DRAFT 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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SCA-TR-TASK4-CN PIID*

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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-CN PIID* Effective Date: February 4, 2005 Revision No. 1 (Draft)
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Project Manager: _____ Date: 02/04/05 John Mauro, PhD, CHP	

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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*. The worker was diagnosed with pancreatic 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.

The claimant was employed at SRS as a PIID* and PIID*, and spent most of his time in PIID*Area. At other times, however, he was assigned to other areas on an as-needed basis. Among PIID*, his duties included PIID*. In fulfilling his duties, the energy employee was exposed to external photons and electrons. However, for dose reconstruction of the pancreas, external exposure to electrons may be excluded.

The records provided by DOE were considered adequate for completing a dose reconstruction. To maximize the probability of causation, NIOSH states that for dose reconstruction, claimant-favorable assumptions were used pertaining to exposure geometry, photon energy range, missed dose, occupational medical exposure, and potential internal exposures that were not recorded.

A dose reconstruction was performed by NIOSH that included a total of 157 dose entries for determining the probability of causation. Dose data entries are #1 through #157 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 #18 identify assigned organ doses that were based on measured and recorded personnel dosimeter data that included film badges and TLDs.

Table 1 below provides a summary of NIOSH's assigned dose estimates that correspond to data contained in Appendix A. Using the dose estimate derived by NIOSH, the probability of causation (POC) was determined by the DOL to be 17.55% 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	1 – 19	0.888
▪ Missed Photon Dose	88 – 111	9.910
▪ Neutron Dosimeter Dose	NC*	—
▪ Missed Neutron Dose	NC*	—
▪ Occupational Medical:	134 – 157	1.705
▪ Onsite Ambient	112 – 124	2.393
Internal Dose (Hypothetical):		
▪ Tritium	66 –88	1.633
▪ All Other Radionuclides	20 –65	1.660
Total:		18.189

* 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 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 auditor 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 No. 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.

Table 2. Case Review Checklist

CASE PIID*	ASSIGNED DOSE: 18.189 rem	POC: 17.55%

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.

CASE PIID*	ASSIGNED DOSE: 18.189 rem	POC: 17.55%

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.

2.0 AUDIT OF EXTERNAL DOSES

As part of this audit, 100% of all DOE external doses were reviewed. These records include lifetime exposure reports that summarized exposure data by year and annual exposure data, which identified exposures for each cycle.

2.1 RECORDED PHOTON DOSE

NIOSH assigned dosimeter doses based on recorded values cited by DOE's historical lifetime dose form for the claimant. For example, this form reports a deep dose of 10 mrem for 1954 and a dose of 115 mrem for 1955. These annual doses were subject to a dosimeter correction factor of 1.119, in accordance with guidance provided in Section 5 of ORAUT-TKBS-0003. Thus, entries #1 and #2 of Appendix A show an adjusted dose of 11 and 129 mrem for the years PIID*. For the entire period of employment, the assigned dosimeter dose corresponds to 888 mrem (0.888 rem).

2.1.1 Reviewer's Comments

SC&A compared all photon dosimeter entries against DOE records and verified the deep dose adjustment factor of 1.119, as given in Table 5.4.1-1 of ORAUT-TKBS-0003. We conclude that these dose entries are correct.

It is noted, however, that all 19 dose entries in Appendix A are defined as point estimates (or constants). When mean dose estimates are used, OCAS-IG-001 or ORAUT-PROC-0006 requires doses to include an estimate of uncertainty. Procedural guidance for defining film or TLD badge uncertainty is provided in Section 2.1.1.3 of OCAS-IG-001 and in Attachment D-2 of ORAUT-PROC-0006.

The failure to include uncertainty for external dosimeter data does not comply with applicable procedures, is scientifically incorrect, and claimant unfavorable.

2.2 MISSED PHOTON DOSES

In compliance with OCAS-IG-001 and ORAUT-TKBS-0003, a zero dosimeter reading must be regarded as a potential missed dose. A best dose estimate for zero dosimeter readings is defined by LOD/2 times the number of zero readings. NIOSH assumed a maximum number of 672 potential zero reading for the PIID*employment period. In order to derive annual missed photon doses, LOD/2 values were further multiplied by the dosimeter correction factor of 1.119 (as provided in Table 5.4.1-1 of ORAUT-TKBS-0003), and entered as a median value with a lognormal distribution having a geometric standard deviation (GSD) of 1.52. Data entries #89 through #111 correspond to missed photon doses for the 23 years of employment/monitoring period.

