REPORT TO THE ADVISORY BOARD ON RADIATION AND WORKER HEALTH

National Institute of Occupational Safety and Health

Audit of Case PIID* from the Oak Ridge National Laboratory – X-10 Site

Contract No. 200-2004-03805
Task Order No. 4

SCA-TR-TASK4-CNPIID*

Prepared by

S. Cohen & Associates
6858 Old Dominion Road, Suite 301
McLean, Virginia 22101

February 2005

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
AUDIT OF CASE PIID* FROM THE OAK RIDGE NATIONAL LABORATORY – X-10 SITE	Page 2 of 18
Task Manager: _____ Date: 02/04/05 U. Hans Behling, PhD, MPH	Supersedes: Draft Rev. 0
Project Manager: _____ Date: 02/04/05 John Mauro, PhD, CHP	

TABLE OF CONTENTS

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). The dose reconstruction was done for an energy employee who worked at the Oak Ridge National Laboratory (ORNL), known historically as the X-10 site, for approximately PIID*, from PIID*, through PIID* This period included the time when X-10 conducted research and development as well as production activities in support of the Department of Energy (DOE) and its predecessor agencies. Activities that involve ionizing radiation and radioactive materials included operating nuclear reactors, processing special nuclear materials, radioisotope production and separation, and processing radioactive wastes.

As a PIID*, the covered employee accessed many onsite areas and spent an indeterminate amount of time in buildings and vehicles that were contaminated.[1] The employee was monitored for external exposure, but the frequency of dosimeter exchange is uncertain and all dosimeters read zero (i.e., less than detectable). The employee was not a part of any formal internal dosimetry program, and there are no bioassay data available. According to the CATI,[2] the employee had at least one medical x-ray as part of employment at X-10. On PIID*, the energy employee was diagnosed with cancer of the colon and subsequently died on PIID*.

NIOSH determined external and medical x-ray doses to the colon using the protocols for **missed doses** described in ORAUT-OTIB-0010 and ORAU-OTIB-0006, respectively. In accordance with ORAUT-OTIB-0007, onsite ambient doses were not considered. Internal doses were determined using a hypothetical protocol described in ORAUT-OTIB-0002, which assumes an intake of a mixture of 28 radionuclides and is intended to maximize any potential internal dose that may have occurred but was not recorded. Doses from radiological incidents were not included.

The external and internal doses to the organ of interest were determined by NIOSH to be 23.106 and 13.912 rem, respectively. The probability of causation (POC) was determined by the Department of Labor to be 37.16% at the 99% confidence interval, and on this basis, the claim was denied. Table 1 summarizes the results of NIOSH's reconstruction of the doses to the energy employee's colon for the purpose of deriving the POC using the IREP protocol.

In some cases, the dose estimates were based on overly conservative assumptions. It should be noted that such values are **intentional overestimates** of the energy worker's dose and differ from assumptions defined as **claimant favorable**. **Claimant favorable** refers to information that is truly lacking or unknowable, and where the employee is given the benefit of the doubt. An **intentional overestimate** applies when applicable data exists, but the dose constructors deliberately assume bounding conditions for reasons of process efficiency.

Table 1. Summary of Internal/External Exposures as Estimated by NIOSH

[1] NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Act (EEOICPA), NIOSH id: PIID*

[2] Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Dose Reconstruction Telephone Interview, conducted 9/3/2002

	Appendix A Exposure Entry No.	Dose (rem)
External Dose:		
▪ Photon Dosimeter Dose	NA*	0
▪ Photon Missed Dose	85 – 105	21.363
▪ Neutron Dosimeter Dose	NC**	—
▪ Neutron Missed Dose	NC**	—
▪ Occupational Medical	106 – 126	1.743
▪ Onsite Ambient	NC**	—
Internal Dose:	1 – 84	13.912
Total		26.337

*NA = Not applicable
**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 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
- 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.

It is worth noting that the Technical Basis Document(s) for the Oak Ridge National Laboratory have not been subjected to a detailed SC&A technical review, as have the equivalent documents from several other sites. Review of these documents could uncover other problems or issues with the potential to affect this claim. At such time that these site documents are reviewed, it is recommended that dose reconstructions performed in behalf of the ORNL site be revisited to assess any changes caused by new information.

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.

Table 2. Case Review Checklist

CASE PIID*	ASSIGNED DOSE: 26.337 rem	POC: 37.16%

No.	Description of Technical Elements of Review	Audit Response			If No, Potential Significance		
		YES	N/A	NO	LOW[3]	MEDIUM[4]	HIGH[5]
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?		✓				
D.3	Is the recorded/assigned dose properly converted to the organ dose of interest for:						
D.3.1	- Recorded Shallow/Electron Dose?		✓				

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

CASE PIID*	ASSIGNED DOSE: 26.337 rem	POC: 37.16%

No.	Description of Technical Elements of Review	Audit Response			If No, Potential Significance		
		YES	N/A	NO	LOW[3]	MEDIUM[4]	HIGH[5]
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				7	✓		

[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

For Case PIID*, NIOSH performed a dose reconstruction that produced a total of 126 dose entries for determining the probability of causation (POC). Appendix A of this report reproduces the IREP dose input used by NIOSH. Throughout this report, reference will be made to select portions of Appendix A; for example, exposure entries #85 through #105 correspond to estimated external doses, which are discussed in more detail in Section 3.1 below.

