Draft

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

National Institute for Occupational Safety and Health

Draft Review of ORAUT-OTIB-0078, Revision 03, *Internal Dosimetry Coworker Data for the Feed Materials Production Center*

Contract No. 211-2014-58081
SCA-TR-2016-SP004, Revision 0

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May 2016

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

DOCUMENT TITLE:	Draft Review of ORAUT-OTIB-0078, Revision 03, *Internal Dosimetry Coworker Data for the Feed Materials Production Center*
DOCUMENT NUMBER/ DESCRIPTION:	SCA-TR-2016-SP004
REVISION NO.:	0 (Draft, Initial Issue)
SUPERSEDES:	N/A
EFFECTIVE DATE:	May 12, 2016
TASK MANAGER:	John Stiver, MS, CHP [signature on file]
PROJECT MANAGER:	John Stiver
DOCUMENT REVIEWER(S):	John Stiver

Record of Revisions

Revision Number	Effective Date	Description of Revision
0 (Draft)	05/12/2016	Initial issue

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ABBREVIATIONS AND ACRONYMS

ABRWH	Advisory Board on Radiation Worker Health
CL	control limit
D	days (solubility)
GSD	geometric standard deviation
HIS	Health Physics Information System
MDA	minimum detectable activity
µg/d	micrograms per day
µg/l	micrograms per liter
NIOSH	National Institute for Occupational Safety and Health
ORAU	Oak Ridge Associated Universities
ORAUT	Oak Ridge Associated Universities Team
OTIB	ORAUT Technical Information Bulletin
SEC	Special Exposure Cohort
TWOPOS	time-weighted one person–one sample
W	weeks (solubility)
Y	years (solubility)

EXECUTIVE SUMMARY

The National Institute for Occupational Safety and Health (NIOSH) approved Revision 03 of ORAUT-OTIB-0078, *Internal Dosimetry Coworker Data for the Feed Materials Production Center* (ORAUT 2015; hereafter referred to as "OTIB-0078") which was put into effect on August 19, 2015. The release of this document was formally announced to the Advisory Board on Radiation Worker Health (ABRWH) during Meeting 108 on November 18, 2015 (ABRWH 2015), at which time the Board tasked SC&A with the review of the revised document. This report presents the results of SC&A's review of the revised coworker model, which identified two findings and six observations. These findings and observations are as follows:

Finding 1: Although claimant favorable, the censoring of negative and zero bioassay results at the minimum observed positive value in a given year is inconsistent with the guidance provided in ORAUT-RPRT-0053, Revision 2, *Analysis of Stratified Coworker Datasets* (ORAUT 2014; hereafter referred to as "RPRT-0053"), which specifies that all negative bioassay values be censored at zero. Note that the treatment of negative, zero, and results less than the minimum detectable activity (MDA) is an ongoing topic of discussion with the Special Exposure Cohort (SEC) Issues Work Group.

Finding 2: NIOSH should closely examine questionable bioassay pairs that demonstrate differences of exactly two orders of magnitude on the same day for the same worker to assure that all of the numerical results used in OTIB-0078 accurately reflect the daily excretion rates for monitored workers at Fernald and are being interpreted correctly.

Observation 1: SC&A was able to recreate the annual daily excretion rates reported in Table 2-3 of OTIB-0078 with a reasonable degree of accuracy for most years. However, SC&A was not able to recreate the values reported for the years 1986–1997. These years appear to contain large numbers of censored results, which may have resulted in the employment of alternate methods to arrive at the daily excretion rates reported. If an alternate calculation approach was, in fact, used, OTIB-0078 would benefit from a discussion of how annual excretion data were derived, the rationale behind the approach, and ultimate effect on derived intakes.

Observation 2: A comparison of the median urinary excretion rates derived in Revision 03 of OTIB-0078 (using the TWOPOS method) with the excretion rates calculated in Revision 01 of OTIB-0078 (using the pooled sample approach) showed very little difference. However, as expected, the use of TWOPOS methods results in a significant reduction in the variability of the derived distributions, and thus excretion rates at the 84th percentile were markedly lower using the TWOPOS method.

Observation 3: Sample results that were below the detection limit were not reported in a consistent fashion in the HIS_20 ORAU database. NIOSH has elected to treat negative and zero results by censoring the value at the lowest observed positive result by year. This approach is claimant favorable compared to using the negative and zero values as is although not consistent with the methodology in RPRT-0053 (see Finding 1).

Observation 4: NIOSH appears to have used reported values at the MDA/control limit (CL) in situations where a lower numerical result was provided in the comments section of the bioassay entry. This is a claimant favorable interpretation of these records.

Observation 5: SC&A observed 313 sample entries that should likely have been removed from the coworker model due to comments indicating the sample was an invalid result or the sample was for pre-employment/re-employment purposes. Given the relatively small incidence of such samples, the cumulative effect of excluding those results is likely to be insignificant.

Observation 6: OTIB-0078 would benefit from a discussion of the additional intake information (intake pathway and solubility type) available in the HIS_20 ORAU database. Neither the pedigree and accuracy of such indicators, nor whether appropriate adjustments to the intake model may be warranted, are not known at this time.

1.0 INTRODUCTION AND BACKGROUND

Internal monitoring data are available for Fernald in a large electronic database, HIS_20 ORAU (ORAUT n.d.), which contains nearly 436,000 individual bioassay results spanning from the early 1950s through October 2006. The vast majority of these entries are urinalysis samples that provide results in the units of micrograms of uranium per liter (µg/l). However, a small fraction of entries remained that are not relevant to the development of a uranium coworker model and were removed from the dataset prior to intake modeling.

Per OTIB-0078, the available data were selected based on the criteria shown in Table 1. As part of its review, SC&A recreated these "scrubbing" steps and indicates how many records were removed from the model (see right-hand column in Table 1).

Table 1. Description of Data Removal Steps Described in OTIB-0078

Step	Description of Entries Removed	Entries Remaining
1	Initial full dataset	435,982
2	Not labelled as urinalysis	431,016
3	Not labelled as "U-Total" or "U-238"	429,328
4	Coded as "10, 5C, 70, VF, VR, and VE"	403,181
5	Units not equal µg/l	403,166
6	Results given as "N/A"	403,027

Although it was not stated directly in OTIB-0078, SC&A assumed that entries with blank dates, nonsensical dates, or results that were before 1952 were also removed. Based on these criteria, SC&A arrived at a final dataset of 403,016 entries. This is very close to, but does not exactly match, the number reported in OTIB-0078 (403,015).

In addition to the scrubbing steps described above, OTIB-0078 states the following about bioassay results that were listed as equal to or less than zero:

> *For years with uncensored data, values less than or equal to zero were treated as being censored at the lowest positive value in that year for TWOPOS*

implementation, however, values equal to the lowest positive value are still considered to be uncensored.

No other adjustments to the raw dataset were specifically discussed in OTIB-0078.

As indicated in the transcript from Meeting 108 of the ABRWH (ABRWH 2015), the internal uranium coworker model was mainly revised to incorporate a time-weighted one person–one sample (TWOPOS) approach to analyzing the available data. To arrive at a TWOPOS value for a given worker, the following steps must be taken per RPRT-0053 (ORAUT 2014):

1. For an individual worker, average all samples taken on a single day.

2. Weight each sample in a given year by the number of days that have passed since the previous sample, or alternately the number of days since January 1 if it is the first sample in the year.

3. For the period of time after the last sample in a given year, two methods are employed depending on the circumstance:

    a. If the worker provided a bioassay sample in the following year, that value is assumed for the remaining period of time in the previous year.

    b. If no sample is available in the following year, the value of the last sample in the year under consideration is assumed for the remaining time.

A hypothetical example of this type of calculation is provided in Table 2 for clarity to the reader.

Table 2. Example of TWOPOS Calculation for a Hypothetical Worker

Date of Sample	Actual Result	Units	TWOPOS Calculation	Time-Weighted Result
1/10/1966	10	µg/l	(Jan. 10, 1966 – Jan. 1, 1966 + 1) × 10	100
7/23/1966	15	µg/l	(July 23, 1966 – Jan. 10, 1966) × 15	2,910
10/4/1966	5, 10[a]	µg/l	(Oct. 4, 1966 – July 23, 1966) × ((10 + 5) / 2)	547.5
11/25/1966	20	µg/l	(Nov. 25, 1966 – Oct. 4, 1966) × 20	1,040
2/5/1967	5	µg/l	(Dec. 31, 1966 – Nov. 25, 1966) × 5	180
1966 TWOPOS Value	**—**	**—**	**(100 + 2,910 + 547.5 + 1,040 + 180) / 365**	**13.1**

[a] There were two samples on this date.

