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OCAS-PER-030, SUBTASK 4

REVIEW OF IMPACTED CASES REWORKED FOR THE EVALUATION OF EXTERNAL AMBIENT DOSES AND INTERNAL INTAKES FROM THE SAVANNAH RIVER SITE

Contract No. 211-2014-58081

Ron Buchanan S. Cohen & Associates 1608 Spring Hill Road, Suite 400 Vienna, VA 22182

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1.0 RELEVANT BACKGROUND INFORMATION

S. Cohen and Associates (SC&A) was tasked by the Advisory Board to conduct a review of OCAS-PER-030, *Savannah River Site TBD Revision* (OCAS-PER-030). OCAS-PER-030 was issued to determine the number of claims impacted by Rev. 01 to the SRS technical basis document (TBD) (ORAUT-TKBS-0003 2003b), as compared to Rev. 00 (ORAUT-TKBS-0003 2003a). The revised TBD contained the following changes:

- No reduction for 1.5 L plutonium bioassay samples
- Revised environmental plutonium intakes
- 2,500 hours per year environmental external exposures
- Environmental plutonium and uranium headings transposed

On July 1, 2013, SC&A submitted to the Procedures Review Subcommittee (PRSC) our review of NIOSH's program evaluation report (PER), OCAS-PER-030 (SC&A 2013). In conducting a PER review, SC&A is committed to perform five subtasks, as specified below:

- Subtask 1: Assess NIOSH's evaluation/characterization of the "issue" and its potential impacts on Dose Reconstruction (DR). Our assessment intends to ensure that the "issue" was fully understood and characterized in the PER.
- Subtask 2: Assess NIOSH's specific methods for corrective action. In instances where the PER involves a technical issue that is supported by document(s) (e.g., white papers, technical information bulletins, procedures) that have not yet been subjected to a formal SC&A review, Subtask 2 will include a review of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science. Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, Subtask 2 will simply provide a brief summary/conclusion of this review process.
- Subtask 3: Evaluate the PER's stated approach for identifying the universe of potentially affected DRs, and assess the criteria by which a subset of potentially affected DRs was selected for re-evaluation. The third step may have important implications in instances where the universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's re-evaluation is confined to a subset of DRs that, based on their scientific judgment, have the potential to be significantly affected by the PER. In behalf of Subtask 3, SC&A will also evaluate the timeliness for the completion of the PER.
- Subtask 4: Conduct audits of DRs affected by the PER under review. The number of DRs selected for audit for a given PER will vary, based on important elements such as (1) the number of target organs/tissues that may be impacted by a PER, (2) the method/data that were employed in the original DR, and (3) the time period, work location, and job function(s) that characterize the DR of a claim. (It is assumed that the selection of the DRs and the total number of DR audits per PER will be made by the Advisory Board.)

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Subtask 5: Prepare a comprehensive written report that contains the results of the above-stated subtasks, along with our review conclusions.

This report fulfills the requirement defined in Subtask 4, "Conduct audits of DRs affected by the PER under review." Under Section 2.0 of OCAS-PER-030, NIOSH identified the following issues, for which some cases may require re-evaluation.

- No reduction for 1.5 L Revision 0 required that [plutonium] urine samples be adjusted to a daily rate by assuming 1.4 liter per day standard rate. However, many samples were reported as activity per 1.5 liters. Revision 1 indicated that samples specified in this way could be considered to be a full day's excretion. Any samples specified as activity per 1.5 liters could have been reduced under revision 0 and would not be now. Therefore, claims completed prior to revision 1 being issued will have to be reviewed to determine if actual urine samples meeting this criterion were reduced.
- Revised Environmental Plutonium Intakes Revision 0 provided a table that contained errors in the pre-calculated missed intakes for plutonium exposure. The values that were miscalculated in revision 0 were corrected in revision 1. All the values for type M plutonium were too high in revision 0 and the values for type S plutonium were too low. Because of this, claims that used the type S values from revision 0 will require a new dose estimate. Since the TBD did not require the use of these values, it is possible some estimates did not include this error. A review of the plutonium intakes will be necessary to determine which claims are affected.
- 2,500 hours per year Environmental Some dose estimates include ambient external dose. The values in revision 0 assumed a 2000 hour work year. This was changed to 2500 hour work year in revision 1. Therefore, claims assigned ambient external dose using revision 0 will require a new dose estimate.
- Environmental Plutonium and Uranium Headings Transposed Revision 0 of the TBD included a table of the maximum site wide ambient intakes of various isotopes. In that table, headings for plutonium and uranium were transposed. This was corrected in revision 1. Most dose estimates completed under revision 0 were performed with the aid of a computational tool. This tool created 7/25/2003 (10 days after revision 0 was issued) contained the appropriate values. However, claims completed using revision 0 must be reviewed to determine if the appropriate value was used.

Using the following criteria as outlined in Section 3.0 of OCAS-PER-030, NIOSH identified 54 cases that were completed before Rev. 01 of the SRS TBD was released (ORAUT-TKBS-0003 2003b):

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- 1. Any of the claims assigned an external ambient dose from table C-19 of revision 0 will require a new dose estimate.
- 2. Any of the claims assigned a uranium or plutonium ambient intake from table C-17 of revision 0 will require a new dose estimate.
- 3. Any of the claims assigned missed type S plutonium intakes from table 4.4.3-1 of revision 0 will require a new dose estimate.
- 4. Any of the claims assigned a plutonium intake from urinalysis that had been adjusted to 1.4 liters per day may require a new dose estimate. A new estimate is required if the sample was reported as activity per 1.5 liters and it was reduced to 1.4 liters of daily excretion.

According to OCAS-PER-030, NIOSH will review these DRs to determine if they meet any of the criteria listed above. NIOSH will provide the Department of Labor (DOL) with the list of 54 claims as well as a determination on each claim as to whether a new dose estimate is required. Documentation for each claim not requiring a new DR will provide the basis for that determination.

SC&A reviewed the potential claims on the NIOSH/DCAS Claims Tracking System (NOCTS) database and concurs with NIOSH's identification of the number of cases potentially impacted by OCAS-PER-030. Therefore, SC&A recommended that the Advisory Board assign the necessary cases for SC&A's evaluation concerning the correct implementation of OCAS-PER-030.

At the November 7, 2013, PRSC meeting, the following criteria for evaluation of reworked cases for OCAS-PER-030 were selected as follows [must have probability of causation (POC) <50% and DR after August 21, 2003]:

- 1. A case that includes ambient external dose assigned from the TBD tables.
- 2. A case that includes uranium and/or plutonium assigned from the TBD tables.
- 3. A case that includes assigned missed type S plutonium from the TBD tables.
- 4. A case that adjusted the plutonium intake from urinalysis to a 1.4 liter sample.

These could be four separate cases, or fewer cases that include the four criteria.

At the February 13, 2014, PRSC meeting, SC&A was tasked with reviewing the applicable cases. It was determined that SC&A's review should be limited to evaluating only those methods and corrective actions introduced in the re-evaluated dose that relate strictly to issues addressed in OCAS-PER-030. Two relevant cases were provided by NIOSH to SC&A on February 14, 2014. Presented in Section 2.0 below is SC&A's focused review to determine whether the ambient external doses and the internal doses (if applicable) associated with the two selected cases were correctly assigned per recommendations in OCAS-PER-030.

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2.0 REVIEW OF OCAS-PER-030 ISSUES FOR CASE #[CASE 1] (SRS)

2.1 BACKGROUND INFORMATION FOR CASE # CASE 1

Case #[Case 1] represents an energy employee (EE) who worked at the SRS from [redacted], through [redacted]. During this worker's employment, the EE worked as a [redacted] at various locations within SRS. The EE was diagnosed with [redacted] cancer (ICD Code [redacted]) in [redacted] and cancer of the [redacted] (ICD Code [redacted]) in [redacted]. The EE was monitored for external exposures during employment and the recorded data were used to assign external doses; additionally, ambient external dose was assigned according to ORAUT-PROC-0060. The EE was monitored for some internal intakes, with most results below the detection limits; therefore, as an efficiency method, the DR used the recommendations for assigning internal intakes from ORAUT-OTIB-0001 (2003) in this case.

2.2 COMPARISON OF NIOSH'S ORIGINAL AND REWORKED DOSE RECONSTRUCTIONS

NIOSH performed the original DR for this case on August 6, 2003, and the revised DR on September 24, 2010. The claim was reworked due to the addition of a [redacted] cancer, and the revision used a more realistic DR approach instead of a gross overestimate as in the first DR.

External Ambient Dose

NIOSH indicated that the original 2003 DR was a **gross overestimate** of dose. In the original DR, NIOSH calculated a total ambient external dose of **4.283 rem** to the bladder (the **[redacted]** cancer was not included at that time), using 2,500 hours per year of exposure. Based on the total dose of 26.185 rem assigned in this case, the DOL determined the POC to be 31.94% and the claim was denied.

Using more realistic DR methods in 2010, and including the additional [redacted] cancer, an external ambient dose to the bladder of **0.296 rem** and **0.490 rem** to the [redacted] was assigned using 2,500 hours per year of exposure through 1979. Based on the total dose assigned in this case, the resulting POC was still <50%.

Table 2-1. Comparison of NIOSH Estimated External Ambient Dose to the [Redacted] and to the Skin of [Redacted] in the Original DR and Revised DR

Organ	Original Dose (rem)	Revised Dose (rem)
[redacted]	4.283	0.296
[redacted]	NA	0.490

Internal Dose Assignment

OCAS-PER-030 recommends several changes to the internal intakes (as outlined in Section 1.0 of this report) <u>if</u> bioassay data or ambient intakes were used. However, in this case (and all cases considered for revision under OCAS-PER-030), the bioassays results were mostly below the level of detection; and hypothetical intakes were used as an overestimating, claimant-favorable,

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and efficiency method to assign internal doses, except for tritium intakes, which were assigned according to the bioassay data. Therefore, the changes in internal intakes outlined by OCAS-PER-030 would not impact this case since ORAUT-OTIB-0001 (2003) was used to assign internal dose.

2.3 SC&A'S REVIEW OF OCAS-PER-030 ISSUES RELATED TO CASE #[CASE 1]

As directed by the PRSC, SC&A's review of Case #[Case 1] focused on revised external ambient and internal dose (if applicable), as specified by the criteria in OCAS-PER-030.

Original DR (2003)

The original DR, performed in 2003, assigned external ambient dose using 2,500 hours per year for all years of employment as a gross overestimate of dose. The original DR assigned internal intakes and resulting doses using ORAUT-OTIB-0001 (2003).

Reworked DR (2010)

In the reworked DR, performed in 2010, NIOSH used 2,500 hours per year for employment though [redacted] (as per ORAUT-PROC-0060) and doses from SRS Area F of Table C-19 of ORAUT-TKBS-0003 (2003b). The reworked dose evaluation assigned internal intakes and resulting doses using ORAUT-OTIB-0001 (2003). The reworked DR did not require adjustment of the bioassay sample volumes or the use of intakes from ORAUT-TKBS-0003 (2003b); therefore, the internal intake changes recommended in OCAS-PER-030 did not apply in this case.

SC&A's Evaluation

SC&A evaluated the reworked DR and concurs that NIOSH used the correct 2,500 hours per year for the external ambient dose assignment for the appropriate time period, and that the internal dose was not impacted by OCAS-PER-030 because of the use of the overestimating ORAUT-OTIB-0001 (2003) method.

Observation #1:

In evaluating the reworked DR of 2010 for the correct number of hours per year for external ambient dose, SC&A noted that it appears NIOSH used the correct external ambient *isotropic* dose conversion factor (DCF) for the bladder of 0.408 from OCAS-IG-001 (2007), page 58; however, back calculating from the assigned doses in the Interactive RadioEpidemiological Program (IREP) table for the skin, it appears that an *A-P* DCF of 0.677 was used instead of 0.564 for *isotropic* geometry (or a DCF of 1.000 for skin as per ORAUT-OTIB-0017, 2005). This would not significantly impact this case.

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3.0 REVIEW OF OCAS-PER-030 ISSUES FOR CASE #[CASE 2] (SRS)

3.1 BACKGROUND INFORMATION FOR CASE #[CASE 2]

Case #[Case 2] represents an energy employee (EE) who worked at the SRS from [redacted] through [redacted]. During this worker's employment, the EE worked as a [redacted] at various locations within SRS. The EE was diagnosed with [redacted] cancer (ICD Code [redacted]) in [redacted]. The EE was monitored for external exposures during employment and the recorded data were used to assign external doses; additionally, external ambient dose was assigned according to ORAUT-PROC-0060. The EE was monitored for some internal intakes, with most results below the detection limits; therefore, as an efficiency method, the DR used the recommendations for assigning internal intakes from ORAUT-OTIB-0018 (2005) in this case.

3.2 COMPARISON OF NIOSH'S ORIGINAL AND REWORKED DOSE RECONSTRUCTIONS

NIOSH performed the original DR for this case on August 22, 2003, and the latest DR for this Case on August 4, 2009. The claim was reworked due to changes in the method of dose assignment for the SRS.

External Ambient Dose

NIOSH indicated that the original 2003 DR was an **overestimate** of dose. In the original DR, NIOSH calculated a total external ambient dose of **3.975 rem** to the bladder for all years of employment, using 2,500 hours per year of exposure. Based on the total dose assigned of 12.366 rem in this case, the DOL determined the POC to be 18.26% and the claim was denied.

Using more realistic DR methods in 2009, an external ambient dose to the [redacted] of **0.413 rem** was assigned using 2,500 hours per year of exposure through [redacted]. Based on the total dose of 10.418 rem assigned in this case, the resulting POC was <50%.

Table 3-1. Comparison of NIOSH Estimated External Ambient Dose to the [Redacted] in the Original DR and Revised DR

Organ	Original Dose (rem)	Revised Dose (rem)
[redacted]	3.975	0.413

Internal Dose Assignment

OCAS-PER-030 recommends several changes to the internal dose assignment <u>if</u> bioassay data or ambient intakes were used. However, in this case, the bioassays results were mostly below the levels of detection; and hypothetical intakes were used as an overestimating, claimant-favorable, and efficiency method to assign internal doses, except for tritium intakes, which were assigned according to other means. Therefore, the changes in internal intakes outlined by OCAS-PER-030 would not impact this case, since ORAUT-OTIB-0018 (2005) was used to assign internal dose.

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3.3 SC&A'S REVIEW OF OCAS-PER-030 ISSUES RELATED TO CASE #[CASE 2]

As directed by the PRSC, SC&A's review of Case #[Case 2] focused on revised external ambient and internal dose, as specified by the criteria in OCAS-PER-030.

Original DR (2003)

The original DR, performed in 2003, assigned external ambient dose using 2,500 hours per year for all years of employment as an overestimate of dose. The original DR assigned internal intakes and resulting doses using ORAUT-OTIB-0018 (2005).

Reworked DR (2009)

In the reworked DR, performed in 2009, NIOSH used 2,500 hours per year for employment through [redacted], and doses from the maximum SRS external ambient doses as listed in Table 3.4-1 of ORAUT-TKBS-0003 (2003b), using a [redacted] DCF of 1.000. The reworked dose evaluation assigned internal intakes and resulting doses using ORAUT-OTIB-0018 (2005).

SC&A's Evaluation

SC&A evaluated the recent DR and concurs that NIOSH used the correct 2,500 hours per year for the external ambient dose assignment, and that the internal dose was not impacted by OCAS-PER-030 because of the use of the overestimating ORAUT-OTIB-0018 (2005) method.

Observation #2:

In evaluating the reworked DR of 2009 for the correct number of hours per year for external ambient dose, SC&A found that NIOSH assigned external ambient dose through [redacted]; however, ORAUT-PROC-0060, page 14, recommends assigning external ambient dose only through [redacted], and explicitly excludes [redacted]—present. This resulted in a slight over assignment of dose of 0.044 rem, which would not impact this case.

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4.0 SUMMARY CONCLUSIONS

Under SC&A's *A Protocol to Review NIOSH's Program Evaluation Reports (PERs)* (SC&A 2009), Subtask 4 requires the audit of DR case(s) as a result of the PER under review. For OCAS-PER-030, there were 54 cases that met the applicable criteria.

During the February 13, 2014, PRSC meeting, SC&A was tasked with evaluating the appropriate cases concerning the application of OCAS-PER-030.

This current report satisfies the Subtask 4 requirement. For the 2 cases selected from the 54 cases impacted by OCAS-PER-030, SC&A provided an overview of the case and a brief comparison of doses assigned in the original DRs and the revised dose estimates. Based on directives from the PRSC, SC&A's audits of the two cases focused on those elements of the DRs that were affected by the issuance of OCAS-PER-030. Therefore, our audit determined if external ambient doses and internal doses were appropriate for these cases, and if so, if they were assigned correctly.

As discussed in Section 2, SC&A found that NIOSH did correctly apply the appropriate ambient external doses as recommended by OCAS-PER-030. In evaluating the cases with DRs performed before Rev. 01 of ORAUT-TKBS-0003 was issued, SC&A found that NIOSH used hypothetical intakes as an overestimating, claimant-favorable, and efficiency method to assign internal doses (except for tritium intakes, which were assigned according to other means). Therefore, the changes in internal intakes outlined by OCAS-PER-030 would not impact any of these prior cases, and internal doses were not re-evaluated by SC&A under Subtask 4. SC&A had no findings in the two cases reviewed concerning the reworked doses as per OCAS-PER-030.

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