2.1 PHOTON DOSES

This worker was monitored for external exposure, where all of the dosimeter readings were zero or less than detectable, but the actual dosimeter exchange frequency was not assessed. To provide an intentional overestimate of the external missed photon dose, an exchange of 12 badges per year was assumed for PIID*, giving a total of 252. Supposedly, missed photon doses were derived as described in ORAUT-OTIB-0010.

For **misses dose**, the dose reconstructor provided the following explanation in the Dose Reconstruction Report:

> *Based on information provided in the Technical Information Bulletin: Overestimating External Doses Measured with Film Badge Dosimeters,[8] the total number of dosimeter cycles assigned was 252 for photons. This number was based on a claimant-favorable assumption of 12 badge exchanges each full or partial year of employment and was maximized to ensure that all possible instances of a zero badge reading were accounted for in this dose reconstruction. Based on information provided in the Technical Information Bulletin: Overestimating External Doses Measured with Film Badge Dosimeters,[8] this results in a maximum potential missed dose . . . of 21.363 rem from photons. For the purpose of calculating probability of causation, this value was divided by 2 in accordance with the External Dose Reconstruction Implementation Guideline.[3]*

In behalf of **uncertainty**, the dose reconstructor provided the following:

> ***Uncertainty***
> *Except for missed dose, point estimates (constant values) were used for organ dose input into the NIOSH-Interactive RadioEpidemiological Program (NIOSH-IREP). Missed doses were divided by 2 and a lognormal distribution was applied in accordance with the NIOSH External Dose Reconstruction Implementation Guideline.[3]*

SC&A's audit of Case PIID* identified a total of four misinterpretations of ORAUT=OTIB-0010, as summarized below:

1. In addition to using the LOD of 40 mrem x 12 monthly cycles/year and the organ DCF of 1.06, the dose reconstructor erroneously also applied the "Standard Correction Factor" of 2.

2. The dose reconstructor corrected the first error by subsequently dividing the above-derived value by 2 ". . . in accordance with NIOSH External Dose Reconstruction Implementation Guideline."

3. For the IREP input, the dose reconstructor erroneously defined values derived in step #2 as values defined by a lognormal distribution and assigned a GSD of 1.52 for parameter 2 in the IREP input code. (Note: Since LOD defined the 95th percentile value of a missed dose, there is **no** need to include uncertainty.)

4. In behalf of Case PIID*, the dose reconstructor applied the ORAUT-OTIB-0010 methodology for a period of 21 years, from PIID*. ORAUT-OTIB-0010, however, states that this procedure only applies to the "late film badge era" that is defined by the four-element film badge. For Case PIID*, who was employed at ORNL, the four-element film badge was replace by a site-specific TLD in 1976. Thus, the procedure ORAUT-OTIB-0010 can only be applied for the years PIID*; and from PIID*, the dose reconstructor should have employed ORAUT-OTIB-0008: *Technical Information Bulletin for a Standard Complex-Wide Conversion/Correction Factor for Overestimating External Doses Measured with Thermoluminescent Dosimeters*.

The fact that these errors were consistently claimant favorable is fortunate, but does not negate SC&A's concern about the misinterpretation of procedures used in dose reconstruction.

2.2 NEUTRON DOSES

The neutron component of external doses was **not** considered for this employee. Based on the information in the X-10 Technical Background Document ORAUT-TKBS-0012-2, there does not seem to be any compelling reason to include a neutron component for this worker. ORAUT-TKBS-0012-6, page 13, states "Neutron sensitive dosimeters were assigned only to individuals whose work involved potential neutron exposure." SC&A finds no issues with the neutron exposure from external dose.

2.3 OCCUPATIONAL MEDICAL EXPOSURES

The exact number of medical x-rays for this worker is unknown based on CATI information and the absence of applicable DOE records. For claimant favorability, an annual chest x-ray was assumed for the PIID*. For each x-ray exam, NIOSH assigned a dose of 82 mrem as an organ dose to the colon, which was further multiplied by 1.3, as given in the following statement in the DR Report:

> *This calculation [i.e., a total x-ray dose of 1.743 rem] is based on an **assumed** dose of 0.083 rem per procedure, which represents the highest x-ray dose recorded in Table 4.0-1 (post 1969) for any organ other than skin, multiplied by **1.3** to account for **uncertainty**.* [Emphasis added.]

