



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

JUL 14 2014

Mr. Jon E. Hoff, Manager
 Quality Assurance
 Nuclear Waste Partnership LLC
 P.O. Box 2078
 Carlsbad, New Mexico 88221-2078

Subject: CBFO Evaluation and Rejection of the CAP for CAR 14-041 Identified During Surveillance S-14-20, SRS/CCP Radiological Characterization of Sealed Sources Activities

Dear Mr. Hoff:

Enclosed are the results of the Carlsbad Field Office (CBFO) evaluation of the proposed Corrective Action Plan (CAP) for CBFO Corrective Action Report (CAR) 14-041, which resulted from Surveillance S-14-20, Savannah River Site Central Characterization Program (SRS/CCP) Sealed Source Characterization Program. The results of the review indicate that the CAP is not acceptable, as documented on the enclosed CAR Continuation Sheet. Please revise the CAP for CAR 14-041, addressing the comments contained in the evaluation, and submit your revised response to me on or before August 5, 2014. Also include a date for completion submittal to the CBFO on your revised CAP.

If you have any questions concerning CAR 14-041, please contact me at (575) 234-7491.

Sincerely,

Dennis S. Miehls
 Senior Quality Assurance Specialist

Enclosure

cc: w/enclosure

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*ED denotes electronic distribution



CAR CONTINUATION SHEET

1. CAR No: 14-041

2. Activity No: S-14-20

3. Page 1 of 3

Block # 16 Acceptance/Rejection of Proposed Corrective Actions:

An evaluation was performed of the Corrective Action Plan (CAP) developed to address Carlsbad Field Office (CBFO) Corrective Action Report (CAR) 14-041. The CAP was submitted via NWP letter QA:14:00203 UFC:2300.00 (CBFO Unique # 1401828), dated June 27, 2014, from Mr. J.E. Hoff, Manager, Quality Assurance, to Mr. D.S. Miehl, Senior Quality Assurance Specialist, CBFO Office of 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.

REMEDIAL ACTIONS

After the changes to procedures CCP-QP-022 and CCP-TP-514 are completed as described in the Actions to Prevent Recurrence, the calculation packages will be reviewed, and revised if necessary, to meet the revised procedural requirements.

Evaluation

The remedial actions described do not adequately address the conditions adverse to quality identified in the CAR.

During the surveillance, documentation of the verification of the spreadsheet used in the calculation SRS RH-88 was found to be inadequate. The spreadsheet may have been checked adequately, indicating that the calculation results are correct, but the check could not be verified. Due to the complexity of the spreadsheet functions, application of software quality assurance is recommended, to include test planning, performance, and documentation. The reference sources for data values must be stated and checks must be performed, and the formulae that gather data and the reference locations of individual data entries within individual sheets must also be tested to verify that correct data are collected from correct locations.

INVESTIGATIVE ACTIONS

The investigation resulted in confirming calculation package SRS-RH-88, Sealed Source Characterization for SRS-630 Drums, received the adequate verification calculations of the radiological results. The Originator creates the calculation package. Then it goes to the ITR to review the collected data and input parameters. The ITR is someone other than the originator and checker of the Radiological Calculation Package, who is qualified to have performed the work. Next, the calculation package goes to the Checker. The Checker verifies every calculation and input parameter. The Checker performs hand calculations to verify the calculations in the calculation package. The checker is a qualified individual to have performed the work and has not been involved in the development of the radiological characterization approach for the waste stream. The Quality Assurance Program Documents for both CBFO and NWP address this situation. System Software, such as Excel, is exempt from the software QA requirements described in the QAPDs, but specific applications written for use within these types of software that can be verified by hand calculations or other means, have to meet the following requirements:

- 1. A listing of the software code (i.e., details of formulas, file/table/cell references, and/or macros) shall be developed and maintained.*
- 2. Documentation shall be prepared to demonstrate by hand or other independent calculations that the specific application provides the correct results for the specified range of input parameters.*

CCP-QP-022 does not address using this approach for system software applications. Currently CCP-QP-022 would require the application to be entered into the software inventory, verified and validated, and retired when the calculation package was approved.

Extent

This condition applies to all calculation packages developed under CCP-TP-514.

CAR CONTINUATION SHEET

1. CAR No: 14-041

2. Activity No: S-14-20

3. Page 2 of 3

Impact

For all calculation packages developed under CCP-TP-514 the Checker verified all the calculations by hand. There is no impact on the usability of the results of the calculation packages.

Evaluation

The investigative actions described do not adequately address the conditions adverse to quality identified in the CAR.

The statement of investigation does not indicate the number of calculation packages that have been developed under CCP-TP-514. At the time of the surveillance, personnel indicated that there have been few calculations packages developed under this procedure. The CAP needs to state the number of calculations that have been developed and that are included in the scope of the investigation of "Extent".

ROOT CAUSE

A root cause analysis was not required for this CAR.

Evaluation

N/A

ACTIONS TO PRECLUDE RECURRENCE

Procedure CCP-QP-022 will be revised to address the use of system software applications that can be verified by hand calculations.

Procedure CCP-TP-514, CCP Procedure for Radiological Calculation Package Submittal, will be revised to provide clear instructions for using hand calculations to verify the calculations in the calculation package and the required documentation.

Evaluation

The actions to preclude recurrence described adequately address the scope of the deficiency identified in the CAR.

SCHEDULE FOR COMPLETION OF CORRECTIVE ACTIONS

The following corrective actions and due dates for CAR 14-041 were presented in the CAP.

COMMITMENTS

Issue revised procedure CCP-TP-514, CCP Procedure for Radiological Calculation Package Submittal, to provide clear instructions for using hand calculations to verify the calculations in the calculation package.

DUE DATES

August 15, 2014

Issue revised procedure CCP-QP-022 to address use of system software applications that can be verified by hand calculations.

August 15, 2014

Revise calculation packages, if necessary.

September 30, 2014

Provide closure documentation to NWP Quality Assurance.

October 6, 2014

Evaluation

The schedule for completion of corrective actions is acceptable. The expected completion date for all corrective actions is October 6, 2014.

CAR CONTINUATION SHEET

1. CAR No: 14-041

2. Activity No: S-14-20

3. Page 3 of 3

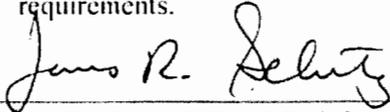
REJECTION

The results of the CAP evaluation indicate that the proposed corrective actions do not satisfactorily address the conditions adverse to quality identified in CAR 14-041. The scope of remedial actions must be revised to address revision to calculation package SRS-RH-88 that shows documentation of testing of the complexities of the "SRS-630 Sealed Source Characterization" spreadsheet. The description of investigation activities must be revised to indicate the number of calculation packages generated under CCP-TP-514 that are included in the investigation of the "Extent" of conditions.

It is recommended that the CAP for CAR 14-041 be rejected and that a revised CAP be submitted for evaluation.

Based on the information provided in this CAP, the following items will be evaluated to verify completion of corrective actions, with supporting documentation provided in the CAR closure package. Other items related to completion of corrective actions and items stated in the revised CAP may be included in verification activities as necessary.

- 1) A review of investigative actions performed to identify the number of calculations developed under CCP-TP-514 (including but not limited to calculation package SRS-RH-88).
- 2) A review of any revisions to calculation packages performed to meet compliance with control of software stated in the new revisions of CCP-TP-514 and any applicable sections of CCP-QP-022.
- 3) A review of revisions to CCP-TP-514 and CCP-QP-022 to determine adequate flow-down of CBFO QAPD requirements.



Evaluation Performed By: J.R. Schuetz

3/9/14

Date: