, EPA  
S. Zappe, NMED  
B. Walker, EEG  
D. Winter, DNFSB  
M. Gerle, WTS Operating Record  
J. Schuetz, CTAC  
E. Bradford, CTAC

010769



Block #    17   

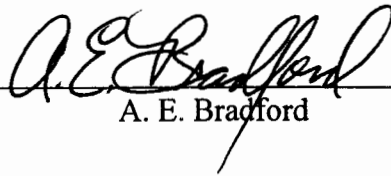
The following is an evaluation of the response to CBFO CAR 01-048 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01047, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective actions, (remedial and investigative actions) for the Conditions Adverse to Quality described in the CBFO CAR are acceptable. However, responses pertaining to root cause and actions to preclude recurrence must be revised to address the following comments:

- Root Cause, Items (1) through (4), (7), and (8) should not reference the remedial actions taken as a definition of the root cause!
- Actions to Preclude Recurrence, Item (3) references back to the remedial action which only provides a statement that the deficiencies identified during the surveillance were corrected. The deficiencies noted resulted from failure to follow the procedure. Some statement about conducting an employee briefing, procedural review, or minimal training should be added to the statement to preclude recurrence.

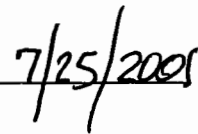
Upon completion of all corrective action(s) as described in the- response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By: \_\_\_\_\_



A. E. Bradford

Date: \_\_\_\_\_



7/25/2001

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-049

2. Activity No.: S-01-19

3. Page 2 of 2

Block # 17


The following is an evaluation of the response to CBFO CAR 01-049 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01046, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective actions, (investigative actions, root cause and actions to preclude recurrence) for the Conditions Adverse to Quality described in the CBFO CAR are acceptable. However, responses pertaining to remedial action must be revised to address the following comment:

- Remedial Actions Taken: This section should address the decision not to use the deficiency form and that nonconforming data packages will be identified by NCRs and CARs in the future and/or list a. through c. under this section of the CAP.

Upon completion of all corrective action(s) as described in the response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By:

  
A. E. Bradford

Date:

7/28/2001

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-051

2. Activity No.: S-01-19

3. Page 2 of 2

Block # 17


The following is an evaluation of the response to CBFO CAR 01-051 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01046, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective actions, (root cause and actions to preclude recurrence) for the Conditions Adverse to Quality described in the CBFO CAR are acceptable. However, responses pertaining to remedial actions and investigative actions must be revised to address the following comments:

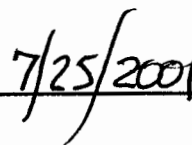
- Remedial Actions: Add the statement that all the HSG Data generated under the current procedures will be rejected and re-evaluated per an NCR.
- Investigative Actions, Extent, 2a: Revise the last sentence and address the rejection of the data with the same statement used on the other CAR. This CAR should stand-alone and not reference the other CAR.

Upon completion of all corrective action(s) as described in the response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By:

  
A. E. Bradford

Date:



# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-054

2. Activity No.: S-01-19

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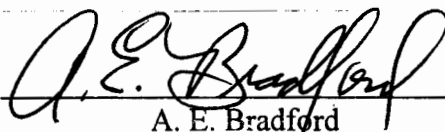
The following is an evaluation of the response to CBFO CAR 01-054 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01047, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective action (root cause) response for the Conditions Adverse to Quality described in the CBFO CAR is acceptable. The proposed corrective actions (remedial, investigative action, and actions to preclude recurrence) must be revised to address the following comments:

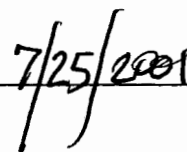
- There is no remedial action, investigative action or action to preclude recurrence for the first item listed on the CAR. This item deals with identification of the minimum qualifications a person must have to qualify for a position, the verification that the person meets these requirements, and finally, documenting the verification of education and experience for determination that the person meets those qualification requirements.

Upon completion of all corrective action(s) as described in the response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By:

  
A. E. Bradford

Date:



# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-057

2. Activity No.: S-0-19

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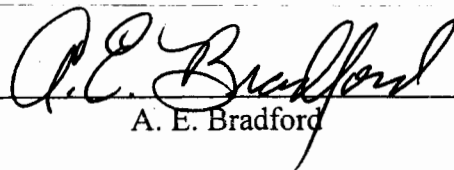
The following is an evaluation of the response to CBFO CAR 01-057 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01047, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective actions, (investigative, root cause and actions to preclude recurrence) for the Conditions Adverse to Quality described in the CBFO CAR are acceptable. The proposed corrective action (Remedial, Part B) needs to be revised to address the following comment:

- The statement is made that a list of all CCP CARs and NCRs was reviewed. This indicates that only a list of the documents was reviewed. Unless the list identified AK in the subject line, the documents would not have been reviewed. Its not clear that documents that did not have a subject title with "AK" identified were evaluated. A number of CARs or NCRs could deal with subject matter that indeed could impact AK. Please clarify this review and if indeed only the listing of these documents was reviewed, the documents themselves should be reviewed to determine if they identified conditions that could have impacted the AK.

Upon completion of all corrective action(s) as described in the response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By:

  
A. E. Bradford

Date:



# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-059

2. Activity No.: S-01-19

3. Page 2 of 2

Block # 17

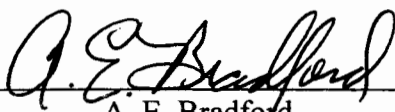
The following is an evaluation of the response to CBFO CAR 01-059 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01046, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective actions, (remedial) for the Conditions Adverse to Quality described in the CBFO CAR is acceptable. The proposed corrective actions, (investigative, root cause, and actions to preclude recurrence) must address the following comments:

- Investigative Actions, Extent: The statement that the lack of Calibration Verification and TMU reports will not affect the batch data is incorrect, if the equipment fails the PDP the data is no good. The data generated with a non calibrated system is suspect.
- Actions to preclude recurrence, Initial Calibration Verification: This section must be revised to address the possibility of failure of the PDP.

Upon completion of all corrective action(s) as described in the response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By: \_\_\_\_\_

  
A. E. Bradford

Date: \_\_\_\_\_



# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-063

2. Activity No.: S-01-19

3. Page 2 of 2

Block # 17

The following is an evaluation of the response to CBFO CAR 01-063 (identified during Surveillance S-01-19) as submitted via TRU Solutions letter dated July 17, 2001 (CP:01:01047, UFC:2300.00), from F. Sharif to S.A. Vega.

The proposed corrective actions, (remedial, investigative, and root cause) for the Conditions Adverse to Quality described in the CBFO CAR are acceptable. The proposed corrective action (actions to preclude recurrence) must be revised to address the following comment:

- The actions to preclude recurrence states that CCP contacted the supplier to obtain a signed copy of the certification, but is not clear that the record was obtained. Please provide clarification of the outcome, and/or clarify that the determination that one of a set of 22 was sufficient justification for acceptance of the set. Also, if the latter was selected, provide a statement that the justification documented.

Upon completion of all corrective action(s) as described in the response, WTS/CCP is to notify and submit documentation supporting closure, to the CBFO assessment team leader (Sam Vega) so that verification activities may be scheduled and performed as soon as possible

Response Evaluated By:

  
A. E. Bradford

Date:

