Draft

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

National Institute for Occupational Safety and Health

SC&A'S EVALUATION OF ORAUT-OTIB-0075, REVISION 01, "USE OF CLAIMANT DATASETS FOR COWORKER MODELING"

Contract No. 211-2014-58081
SCA-TR-2017-PR011, Revision 0

Prepared by

Ron Buchanan, PhD, CHP
Harry Chmelynski, PhD

SC&A, Inc.
2200 Wilson Boulevard, Suite 300
Arlington, Virginia, 22201

Saliant, Inc.
5579 Catholic Church Road
Jefferson, Maryland 21755

October 2017

SC&A, INC.: ***Technical Support for the Advisory Board on Radiation and Worker Health Review of NIOSH Dose Reconstruction Program***

DOCUMENT TITLE:	SC&A's Evaluation of ORAUT-OTIB-0075, Revision 01, "Use of Claimant Datasets for Coworker Modeling"
DOCUMENT NUMBER/ DESCRIPTION:	SCA-TR-2017-PR011
REVISION NO.:	0 (Draft)
SUPERSEDES:	N/A
EFFECTIVE DATE:	October 9, 2017
TASK MANAGER:	Kathy Behling [signature on file]
PROJECT MANAGER:	John Stiver, MS, CHP [signature on file]
DOCUMENT REVIEWER(S):	Kathy Behling [signature on file] John Stiver, MS, CHP [signature on file]

Record of Revisions

Revision Number	Effective Date	Description of Revision
0 (Draft)	10/9/2017	Initial issue

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

ABRWH	Advisory Board on Radiation and Worker Health
b	slope
d	day
dpm	disintegration per minute
e	natural logarithm (value of 2.72)
GM	geometric mean
GSD	geometric standard deviation
m	intercept
m	number of iterations
Mound	Mound Laboratory
NIOSH	National Institute for Occupational Safety and Health
NOCTS	NIOSH OCAS Claimant Tracking System
OCAS	Office of Compensation Analysis and Support
ORAUT	Oak Ridge Associated Universities Team
pCi	picocurie
R^2	coefficient of determination for regression analysis
SRS	Savannah River Site
Y-12	National Security Complex
Z-score	probability distribution

1.0 INTRODUCTION AND BACKGROUND

In June 2017, the Advisory Board on Radiation and Worker Health tasked SC&A with a technical review of ORAUT-OTIB-0075, *Use of Claimant Datasets for Coworker Modeling*, Revision 01, issued June 17, 2016 (NIOSH 2016, referred to as "OTIB-0075").

The National Institute for Occupational Safety and Health (NIOSH) had issued ORAUT-OTIB-0075, Revision 00, in 2009 (NIOSH 2009). SC&A had evaluated ORAUT-OTIB-0075, Revision 00, in 2010 (SC&A 2010). This current report consists of SC&A's evaluation of OTIB-0075, Revision 01.

2.0 OVERVIEW OF ORAUT-OTIB-0075

OTIB-0075 is a detailed document. For evaluation purposes, it is advantageous to provide a brief outline as follows.

- **Purpose**: In OTIB-0075, NIOSH states:

  > *the purpose of this document is to present the results of a study to determine if claimant datasets can be treated as random samples from the complete datasets from which they were drawn for the purpose of developing coworker models. The study consisted of taking sites where well-defined complete datasets are available and comparing these datasets with the claimant datasets.*

- **The claimant and complete databases addressed in OTIB-0075 were:**
  - National Security Complex (Y-12) uranium urine bioassay, 1950–1988 (Sections 3 through 5 and Attachments A, B, and C).
  - Mound Laboratory (Mound) plutonium urine bioassay, 1960–1990 (Section 6 and Attachments D, E, and F).
  - Savannah River Site (SRS) tritium dose, 1991–2000 (Sections 6 and 7 and Attachments G, H, and I).

- **Terms:**
  - Complete dataset – Refers to all of the monitoring records in the database for the site relevant to the analysis. Note that the term "complete" does not necessarily indicate that all the workers were monitored at the site.
  - Claimant dataset – Refers to the claimants' monitoring records in the database obtained from the NIOSH OCAS Claimant Tracking System (NOCTS) relevant to the analysis.

- **Outline of procedure used to determine annual 50th and 84th percentile values for each dataset:**

  – NIOSH constructed a table showing number of workers monitored in the complete dataset, number of workers monitored in the claimant dataset, ratio of the number of claimants to the number of workers, number of samples from the complete dataset, number of samples from the claimant dataset, and the ratio of the number of samples from the claimants to the number of samples from the complete dataset. For example, see Table 3-1, page 10, of OTIB-0075 for the Y-12 data.