2.2.1 Reviewer's Comments

The overall methodology used to account for missed photon doses does comply with applicable procedures and is clearly claimant favorable in light of the 672 total number of zero readings that NIOSH assumed. The DR report states that ". . . This number [i.e., 672] was maximized to ensure that all possible instances of a zero badge reading were accounted for in this dose reconstruction.

SC&A reviewed DOE's 86 pages of dosimeter records, which contained assigned deep doses to the claimant for any given cycle. Our review of DOE records shows that there are a substantial number of dosimeter cycles that are missing.

It appears that NIOSH did not base their number of missed zero doses on DOE records but made use of generic SRS data contained in Table 5.5.1-1 of ORAUT-TKBS-0003. Table 5.5.1-1 provides specific time periods and their corresponding exchange frequencies as well as LOD values. For example, PIID*, the two-element film dosimeter was assessed weekly and had a LOD value of 40 mrem.

When SC&A applied data contained in Table 5.5.1-1 to the PIID*employment period, a maximum number of zero readings of 533 was determined. (This value is considered maximal because we did not subtract those cycles during which the claimant had a recorded dose in excess of LOD/2.)

NIOSH's assumption of 672 missed photon doses must, therefore, be viewed as very claimant favorable.

2.3 OCCUPATIONAL MEDICAL EXPOSURE

DOE records provide no documentation pertaining to occupational medical exposure. In the absence of records, NIOSH assumed an annual medical x-ray in behalf of the claimant. Dose entries #135 through #157 define annual point estimates for organ doses to the pancreas. For the years PIID*, the annual organ dose of 85 mrem was assigned; and for the years PIID*, the annual organ dose of 35 mrem was assigned. From these data, the total occupational medical dose of 1.705 rem is determined.

2.3.1 Reviewer's Comments

SC&A assumes that the above-cited annual organ doses to the pancreas of 85 mrem per year and 35 mrem per year correspond to Group 2 default values given in Table 2.5.1-1 of ORAUT-TKBS-0003. For Group 2 organs, the values 85 mrem and 35 mrem per x-ray are, in fact, correct.

SC&A considers the assigned occupational medical dose of 1.705 rem as procedurally compliant and claimant favorable.

2.4 ONSITE AMBIENT DOSE

Although the energy employee was monitored throughout the period of employment, there exists the possibility that occupational exposure from elevated ambient levels of external radiation (EALER) may have erroneously been subtracted by means of EALER-exposed control badges. For this reason, NIOSH elected to include onsite ambient dose as part of dose reconstruction.

Maximum SRS onsite ambient annual doses were selected as default values and adjusted to a 50-hour workweek. Table 3.4-1 of ORAUT-TKBS-0003 identifies corresponding doses for the years of employment. Entries #112 to #134 of Appendix A correspond to default values cited in Table 3.4-1. Since these values are considered bounding, they are entered as constant or point values. A total onsite ambient dose of 2.393 rem was assigned.

2.4.1 Reviewer's Comments

The assigned onsite dose complies with the applicable procedure and is scientifically valid and claimant favorable.

3.0 AUDIT OF INTERNAL DOSES

NIOSH acknowledged data in the DOE record, which included bioassay data. Based on the results, which showed either marginal or zero levels of tritium and a single positive urine test for plutonium, NIOSH concluded that the dose to the pancreas would be significantly larger if a hypothetical intake was assigned to internal exposure.

Based on procedure guidance contained in OCAS-IG-002 and ORAUT-TKBS-0003, missed internal doses were assigned for tritium and radionuclides other than tritium, using a hypothetical intake.

3.1 TRITIUM DOSE (HYPOTHETICAL)

Annual doses for hypothetical tritium intakes are given as entries #66 through #88 in Appendix A. For each year, the value of 71 mrem is cited as a point value, which yields a total dose of 1.633 rem.

3.2 INTERNAL DOSE FROM OTHER RADIONUCLIDES (HYPOTHETICAL)

For all radionuclides other than tritium, NIOSH assumed a single acute hypothetical intake on the first day of employment, as provided in Section 4.5.3 of ORAUT-TKBS-0003. Table 4.5.1-1 contains annual doses starting with year one of employment and extending to the year of cancer diagnosis.

