REPORT TO THE ADVISORY BOARD ON RADIATION AND WORKER HEALTH

National Institute of Occupational Safety and Health

Audit of Case PIID* from the Savannah River Site

Contract No. 200-2004-03805
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S. Cohen & Associates: ***Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program***	Document No. SCA-TR-TASK4-CNPIID*
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1.0 SUMMARY BACKGROUND INFORMATION

This report presents the results of an independent audit of a dose reconstruction performed by the National Institute of Occupational Safety and Health (NIOSH) for an energy employee who worked at the Savannah River Site (SRS) from PIID* through PIID* as an PIID*. The worker was diagnosed with colon cancer on PIID* and prostate cancer on PIID*.

SRS operations played an important role in the U.S. nuclear weapons program. SRS processes included nuclear fuel fabrication, reactor operation, radiochemical processing, uranium recycling, plutonium production, neutron source production, and waste management.

Although documents provided by the Department of Labor (DOL) confirm that the energy employee worked at SRS from PIID*, through PIID*, the Department of Energy (DOE) has no records for this claimant. In response to NIOSH's request for Personnel Exposure Information, DOE indicated that no records exist for external dosimetry, internal dosimetry, occupational medical x-rays, incident investigation reports, and other monitoring results. In summary, the absence of DOE records/documentation pertaining to the claimant's employment at SRS, the nature of work performed by the claimant, assigned work locations, and radiation monitoring records provide a limited basis for dose reconstruction.

Thus, it is uncertain whether the absence of records for the claimant implies that this individual was never engaged in work activities that required radiation monitoring, or whether this is a case of misplaced/missing records. Support for the latter is discussed in Section 4.0 of this audit report. For dose reconstruction, NIOSH assumed that the energy employee was not monitored, since no internal or external dose records were provided.

In the absence of monitoring data, NIOSH limited the assignment of doses for the claimant to the following exposure categories.

- Onsite ambient external doses
- Occupational medical X-rays
- Internal exposures for radionuclides other than tritium, based on an acute hypothetical intake

In summary, a dose reconstruction was performed by NIOSH that included a total of 71 exposure data entries to be used for determining the probability of causation. These dose entries are #1 through #77 and are reproduced herein as Appendix A. Throughout this report, reference will be made to select portions of Appendix A; for example, exposure entries #1 through #62 identify hypothetical internal doses, while entries #69 through #71 correspond to occupational medical exposure.

Table 1 provides a summary of dose estimates derived by NIOSH that correspond to data contained in Appendix A. Using NIOSH's dose estimates, the probability of causation (POC) was determined by the DOL to be 11.28% at the 99% confidence interval, and on this basis, the claim was denied.

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Table 1. Summary of NIOSH-Derived External/Internal Dose Estimates

	Appendix A Exposure Entry No.	Dose (rem)
External Dose:		
▪ Photon Dosimeter Dose	NC*	—
▪ Missed Photon Dose	NC*	—
▪ Neutron Dosimeter Dose	NC*	—
▪ Missed Neutron Dose	NC*	—
▪ Occupational Medical:	69 – 71	0.125
▪ Onsite Ambient	66 – 68	0.273
Internal Dose (Hypothetical):		
▪ Tritium	63 – 65	1.065
▪ All Other Radionuclides	1 – 62	2.143
Total:		3.606

* NC – Not considered

1.1 AUDIT OBJECTIVES

SC&A's audit was performed with the following objectives:

- To determine if NIOSH assigned doses that are consistent with monitoring records provided by the DOE and with information contained in the CATI report
- To determine if the dose reconstruction process complied with applicable procedures that include generic procedures developed by NIOSH and ORAUT, as well as data/procedures that are site-specific to SRS
- In instances when procedure(s) provide more than one option or require subjective decisions, determine if the process is scientifically defensible and/or claimant favorable.

In pursuit of these objectives, a two-step process is followed. The first step of this audit is to independently duplicate and, therefore validate, doses derived by NIOSH. This step of the audit process is not only contractually mandated under Task 4, but provides NIOSH and the Advisory Board with a high level of assurance that the SC&A reviewer understands which procedures, models, site-specific data, and assumptions NIOSH used to perform its dose reconstruction. The second step of the audit critically evaluates whether the methods employed by NIOSH are technically defensible, consistent with applicable procedures, and claimant favorable.

Lastly, in compliance with the Privacy Act, this report makes no reference to the claimant's name, SSN, address, or any personal data that might reveal the identity of the claimant.

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1.2 SUMMARY OF AUDIT FINDINGS

An overview of SC&A's audit findings for Case PIID* is provided in Table 2 in the form of a checklist. This checklist evaluates the data collection process, information obtained from the CATI interview, and all methods used in the dose reconstruction. When deficiencies are identified by the audit, such deficiencies are further characterized with regard to their impact(s) by means of the following definitions: (1) **low** means that the deficiency has only a marginal impact on dose; (2) **medium** means that the deficiency substantially impacts the dose, but is unlikely to impact the compensability of the case; and (3) **high** means that the deficiency substantially impacts the dose and may also impact the compensability of the case. A full description of deficiencies identified in the checklist is provided in the text of the audit that follows.

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Table 2. Case Review Checklist

CASE PIID*	ASSIGNED DOSE: 3.606 rem	POC: 11.28%

No.	Description of Technical Elements of Review	Audit Response			If No, Potential Significance		
		YES	N/A	NO	LOW[1]	MEDIUM[2]	HIGH[3]
A. REVIEW OF DATA COLLECTION:							
A.1	Did NIOSH receive all requested data for the DOE or AWE site from any relevant data source?	✓					
A.2	Is the data used by NIOSH for the case adequate to make a determination with regard to POC?	✓					
B. REVIEW OF INTERVIEW AND DOCUMENTATION PROVIDED BY CLAIMANT							
B.1	Did NIOSH properly address all work history dates/locations of employment reported by claimant?	✓					
B.2	Did NIOSH properly address all incidents/occurrences reported by claimant?	✓					
B.3	Did NIOSH properly address monitoring/ personal protection/work practices reported by claimant?	✓					
B.4	Is the interview information consistent with data used for dose estimate?			✓	✓		
C. REVIEW OF PHOTON DOSES							
C.1	Was the appropriate procedure used for determining:						
C.1.1	- Recorded Photon Dose?		✓				
C.1.2	- Missed Photon Dose?		✓				
C.1.3	- Occupational Medical Dose?	✓					
C.1.4	- Onsite-Ambient Dose?	✓					
C.2	Did the DR properly account for all:						
C.2.1	- Recorded Photon Dose?		✓				
C.2.2	- Missed Photon Dose?		✓				
C.2.3	- Occupational Medical Dose?	✓					
C.2.4	- Onsite-Ambient Dose?	✓					
C.3	Is the recorded/assigned dose properly converted to the organ dose of interest for:						
C.3.1	- Recorded Photon Dose?		✓				
C.3.2	- Missed Photon Dose?		✓				
C.3.3	- Occupational Medical Dose?	✓					
C.3.4	- Onsite-Ambient Dose?	✓					
C.4	Is the organ dose uncertainty properly determined for:						
C.4.1	- Recorded Photon Dose?		✓				
C.4.2	- Missed Photon Dose?		✓				
C.4.3	- Occupational Medical Dose?	✓					
C.4.4	- Onsite-Ambient Dose?	✓					
D. REVIEW OF SHALLOW (i.e., 7 mg/cm^2)/ELECTRON DOSES							
D.1	Was the appropriate procedure used for determining:						
D.1.1	- Recorded Shallow/Electron Dose?		✓				
D.1.2	- Missed Shallow/Electron Dose?		✓				
D.1.3	- Onsite Ambient Dose?		✓				
D.2	Did the DR properly account for all:						
D.2.1	- Recorded Shallow/Electron Dose?		✓				
D.2.2	- Missed Shallow/Electron Dose?		✓				
D.2.3	- Onsite Ambient Dose?		✓				

[1] **Low** means that the deficiency has only a marginal impact on dose.
[2] **Medium** means that the deficiency substantially impacts the dose, but is unlikely to impact the compensability of the case.
[3] **High** means that the deficiency substantially impacts the dose and may also impact the compensability of the case.

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CASE PIID*	ASSIGNED DOSE: 3.606 rem	POC: 11.28%

No.	Description of Technical Elements of Review	Audit Response			If No, Potential Significance		
		YES	N/A	NO	LOW[1]	MEDIUM[2]	HIGH[3]
D.3	Is the recorded/assigned dose properly converted to the organ dose of interest for:						
D.3.1	- Recorded Shallow/Electron Dose?		✓				
D.3.2	- Missed Shallow/Electron Dose?		✓				
D.3.3	- Onsite Ambient Dose?		✓				
D.4	Is the organ dose uncertainty properly determined for:						
D.4.1	- Recorded Shallow/Electron Dose?		✓				
D.4.2	- Missed Shallow/Electron Dose?		✓				
D.4.3	- Onsite Ambient Dose?		✓				
E. REVIEW OF NEUTRON DOSES							
E.1	Was the appropriate procedure used for determining:						
E.1.1	- Recorded Neutron Dose?		✓				
E.1.2	- Assigned Neutron Dose?		✓				
E.1.3	- Missed Neutron Dose?		✓				
E.2	Did the DR properly account for all:						
E.2.1	- Recorded Neutron Dose?		✓				
E.2.2	- Assigned Neutron Dose?		✓				
E.2.3	- Missed Neutron Dose?		✓				
E.3	Is the recorded/assigned dose properly converted to the organ dose of interest for:						
E.3.1	- Recorded Neutron Dose?		✓				
E.3.2	- Assigned Neutron Dose?		✓				
E.3.3	- Missed Neutron Dose?		✓				
E.4	Is the organ dose uncertainty properly determined for:						
E.4.1	- Recorded Neutron Dose?		✓				
E.4.2	- Assigned Neutron Dose?		✓				
E.4.3	- Missed Neutron Dose?		✓				
F. REVIEW OF INTERNAL DOSE: BASED ON HYPOTHETICAL MODEL							
F.1	Is the use of the selected hypothetical internal dose model appropriate, based on the likely POC value?	✓					
F.2	Is the use of a hypothetical internal dose model appropriate/conservative, based on claimant's available bioassay data,?	✓					
F.3	Was the hypothetical dose value correctly derived?	✓					
G. REVIEW OF INTERNAL DOSE: BASED ON BIOASSAY/IMBA							
G.1	Was the appropriate procedure (or section of procedure) used for determining likely (>50%), unlikely (<50%), or undetermined POC and compensability?		✓				
G.2	Are bioassay data sufficiently adequate for internal dose reconstruction?		✓				
G.3	Are assumptions pertaining to dates of uptake reasonable/conservative?		✓				
G.4	Are critical parameters (e.g., solubility class, particle size, etc.) used for IMBA organ dose estimates appropriate?		✓				
G.5	Are assigned uncertainties (measurement errors) for bioassay data (used as input to IMBA) appropriate?		✓				
H. Total Number of Deficiencies and Their Combined Potential Significance				1	✓		

[1] **Low** means that the deficiency has only a marginal impact on dose.
[2] **Medium** means that the deficiency substantially impacts the dose, but is unlikely to impact the compensability of the case.
[3] **High** means that the deficiency substantially impacts the dose and may also impact the compensability of the case.

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2.0 AUDIT OF EXTERNAL DOSES

2.1 OCCUPATIONAL MEDICAL DOSE

In spite of the absence of records, NIOSH assumed the energy employee was given an annual medical x-ray examination as a condition of employment for the years PIID* through PIID* . Based on guidance contained in Section 2 of ORAUT-TKBS-0003, NIOSH assigned a dose of 42 mrem as the organ dose to the colon and prostate for each annual x-ray exam (see entries #69 through #71 of Appendix A).

2.1.1 Reviewer's Comments

SC&A reviewed Section 2 of ORAUT-TKBS-0003 and the default data contained in Table 2.5.1-1 for Group 3 organs. The assigned doses by NIOSH match those given in Table 2.5.2-1 and are, therefore, scientifically valid and comply with the applicable data, as defined in ORAUT-TKBS-0003.

2.2 ONSITE AMBIENT DOSE

Because the energy employee was assumedly not monitored, NIOSH assigned an external onsite ambient dose (chronic) for the years PIID* to PIID*. To maximize the probability of causation, ambient photon doses were assigned to the energy range 30–250 keV, and the energy employee was assumed to have worked an average of 50 hours per week for the full duration of each year.

Onsite ambient doses were based on the maximum annual onsite ambient external doses reported for any area of the SRS during the 3 years of employment. NIOSH assigned annual doses of 101 mrem, 94 mrem, and 78 mrem (see entries #66 through #68 of Appendix A) for PIID*, PIID*, and PIID*, respectively.

2.2.1 Reviewer's Comments

SC&A reviewed Section 3 of the Savannah River Technical Basis Document (ORAUT-TKBS-0003) and verified the above-cited values as the appropriate values provided in Table 3.4-1.

The assigned onsite ambient doses for the claimant are compliant with applicable procedures, are scientifically valid, and claimant favorable.

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3.0 AUDIT OF INTERNAL DOSES

3.1 TRITIUM

Due to the short biological and therefore effective half-life of tritium, hypothetical internal doses were assigned for each of the 3 years of employment; for all other radionuclides, the hypothetical internal doses extend from PIID* to the time of cancer diagnosis in PIID*. For tritium, an internal organ dose of 1.065 rem was assigned to the colon/prostate.

3.2 RADIONUCLIDES OTHER THAN TRITIUM

In order to account for any incidental dose that might have been received but not documented, NIOSH assigned yearly internal doses based on a single hypothetical acute intake on the first day of employment through the year of cancer diagnosis. Assigned internal doses for hypothetical exposure included all nuclides other than tritium. The technical basis for hypothetical internal doses is described in Section 4 of ORAUT-TKBS-0003. For radionuclides other than tritium, NIOSH derived an internal dose of 2.143 rem.

3.2.1 Reviewer's Comments

As part of SC&A's audit of hypothetical internal exposures, we verified all data entries against the default values cited in Table 4.5.3-1 for tritium, and Table 4.5.1-1 for all other radionuclides.

At this time, we conclude that all assigned internal doses for tritium and nuclides other than tritium are correct and comply with applicable procedures. However, there may be a generic flaw in the hypothetical internal exposure model for tritium and all other nuclides that may not only adversely affect the scientific validity and claimant favorability of this claim, but other SRS claims as well. The following provides a brief explanation.

The potential exception to scientific validity/claimant favorability reflects two issues. The first involves the unconfirmed assumption that all tritium exposures are those involving tritiated water. If, in fact, intakes involved a significant fraction of organified tritium, with a biological/ effective half-life that is about 2.3-fold higher, then the assigned doses herein may be too low.

The second issue is considerably more complex and involves estimated yearly doses from all other internal radionuclides, as defined in Table 4.5.1-1 of ORAUT-TKBS-0003, which in turn were derived from data contained in ORAUT-OTIB-0001. In brief, ORAUT-OTIB-0001 models intakes that are based on ICRP 30 biokinetic models instead of the current ICRP models, as required in 42 CFR 82. We believe that the use of ICRP 30 calculated intakes may not be claimant favorable for several important radionuclides and that ICRP 68 models should have been used to derive intakes.

Although the two issues cited above may impact both **recorded** internal doses (defined by bioassay data and IMBA) and **assigned** hypothetical doses, an agreement has been reached by the Advisory Board, SC&A, and NIOSH to evaluate these issues under Task 1 (i.e., Review of Site Profiles).

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4.0 CATI REPORT AND RADIOLOGICAL INCIDENTS

As previously acknowledged, DOE has no radiological records for this claimant. Consequently, there is no formal documentation of any radiological incidents. According to NIOSH records, because the claimant declined to be interviewed, there is also no CATI report available for audit.

However, what is part of the claimant's file is the NIOSH OCAS Phone Log Report, which identifies several critical statements that may have relevance to the dose reconstruction/claim. A copy of this phone log is enclosed herein as Exhibit 1. (In compliance with the Privacy Act, all personal identifiers have been blacked out.)

It must be noted, however, that Column 1 of Exhibit 1 identifies phone dates which **post-date** the completion of the dose reconstruction on December 1, 2003. Thus, the dose reconstructor was **not** aware of allegations brought up by claimant's spouse/family members during the closeout interview. Nevertheless, the following issues appear to conflict with assumptions by NIOSH in the dose reconstruction and may require a follow-up evaluation.

Issue of Concern 1: In the phone log entry for December 23, 2003, the spouse of the employee insists that the claimant "wore a dosimeter all the time." This conflicts with the NIOSH assumption that the claimant was not monitored. In support of claimant favorability, a reversal of NIOSH's assumption would imply that the dose reconstruction might have to consider assignment of doses for photons and neutrons based on co-worker data, if such could be found. In the absence of co-worker data, an alternate approach may be to assign doses corresponding to annual dose limits for the claimant for each year of employment.

Issue of Concern 2: In the phone log entry dated December 13, 2003, the spouse of the energy employee further raises questions about dates of employment. It is uncertain if the reference to the employee's "whole employment" is a statement of disagreement with the employment period of PIID*, through PIID*, that was used by NIOSH for dose reconstruction. A longer employment period would clearly raise assigned radiation doses for the claimant.

Issue of Concern 3: In the phone log entry dated February 20, 2004, the spouse of the energy employee states that the employee may have also worked at/visited other DOE sites that include the Los Alamos and Hanford sites. If this statement can be confirmed, the dose reconstruction may have to be further amended to account for non-SRS exposures.

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Exhibit 1: Phone Log Report

Phone log deleted – please see hard copy marked '#10 – Savannah River Site'

5.0 SUMMARY CONCLUSION

On the condition that the absence of monitoring records for the claimant is due to the fact that the claimant was never monitored, our audit shows that the dose reconstruction complied with applicable procedures and is generally scientifically correct and claimant favorable (with exceptions noted in text). However, there remains reasonable concern that the absence of records may reflect misplaced/missing records, in which case the dose reconstruction must clearly be viewed as incomplete, scientifically invalid, and claimant unfavorable.

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REFERENCES

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APPENDIX A: IREP INPUT

Tables deleted – Please see hard copy marked "#10 – Savannah River Site'

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APPENDIX A (continued)