  – The methodology in ORAUT-RPRT-0053, *Analysis of Stratified Coworker Datasets, Revision 02* (NIOSH 2014), was used to create a lognormal probability plot—uranium in urine (dpm/day) versus Z-Score probability—on an annual basis for each dataset. For example, see Figure 4-1, page 11, of OTIB-0075 for the Y-12 1952 complete dataset. Attachments A, B, D, E, G, and H contain the annual lognormal probability plots for the claimant and complete datasets for the three sites analyzed in OTIB-0075.

  – The slope value (b) and intercept value (m) were obtained from the lognormal probability plot. For example, for the lognormal probability plot in Figure 4-1 of OTIB-0075, the slope was 3.216 and the intercept was 0.6092.

  – The 50th percentile (geometric mean [GM]) was calculated using Equation 4-1, page 10, of OTIB-0075:

  $$GM = e^{b}$$

  For the lognormal probability plot in Figure 4-1 of OTIB-0075, the value of $GM = e^{3.216} = 24.93$ disintegrations per minute per day (dpm/d).

  – The geometric standard deviation (GSD) was calculated using Equation 4-2, page 11, of OTIB-0075:

  $$GSD = e^{m}$$

  For the lognormal probability plot in Figure 4-1 of OTIB-0075 the value of $GSD = e^{0.6092} = 1.839$ dpm/d.

  – The 84th percentile is the GM value multiplied by the GSD. For the lognormal probability plot in Figure 4-1 of OTIB-0075, the 84th percentile = 24.93 dpm/d × 1.839 = 45.85 dpm/d.

  – A table was constructed showing the slope and intercept annual values from the complete dataset, the slope and intercept annual values from the claimant dataset, the 50th and 84th percentile values for the complete dataset, and the 50th and 84th percentile values for the claimant dataset. For example, see Table 4-1, page 13, of OTIB-0075 for the Y-12 data.

- **Random Samples:** To ensure that the claimant dataset is useful for estimating the slopes and intercepts of the complete dataset, it must be shown that the claimant dataset can be treated as if it were a random sample. Section 5 of OTIB-0075 provides the process of selecting and analyzing random samples, and then comparing them to the results from the claimant and complete datasets. NIOSH used the following process:

  – A sample of *k* number of workers was randomly drawn from the complete dataset of *n* workers, without replacement.

  – A lognormal model was fitted to the bioassay results for the *k* workers for each year.

  – These two steps were repeated m number of times (i.e., m number of iterations) for each year.

  – The values of the intercept versus the slope were plotted for each sample for each year (total of m points plotted on each annual plot).

  – A 95% joint confidence ellipse for m number of slope and intercept values was calculated for each year and plotted on the same annual plot as the random sample results.

  – The intercept-versus-slope value from the claimant dataset was plotted on the same annual plot as the random sample results.

  – The intercept-versus-slope values from the complete set were plotted on the same annual plot as the random sample results.

  An example of a completed plot is illustrated for the Y-12 1952 data in Figure 5-1, page 17, of OTIB-0075. Attachments C, F, and I provide the annual plots containing the results for the random samples, claimant dataset, and complete dataset for the three sites analyzed in OTIB-0075.

- **NIOSH's Conclusions:**

  NIOSH presents its conclusions in Section 8.0, page 28, of OTIB-0075, as summarized below.

  – At the three sites analyzed, a total of 4 years out of 80 years (5%) had coworker model parameters outside of the respective 95% confidence ellipses (Y-12 in 1950, Mound in 1982 and 1990, and SRS in 1991).

  – This result is in excellent agreement with what would be expected if the NOCTS datasets were random draws from the complete datasets (i.e., in the long run, we would expect to see 5% of the parameter estimates outside of the 95% confidence ellipse).

- This proof-of-principle technique was used to show that the claimant datasets from Y-12, Mound, and SRS can, in general, be used as if they were random samples for the purpose of estimating the slopes and intercepts of lognormal fits to the data.

- This exercise can be used as a technical justification for applying the assumption that the claimant datasets can be used as if they were random samples for the purpose of estimating the slopes and intercepts of lognormal fits to the data to other sites for which complete datasets are not available.

