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
Task Order No. 4

SCA-TR-TASK4-CNPIID*

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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* Effective Date: February 4, 2005 Revision No. 1
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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) intermittently from PIID* through PIID*. The exact periods of employment included the following: PIID* to PIID*; PIID* to PIID*; and PIID*. The claimant was employed as an electrician at various onsite locations. The energy employee was diagnosed with squamous cell skin cancers on PIID*, and was diagnosed with basal cell skin caner on PIID*.

Throughout the employment period, the claimant was not monitored for external exposure by means of film dosimeters or TLDs. The claimant was also not monitored for internal exposure by any of the standard bioassay methods that include whole-body counting, chest counting, and urinalysis. (Note: DOE records show a single whole-body count in **PIID***, which was, however, a "new hire" baseline count that indicated no body burden of non-natural nuclides and is not considered a "monitoring" bioassay.)

A dose reconstruction was performed by NIOSH that included a total of 60 exposure data entries to be used for determining the probability of causation (POC). These dose data entries are #1 through #60 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 #52 identify hypothetical internal exposures, and entries #52 through #56 represent onsite ambient doses.

Table 1 below provides a summary of organ dose estimates/assignments derived by NIOSH that correspond to data contained in Appendix A. Using NIOSH's dose estimate, the POC was determined by the Department of Labor (DOL) to be 5.46% at the 99% confidence interval, and on this basis, the claim was denied.

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	57 – 60	0.282
▪ Onsite Ambient	53 – 56	0.580
Internal Dose (Hypothetical):		
▪ Tritium	49 – 52	0.568
▪ All Other Radionuclides	1 - 48	1.894
Total		3.324

* NC – Not considered

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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 the 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 in this audit. 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.

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: 3.324 rem	POC: 5.46%

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: 3.324 rem	POC: 5.46%

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				2	✓		

[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

Records received from DOE show that the energy employee was never monitored for external radiation. Therefore, there is no basis for assigning external dosimeter doses and missed doses for photons, electrons, and neutrons. External exposure doses were, therefore, limited to onsite ambient doses and occupational medical doses.

2.1 OCCUPATIONAL MEDICAL DOSES

Although DOE records provide no indication of occupational medical exposures, NIOSH assumed an annual chest x-ray and assumed organ doses of 81 mrem each for PIID*, and 60 mrem each for PIID*.

2.1.1 Reviewer's Comments

Default values for organ doses associated with occupational medical exposure for SRS are defined in Section 2.51 of ORAUT-TKBS-0003. For the corresponding years, Table 2.5.1-1 identifies 81 mrem and 60 mrem for Group 1, which includes the skin.

Occupational medical doses assigned by NIOSH were derived by means of applicable procedures and quantitatively conform to values provided. The assigned doses are also scientifically valid and claimant favorable.

2.2 ONSITE AMBIENT DOSE

Because the claimant was not monitored, the *External Dose Implementation Guideline* (OCAS-IG-001) requires that onsite ambient doses be included in dose reconstruction. According to NIOSH's dose reconstruction (DR) Report, the onsite ambient doses assigned by NIOSH for entries #53 through #56 were based on the maximum average annual doses reported for SRS, as given in the *Savannah River Technical Basis Document* (ORAUT-TKBS-0003).

Because three independent skin cancers were diagnosed (the first in PIID*, the second in PIID*, and the third in PIID*), two different time periods were defined for ambient onsite dose. The first period assumes a 50-hour workweek starting the day of employment until the date of the first cancer diagnosis; the second period (associated with the second and third skin cancers) ended in PIID*, when the claimant terminated employment.

2.2.1 Reviewer's Comments

The assigned onsite doses defined as entries #53 through #56 in Appendix A could **not** be reproduced by means of guidance contained in Section 3.4 of ORAUT-TKBS-0003. Guidance herein identifies the following doses for a 50-hour workweek, along with the assumption of a lognormal distribution and a geometric standard deviation (GSD) of 1.3:

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Year	Onsite Dose (rem)	Uncertainty
PIID*	0.044	1.3
PIID*	0.093	1.3
PIID*	0.053	1.3
PIID*	0.050	1.3

In summary, NIOSH dose reconstruction failed to comply with the procedural guidance that identifies the above-cited doses, and the assumption of a lognormal distribution with a GSD of 1.3. (Note: Entries #53 through #56 of Appendix A are entered as point values (i.e., constant) that represent a dose substantially higher than what would be expected from the median values and uncertainty given above.)

A second, but minor, issue centers on the definition of onsite ambient dose and the means by which these values were determined. If the empirically measured onsite dose rates represent a deep dose (i.e., $H_P(10)$), then the dose to the skin (or shallow dose) may have been significantly underestimated for the claimant. A review of Attachment C.2 of ORAUT-TKBS-0003 provides no insight regarding this matter.

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3.0 AUDIT OF INTERNAL DOSES

In the absence of bioassay monitoring data, NIOSH estimated any potential incidental dose that may have been received but not documented. The assigned dose was based on a hypothetical intake, as defined in Section 4.5 of ORAUT-TKBS-0003 and Table 4.5.1-1 for the years of concern and for radionuclides other than tritium. For tritium, hypothetical doses for corresponding years are defined in Table 4.5.3-1 of ORAUT-TKBS-0003.

3.1 REVIEWER'S COMMENTS

All NIOSH entries for hypothetical doses for tritium and all other nuclides were compared against values in Tables 4.5.1-1 and 4.5.3-1.

All entry doses matched values provided in the Technical Basis Document. Therefore, internal doses assigned by NIOSH comply with applicable procedures, and are conditionally scientifically valid and claimant favorable, as explained below.

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-TIB-0001 models intakes that are based on ICRP 30 biokinetic models instead of the current ICRP 68 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

Neither the CATI Report nor DOE records identify any radiological incidents involving the claimant. However, there are several discrepancies regarding statements contained in the CATI Report and DOE records/NIOSH assumptions. These include the following:

- In the CATI report, claimant states dosimeter badges were worn. DOE records provide no supportive data for external monitoring.

- The claimant also identified the following bioassays: urine, breath, and in vivo (assumedly whole-body count). DOE records, however, only acknowledge a single pre-hire or baseline WBC, which is not regarded as a monitoring bioassay.

- The claimant stated that routine self-frisking for external contamination was performed, which suggests the claimant must have routinely worked in contaminated/radiological-controlled areas (RCAs). DOE records provide no information, such as radiation work permits (RWPs), that would support this claim.

- The claimant mentioned once working in an area "with heavy water" and seeing people with instruments, but did not know what they were measuring.

4.1 REVIEWER'S COMMENTS

In the DR Report, NIOSH only acknowledges the claimant's statements of having once worked in an area with heavy water. It is uncertain if the claimant was re-interviewed to resolve discrepancies identified in the first three statements above. Failure to resolve these issues may imply that DOE records are missing/incomplete, and that the NIOSH dose reconstruction may therefore also be incomplete. However, it is also acknowledged that the assigned hypothetical internal exposures are likely to be well in excess of potential exposures involving issues/ discrepancies raised by the claimant in the CATI report.

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5.0 SUMMARY CONCLUSION

For most of the doses assigned by NIOSH to the claimant, we were able to identify the procedures and the modifying parameters that were assumed in deriving dose estimates. In general, the dose estimates were verified and are viewed as scientifically valid and claimant favorable. As noted in the text of this audit, there are some unresolved issues that may justify a limited review of this claim.

A generic concern that is not confined to this DR Report, but characterizes all 20 cases that SC&A has reviewed to date, is the brevity of the DR Reports. In its current form, the NIOSH Dose Reconstruction Report provides only a brief summary explanation for assigned doses. In some instances, the explanation is confined to just a reference of a procedure/TBD.

The failure to explain how individual categories of internal/external exposures were derived, and the absence of a well-defined paper trail, pose limitations on NIOSH's internal QA review process. Similarly, these shortcomings force SC&A reviewers to engage in time-consuming speculations regarding the choice of procedures, methodology, and parameters selected by the dose reconstructor.

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REFERENCES

42 CFR 82. 2002. "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000." Final Rule, Federal Register/Vol. 67, No 85/Thursday, May 2, 2002, pg. 22314.

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ORAUT-OTIB-0001. 2003. "Technical Information Bulletin: Maximum Internal Dose Estimates for Savannah River Site (SRS) Claims," Rev. 00. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

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APPENDIX A: IREP INPUT

Deletions made to the following table -- please see hard copy labeled "#11- Savannah RS"