From Table 4.0-1 of ORAUT-OTIB-0006, SC&A determined that the assigned dose of 83 mrem represents the organ dose to the **breast** at 63.8 mrem times 1.3 to account for uncertainty. While this value is clearly high and benefits the claimant, use of the breast as the surrogate organ for the colon is scientifically difficult to justify in behalf of the definition of "claimant favorable," which is to be used in instances of "unknown" values. Table 4.0-1, in fact, identifies a dose to the **colon** of 1E-04 rem (or 1 mrem), which is nearly a factor of 100-fold lower.

While SC&A fully endorses the use of claimant-favorable values in instances of unknown(s), the deliberate assignment of an excessively higher value may lead to problems if such excess values are **not** assigned **consistently** among claimants.

3.0 AUDIT OF INTERNAL DOSES

This worker was not a part of any formal bioassay or other internal dosimetry program as far as the available information indicates. The protocol outlined in ORAU-0TIB-0002 assumes an intake of a mixture of 28 radionuclides from reactor and non-reactor sites (Table 3.1.1-2) and specifically excludes Tritium (H-3). This is an overestimate, because it is improbable that this worker could have had an intake of these radionuclides as described in ORAUT-OTIB-0002, and the output derived by NIOSH was verified by independent calculation as described below. The value derived from this calculation is not supposed to resemble a realistic determination of the internal dose to this worker; by design it is an intentional overestimate. We find no issues with the calculation of the internal dose.

4.0 CATI REPORT AND RADIOLOGICAL INDICENTS

The CATI report makes no mention of radiological incidents or to any data that could impact any assigned doses that reflect measured or assumed doses.

5.0 SUMMARY CONCLUSIONS

Regarding the dose reconstruction for this worker, SC&A finds the following:

- In general, the dose reconstruction process for this energy worker was based on adequate information.

- For missed photon dose, the dose reconstructor misuse/misinterpreted the cited procedures at multiple steps. The combination of errors in behalf of missed doses for this case is nearly identical to those of two other cases (Case # PIID* and Case # PIID*.

- The exclusion of a neutron component for the external dose calculation is acceptable.

- Select dose calculations are intentional overestimates, which exceed the definition of claimant favorable and result in doses that are clearly in excess of the actual dose.

REFERENCES

OCAS-IG-001. 2002. "External Dose Reconstruction Implementation Guideline," Rev 1. National Institute of Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

OCAS-IG-002. 2002. "Internal Dose Reconstruction Implementation Guideline," Rev 0. National Institute of Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

ORAUT-OTIB-0002. 2004. "Technical Information Bulletin – Maximum Internal Dose Estimates for certain DOE Complex Claims," Revision No. 01. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-OTIB-0004. 2003. "Technical Information Bulletin: Technical Basis for Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities," Revision No. 02. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-OTIB-0006. 2003. "Technical Information Bulletin: Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures," Revision No. 02. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-OTIB-0007. 2003 "Technical Information Bulletin: Occupational Dose from Elevated Levels of External Radiation," Revision No. 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-OTIB-0008. 2003. "Technical Information Bulletin for a Standard Complex-Wide Conversion/Correction Factor for Overestimating External Doses Measured with Thermoluminescent Dosimeter," Revision No. 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-OTIB-0010. 2004. "Technical Information Bulletin: A Standard Complex-Wide Correction Factors for Overestimating External Doses Measured with Film Badge Dosimeters," Revision No. 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-PROC-0002. 2003. "Use of Integrated Modules for Bioassay Analysis (IMBA)," Revision No. 01. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-PROC-0003. 2003. "Internal Dose Reconstruction," Revision No. 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-PROC-0006. 2003. "External Dose Reconstruction," Revision No. 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

REFERENCES (Continued)

ORAUT-TKBS-0012-2. 2003. "Technical Basis Document for the Oak Ridge National Laboratory - Site Description" ORAUT-TKBS-0012-2, Revision 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-TKBS-0012-3. 2004. "Technical Basis Document for the Oak Ridge National Laboratory – Occupational Medical Dose," Revision 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-TKBS-0012-4. 2004. "Technical Basis Document for the Oak Ridge National Laboratory – Occupational Environmental Dose," Revision 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-TKBS-0012-5. 2004. "Technical Basis Document for the Oak Ridge National Laboratory – Occupational Internal Dose," Revision 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

ORAUT-TKBS-0012-6. 2004. "Technical Basis Document for the Oak Ridge National Laboratory – Occupational External Dose," Revision 00. Oak Ridge Associated Universities, Cincinnati, Ohio.

APPENDIX A: IREP INPUT

Deletions made to the following table -- please see hard copy labeled "#19 - Oak Ridge Natl. Lab."

APPENDIX A (continued)

Deletions made to the following table -- please see hard copy labeled "#19 - Oak Ridge Natl. Lab."