3.0 SC&A'S EVALUATION OF ORAUT-OTIB-0075

The following sections summarize SC&A's evaluation of the approach, statistical analysis, and documentation used by NIOSH in developing OTIB-0075.

3.1 EVALUATION OF NIOSH'S APPROACH IN ORAUT-OTIB-0075

SC&A did not identify any issues with the general approach used in OTIB-0075 to compare claimant datasets to complete datasets.

3.2 EVALUATION OF NIOSH'S STATISTICAL METHODS USED IN ORAUT-OTIB-0075

NIOSH issued the guide, *Draft Criteria for the Evaluation and Use of Coworker Datasets*, Revision 4, on February 26, 2015 (NIOSH 2015). In that guide, NIOSH recommended four areas that should be addressed when considering a dataset for use in constructing a coworker model:

1. Data Adequacy
2. Data Completeness
3. Review and Analysis of Monitoring Program Data
4. Evaluation of Stratification.

In OTIB-0075, NIOSH analyzed the use of claimant data in the NOCTS database in place of using the complete dataset for constructing a coworker model and concluded that claimant datasets can be used for a site where the complete datasets are not available. The main areas in the guide (NIOSH 2015) that are applicable to OTIB-0075 are (1) the evaluation of the adequacy of the available data for assigning dose to unmonitored workers and (2) stratification according to job/title, area, time, radionuclides, etc.

3.2.1 SC&A's Evaluation of Revision 00 to ORAUT-OTIB-0075

SC&A's evaluation (SC&A 2010) of ORAUT-OTIB-0075, Revision 00 (NIOSH 2009), identified 13 findings concerning the Y-12, Mound, and SRS databases, which are summarized in Appendix A to this report. From the 2010 evaluation, SC&A concluded the following (page 55):

(1) The uranium dataset for Y-12 conforms to the OTIB-0075 hypothesis of claimant data representativeness.

(2) The data for Mound indicate significant differences between claimant and all-worker plutonium bioassay data.

(3) The SRS tritium data cover a very narrow period from 1990 to 2001. These data show no significant differences at the annual level of aggregation, but the sample size is very small...

SC&A's summary of the SRS NOCTS data, which was compiled by NIOSH as the basis for a coworker model to demonstrate the ability to reconstruct dose with sufficient accuracy, is as follows (page 55):

(1) A conclusion that the claimant data from the 1990s for tritium are representative of the claimant population can, at best, be applied to that radionuclide and that period. This conclusion cannot be back-extrapolated to other periods. Even within this period, there are differences between construction workers disaggregated by craft and non-construction workers.

(2) There are considerable differences in exposure between job types and areas, even when data are aggregated by decade. This applies to all non-construction workers, as well as construction workers, when compared to others in the same group.

(3) The data indicate that construction workers in some areas and periods had greater exposure potential than all non-construction workers.

SC&A's overall conclusion for the SRS coworker model is that the NOCTS claimant dataset is inadequate for dose reconstruction with sufficient accuracy for SRS construction workers. A more complete compilation of the data and analyses by area, radionuclide, and job type are necessary to determine whether dose reconstruction with sufficient accuracy is feasible for SRS construction workers (i.e., stratification tests need to be performed).

3.2.2 SC&A's Evaluation of Revision 01 to ORAUT-OTIB-0075

NIOSH's OTIB-0075, Revision 01 (NIOSH 2016), is very much like the original document (NIOSH 2009), with the following changes:

1. The number of monitored workers in the Y-12 claimant dataset increased from 731 to 1,585, with the illustrative example based on 1952 data instead of 1953 data.

2. The number of workers in the Mound claimant dataset increased from 225 to 301.

3. The number of workers in the SRS claimant dataset increased from 451 to 920.

4. The data used in the analysis in Revision 01 were time-weighted-one-person-one-statistic.

The methodology used for the analyses and the number of workers in the complete dataset remained essentially the same as in Revision 00.

SC&A analyzed the 13 original SC&A findings and found that Findings 2 and 6 are the only ones that may be influenced by the additional claimant data in ORAUT-0075, Revision 01. All the other findings (except Findings 1 and 3, which SC&A concurred with) were concerned with stratification issues that were not addressed in either Revision 00 or Revision 01 to OTIB-0075; these findings remain open.