Entries #20 through #42 of Appendix A define alpha radiation doses, and entries #43 through #65 represent electron doses. Since these doses are considered maximum values, they are entered as constant or point estimates. For all radionuclides other than tritium, NIOSH estimated a total internal dose of 1.66 rem.

3.2.1 Reviewer's Comments

SC&A reviewed available DOE internal dosimetry records, which included whole-body counts (WBC), what appear to be chest counts, and plutonium (Pu) urinanalysis. The two urinalyses for Pu are dated PIID*, with results showing levels of less than 0.05 dpm/1.5 liter and 0.1 dpm/1.5 liter, respectively.

DOE records for three "chest counts" contain a matrix of handwritten numbers. However, there is no explanation as to what the numbers mean or how to interpret the data.

Lastly, DOE records contain ten data sets for whole-body counts. Here too, the data are presented only as net counts per minute for individual radionuclides (see Exhibit 1). Without knowing the instrumentation used for whole-body counting and the corresponding calibration factors for converting observed cpm to activity levels in the body, these data are of limited value. (Note: A crude estimate may be based on the K-40 values, which could be used to scale other radionuclides.)

Exhibit 1: Whole-Body Count Data

Deletions made to the following table – please see hard copy labeled "#9— Savannah River Site"

Due to the inability to properly interpret DOE bioassay data, SC&A concurs with NIOSH's decision to assign hypothetical doses for both tritium and other radionuclides. SC&A also concurs with the assumption that these hypothetical intakes are likely to exceed the real doses that may correspond to bioassay data submitted by DOE. Nevertheless, SC&A has the following issues of concern pertaining to internal doses assigned to the claimant.

Issue 1: Assignment of Tritium Dose

For the years PIID* through PIID*, NIOSH assigned a yearly dose of 71 mrem for tritium. Table 4.5.1-1 of ORAUT-TKBS-0003 as well as Table 13 of ORAUT-OTIB-0001, however, cite the dose of 355 mrem per year for the time period in question. This value is five times higher than the value assigned by NIOSH. Thus, the correct tritium dose for all years should have been 8.165 rem, as opposed to the dose of 1.633 rem assigned by NIOSH. It should further be noted that the five other SRS cases that are among the first 20 cases reviewed herein all assigned 355 mrem/yr for employment periods prior to PIID*.

The lower assigned dose for tritium is, therefore, not in compliance with the applicable procedure and is scientifically invalid and claimant unfavorable.

Issue 2: The Uncertainty of Chemical Form for Tritium

Default dose values for tritium (as given in Table 4.5.3-1 of ORAUT-TKBS-0003) are based on the assumption that tritium exists as water, which has an effective half-life of about 10 days. Organified tritium is likely to have a 2.3-fold longer effective half-life and, therefore, a proportionately higher dose per unit intake. A claimant-favorable assumption may assume that all or at least some fraction of tritium exists in organic form.

Issue 3: Use of the ICRP 30 Biokinetic Model for Deriving Internal Hypothetical Dose

This 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 by 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 above-cited issues #2 and #3 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).

4.0 CATI REPORT AND RADIOLOGICAL INCIDENTS

Upon review of DOE records and the CATI report, NIOSH concluded that there was no indication of radiological incidents involving the claimant that would affect the dose reconstruction.

4.1 REVIEWER'S COMMENTS

Upon review of available records, SC&A concurs.

5.0 SUMMARY CONCLUSIONS

SC&A's audit of the claimant found two significant errors. These errors principally reflect the failure to follow procedural guidance and are:

- The failure to assign an uncertainty value to dosimeter doses
- Assignment of the wrong (and much lower) annual tritium dose value.

Lastly, SC&A has raised two generic issues of concern for tritium and radionuclides other than tritium. At issue is the assumption that tritium exists 100% as tritiated water and the use of ICRP 30 biokinetic models for deriving internal doses for radionuclides other than tritium.

A generic concern that is not confined to this DR, but characterizes all 20 claims that SC&A has reviewed to date, is the brevity of the DR reports. In its current form, the NIOSH dose reconstruction report at best provides only a brief summary explanation for assigned doses. In some instances, the explanation is confined to a mere 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 auditors to engage in time-consuming speculations regarding the choice of procedures, methodology, and parameters selected by the dose reconstructor.

REFERENCES

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APPENDIX A: IREP INPUT

Deletions made to the following table – please see hard copy labeled "#9— Savannah River Site"

APPENDIX A (continued)

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