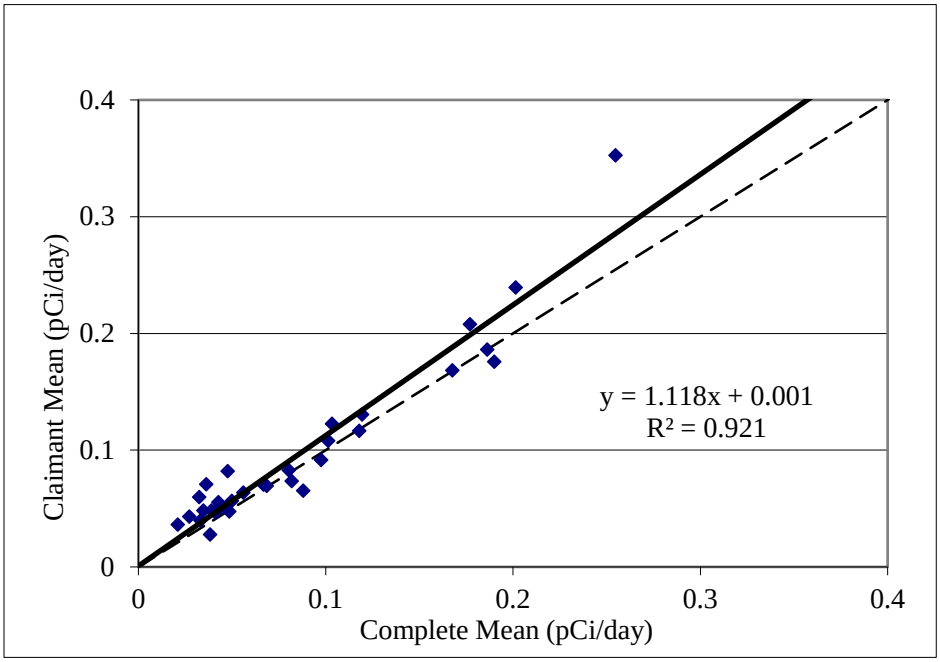
The following is SC&A's review of Finding 2 and Finding 6 in view of the additional claimant data in OTIB-0075, Revision 01.

Finding 2 (SC&A 2010)

> ***FINDING #2: At the Mound Laboratory, the complete (all-worker) and claimant datasets for plutonium in urine from 1960 to 1990 show significant differences at the annual level of aggregation. This finding raises questions concerning the conclusions reached in OTIB-0075 for plutonium at the Mound Laboratory.***

SC&A reran the analysis for the Mound 1960–1990 plutonium bioassay data using the new data from Tables 6-1 and 6-2 of OTIB-0075, Revision 01 (NIOSH 2016). SC&A found that the additional claimant data indicate that the claimant dataset was similar to the complete dataset, as indicated in Figure 1. Appendix B to this report provides additional figures and a summary table supporting this conclusion.

Figure 1. Comparison of Mean Plutonium Concentration in Urine at Mound (1960 to 1990)



Considering these additional data and analyses, SC&A finds that Finding 2 has been resolved and recommends closure.

Finding 6 (SC&A 2010)

> ***FINDING #6: At Y-12, only 37% of all claimants (3 out of 8) have data in the "complete" Y-12 uranium urine bioassay coworker database for 1950 to 1988. This subset of 731 claimants with uranium bioassay data had a total of approximately 70,000 bioassays.***

OTIB-0075, Revision 00, page 10, footnote 7, states that out of 1971 claimants, 731 claimants had bioassay records in the complete dataset, which is 37%. OTIB-0075, Revision 01, page 8, states that a total of 1,585 claimants submitted 119,044 uranium urine samples. However, there was no indication in the text or footnotes stating how many total claimants there were. Therefore, with the present information, SC&A could not determine the fraction of the number of claimants who were monitored (i.e., had bioassay records in the complete dataset) compared to the total number of claimants in the dataset. Therefore, Finding 6 remains open.

Original Concerns Not Addressed

The increase in the number of workers in the claimant datasets may have improved the statistics for the claimant dataset but, except for Finding 2, it did little to address SC&A's original concerns as expressed in our 2010 review (SC&A 2010) of OTIB-0075, Revision 00. These concerns are (1) the adequacy of the data in the claimant dataset in NOCTS to represent the unmonitored workers (who were subjected to a wide variety of exposure potentials) and (2) in Revision 01 to OTIB-0075, there was no indication in the text or footnotes of how many total claimants there were to compare to the 1,585 claimants who submitted uranium urine samples

(as related to the original Finding 6). The datasets may need to be tested to determine if stratification is needed concerning areas, time, radionuclide, construction versus non-construction workers, subcontractors versus prime, etc. Therefore, Findings 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 remain open.

3.3 EVALUATION OF DOCUMENTATION IN ORAUT-OTIB-0075

SC&A's review of OTIB-0075 identified the following observations about documentation items.

- **Observation 1:** Tables 4-1, 5-1, 6-2, and 7-2 should have the units of dpm/d in the column headings as appropriate.

- **Observation 2:** The data for 2001 were included in Table 7-1, Table 7-2, Figure 7-3, and Figure 7-4 in Revision 00 to OTIB-0075. However, the year 2001 was not included in these tables and figures in Revision 01 to OTIB-0075.

4.0 SUMMARY AND CONCLUSIONS

SC&A found the approach NIOSH used to be reasonable and without technical errors.

However, while SC&A generally found the statistical methods used by NIOSH to be acceptable, the increase in the number of workers in the claimant datasets only served to improve the statistics of the claimant datasets. Except for Finding 2, the increase did little to address SC&A's original concerns as expressed in our 2010 evaluation (SC&A 2010) of OTIB-0075, Revision 00, regarding the need to test for stratification of the data (i.e., Findings 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13), and Revision 01 to OTIB-0075 did not indicate how many total claimants there were to compare to the 1,585 claimant who submitted uranium urine samples (as related to Finding 6).

SC&A also found several minor documentation issues (i.e., Observations 1 and 2) that could affect the readability or application of the information presented.

5.0 REFERENCES

NIOSH 2009. *Use of Claimant Datasets for Coworker Modeling*, ORAUT-OTIB-0075, Revision 00, National Institute for Occupational Safety and Health, Cincinnati, Ohio. May 25, 2009.

NIOSH 2014. *Analysis of Stratified Coworker Datasets*, ORAUT-RPRT-0053, Revision 02, National Institute for Occupational Safety and Health, Cincinnati, Ohio. October 8, 2014.

NIOSH 2015. *Draft Criteria for the Evaluation and Use of Coworker Datasets*, Revision 4, National Institute for Occupational Safety and Health, Cincinnati, Ohio. February 26, 2015. [SRDB Ref. ID 154214]

NIOSH 2016. *Use of Claimant Datasets for Coworker Modeling*, ORAUT-OTIB-0075, Revision 01, National Institute for Occupational Safety and Health, Cincinnati, Ohio. June 17, 2016.

SC&A 2010. *Review of ORAUT-OTIB-0075: Use of Claimant Datasets for Coworker Modeling for Construction Workers at Savannah River Site*, SC&A, Inc., Vienna, Virginia, and Saliant, Inc., Jefferson, Maryland. January 13, 2010.

APPENDIX A: SUMMARY OF FINDINGS FROM SC&A'S 2010 EVALUATION OF ORAUT-OTIB-0075

FINDING 1: At the Y-12 Plant, the complete (all-worker) and claimant datasets for uranium in urine from 1950 to 1988 show no significant difference at the annual level of aggregation. This finding confirms the conclusions reached in OTIB-0075 for uranium at the Y-12 Plant.

FINDING 2: At the Mound Laboratory, the complete (all-worker) and claimant datasets for plutonium in urine from 1960 to 1990 show significant differences at the annual level of aggregation. This finding raises questions concerning the conclusions reached in OTIB-0075 for plutonium at the Mound Laboratory.

FINDING 3: At SRS, the complete (all-worker) and claimant datasets for annual tritium doses from 1991 to 2001 show no significant difference at the annual level of aggregation, but the sample size is very small and the regression results were dominated by a single year with high exposure, 1991. If this year is omitted, the complete and claimant datasets for annual tritium doses period from 1992 through 2001 again show no significant difference at the annual level of aggregation.

FINDING 4: At SRS, OTIB-0075 includes data only for tritium from 1991 to 2001 in comparing the claimant population to that of all workers. No analysis of uranium or plutonium exposures at SRS was possible, because the available hardcopy data have not been reduced to electronic form. Similarly, no analysis of uranium or fission product exposures regarding the validity of the central hypothesis of OTIB-0075 for SRS could be done for any period. No analysis of tritium exposures before 1991 was done for the same reason. Furthermore, the tritium conclusion cannot be back-extrapolated in time, since the production and work conditions relating to tritium were different in earlier periods.

FINDING 5: Data for the entire SRS were aggregated by year for the NIOSH analysis, with no detail by work area or by job type. The proposed NIOSH coworker model for SRS construction workers includes no analysis of these details.

FINDING 6: At Y-12, only 37% of all claimants (3 out of 8) have data in the "complete" Y-12 uranium urine bioassay coworker database for 1950 to 1988. This subset of 731 claimants with uranium bioassay data had a total of approximately 70,000 bioassays.

FINDING 7: Data for the entire Y-12 site were aggregated by year for the NIOSH analysis, with no detail by work area or by job type. The NIOSH approach includes no analysis of these details.

FINDING 8: Data for the entire Mound Laboratory were aggregated by year for the NIOSH analysis, with no detail by work area or by job type. The NIOSH approach includes no attention to these details.

FINDING 9: At SRS, the 84th percentile of exposures to tritium, plutonium, uranium, and other radionuclides for non-construction workers in specific work areas show considerable differences from the 84th percentile of exposures to non-construction workers site-wide. Similar results are observed for the corresponding ratio of the GSDs.

FINDING 10: At SRS, the 84th percentile of exposures to tritium, plutonium, and other radionuclides for construction workers in specific work areas show considerable differences from the 84th percentile of exposures to all construction workers site-wide. Similar results are observed for the corresponding ratio of the GSDs.

FINDING 11: At SRS, the 84th percentile of exposures to tritium and plutonium for construction workers in specific work areas show large differences from the 84th percentile of site-wide exposures to construction workers. Similar results are observed for the corresponding ratio of the GSDs. In many cases, there are insufficient data for construction workers to make a comparison for uranium, enriched uranium, and fission products.

FINDING 12: At SRS, the 84th percentile of exposures to tritium for construction workers in specific crafts shows large differences from the 84th percentile of exposures to all construction workers. Similar results are observed for the corresponding ratio of the GSDs.

FINDING 13: At SRS, the 84th percentile of exposures to tritium for construction workers in specific crafts shows large differences from the 84th percentile of site-wide exposures for non-construction workers. Similar results are observed for the corresponding ratio of the GSDs.

APPENDIX B: SC&A'S ANALYSES OF REVISED TABLES 6-1 AND 6-2 OF ORAUT-OTIB-0075, REVISION 01

Figure B1. Mean Plutonium Concentrations in Urine at Mound for Claimant and Complete Datasets

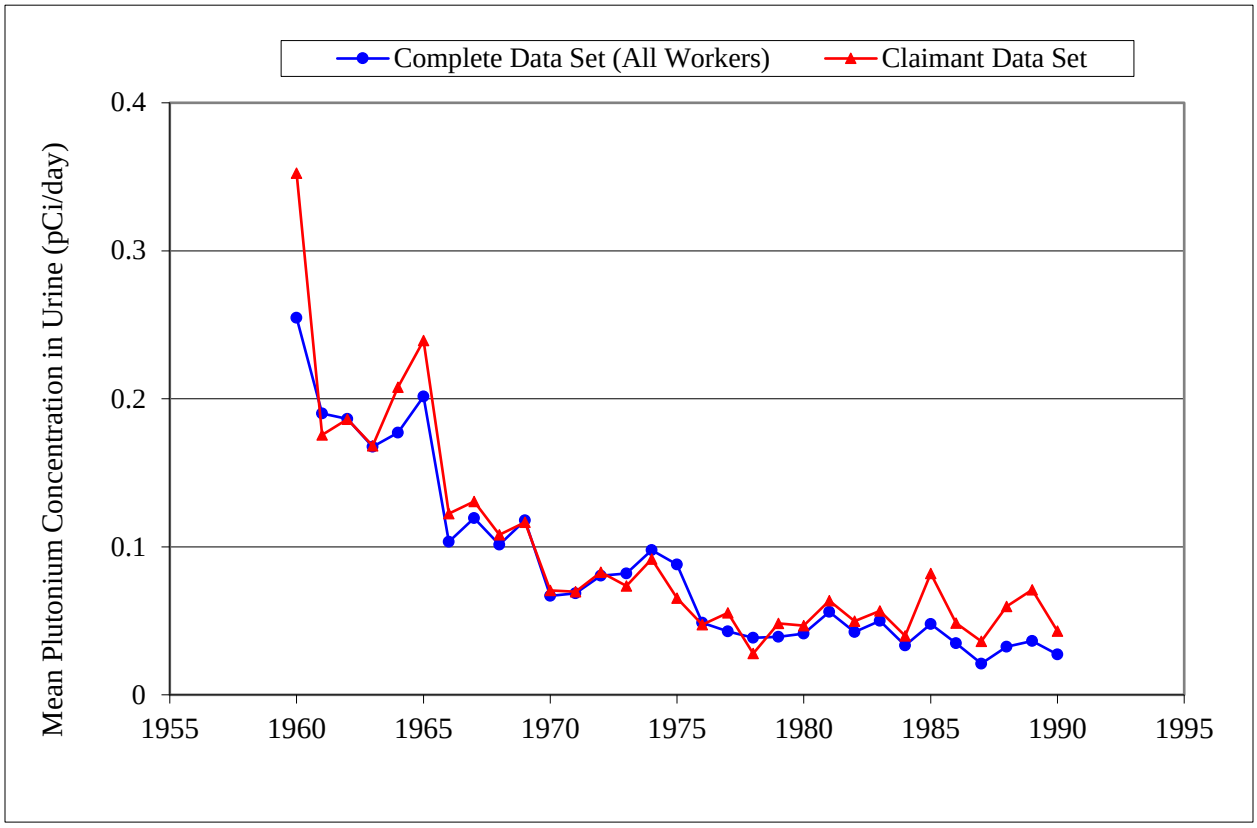


Figure B2. GSD of Plutonium Concentrations in Urine at Mound for Claimant and Complete Datasets

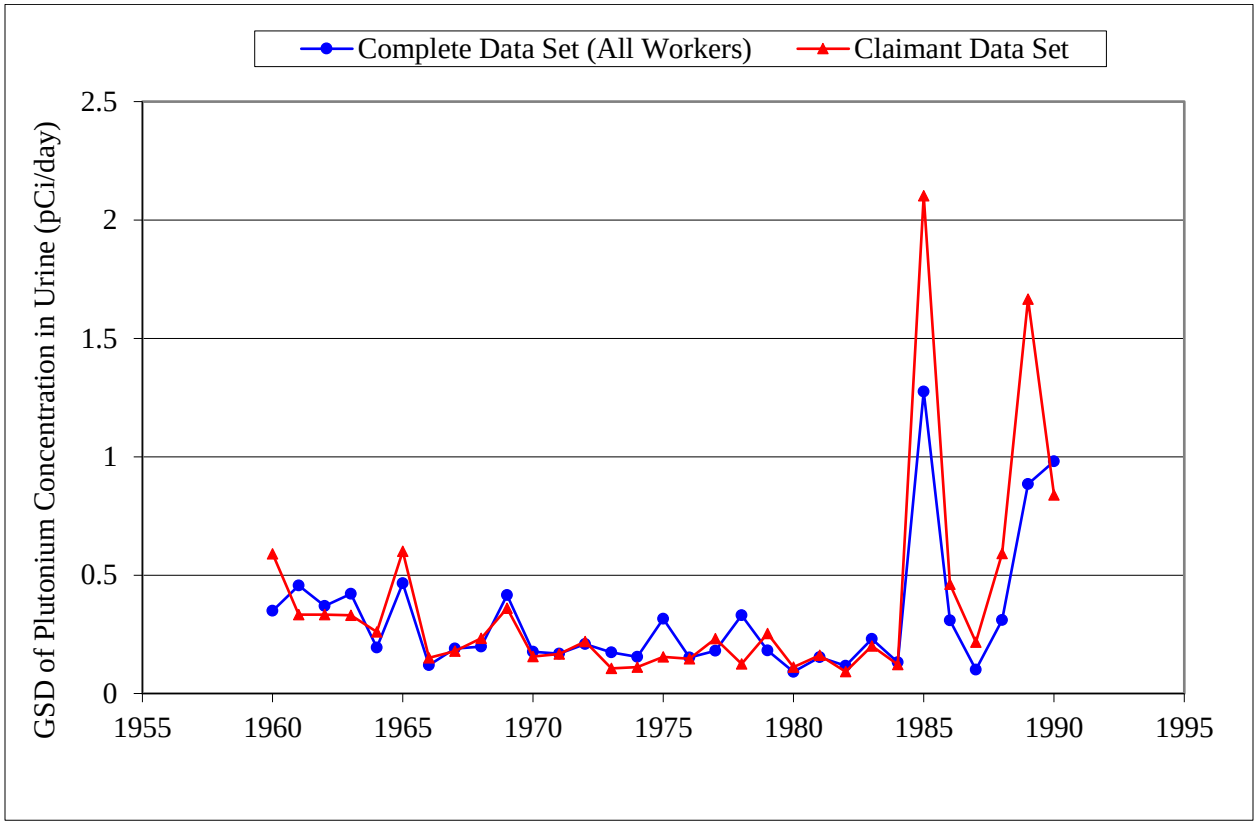


Figure B3. Comparison of GSD of Plutonium Concentration in Urine at Mound (1960 to 1990)

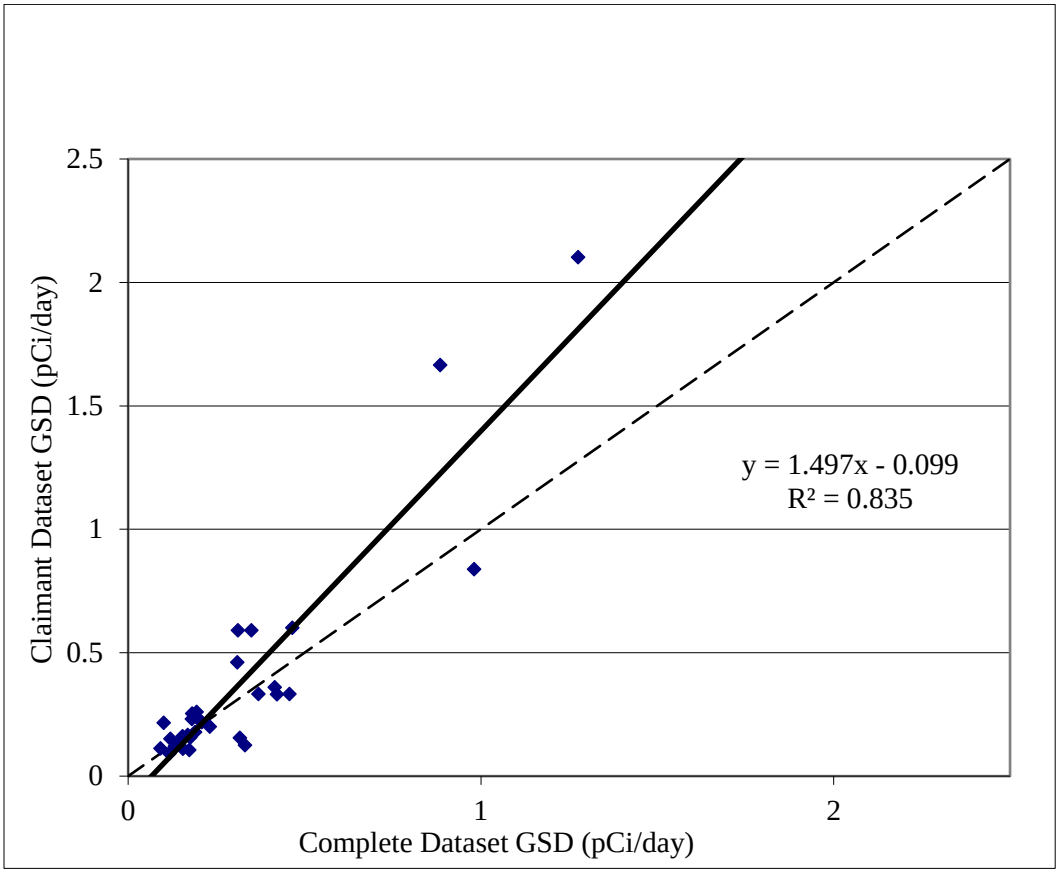


Table B1. Summary of Regression Comparisons of Complete (All-Worker) and 31 Claimant-Only Distributions for Plutonium at Mound (1960–1990)

Lognormal Distribution Parameter	Regression Coefficient	Estimated Coefficient	Standard Error of Estimate	Hypothesis Tested	t-statistic for Test	p-level Pr{|X|>|t|}	Hypothesis Test Result
Mean	Intercept	0.001	0.006	Intercept=0 ?	0.119	0.906	Accept
Mean	Slope	1.118	0.061	Slope=1?	1.947	0.061	Accept
Mean	R^2	0.921	NA	NA	NA	NA	NA
GSD	Intercept	-0.099	0.051	Intercept=0 ?	-1.941	0.062	Accept
GSD	Slope	1.497	0.124	Slope=1?	4.021	0.000	Reject*
GSD	R^2	0.835	NA	NA	NA	NA	NA

* Although the null hypothesis that the slope is equal to 1 is rejected at the 95% confidence level, the estimated slope is significantly greater than 1, which is claimant favorable.