Note that if there had not been a bioassay sample in 1967, the final sample in 1966 (20 µg/l on November 25, 1966) would have been weighted by the remaining time in the year. This would have resulted in the final time-weighted value increasing by a factor of 4, and the TWOPOS value for 1966 would increase from 13.1 to 14.6.

Although not specific to OTIB-0078 and Fernald, SC&A observed what could be considered an unintended consequence when applying Step 3.a of the TWOPOS calculation. Specifically, one particular worker had his or her final sample for Year 1 on February 15; the next sample

observed was not until November 2 of Year 2. This results in the single sample being weighted by 319 days in Year 1 and 306 days for Year 2 (625 total days).

In another example, the final sample for Year 1 was on December 15, and the next observed sample was not until January 17 of Year 3 (a combined 398 days between the two samples). In this case, no TWOPOS value would be calculated for Year 2, and the Year 1 TWOPOS would post-weight[1] the last sample in Year 1 even though far fewer days had passed between the two samples than in the first example.

One potential alternative would be to set a limit on the number of days that can pass between samples for the purposes of calculating TWOPOS results (in the worst case scenario, 730 days could potentially pass between sample results and still be used in the TWOPOS calculation). Certainly, one could argue that a sample taken 730 days after the last monitoring result may not accurately represent the intake potential for the entire intervening period. In this case, a post-weighted result might be more appropriate for the TWOPOS calculation.

An alternate variation might be to allow for a TWOPOS result to be calculated for a year with no actual sample results, provided there is a sample in the following year that is sufficiently close to the unmonitored year. This would allow for a TWOPOS result to be included even though the worker was technically unmonitored during the second year.

SC&A concedes that any combination of rules adopted to perform the TWOPOS calculation will necessarily result in some samples being unintendedly biased; however, alternate methods of interpreting the one person–one sample statistic may be beneficial to explore. Regardless, the potential issue is universal to the formation of all coworker models and is not specific to Fernald or OTIB-0078. Thus, further discussion beyond the general concept is not warranted in this report.

2.0 SC&A REVIEW OF THE HIS_20 ORAU DATABASE

2.1 COMPARISON OF DERIVED TWOPOS DISTRIBUTIONS

SC&A analyzed the available dataset using the criteria specified in OTIB-0078 with one exception. As described in the previous section, OTIB-0078 states that bioassay samples that are listed as zero or less than zero (negative) are evaluated at the lowest positive value for that particular year. A review of the calculation files provided by NIOSH, as well as the data in HIS_20, indicate that the following minimum positive values were used by year (see Table 3 and Figure 1). As seen in Table 3 and Figure 1, many years had a minimum positive result of 1 µg/l, although a minimum value of 0.01 µg/l was observed as early as 1953.[2] The lowest annual positive bioassay value (0.001 µg/l) was observed starting in 1997.

[1] Note: "Post-weighting" refers to weighting the sample by the number of days remaining in that specific year in addition to the pre-weighting.
[2] See Section 2.4 for a discussion of questionable bioassay results on the order of one hundredth of a µg/l.

Table 3. Censoring Level by Year Used to Modify Zero and Negative Bioassay Results

Year	Result	Year	Result	Year	Result	Year	Result	Year	Result
1952	1	1963	1	1974	1	1985	1	1996	0.8
1953	0.01	1964	1	1975	1	1986	1	1997	0.001
1954	0.01	1965	0.01	1976	1	1987	3	1998	0.001
1955	0.19	1966	0.01	1977	1	1988	3	1999	0.001
1956	1	1967	1	1978	1	1989	5	2000	0.001
1957	0.49	1968	1	1979	1	1990	5	2001	0.001
1958	1	1969	0.8	1980	1	1991	7	2002	0.001
1959	0.17	1970	1	1981	1	1992	9	2003	0.001
1960	0.01	1971	1	1982	0.002	1993	0.8	2004	0.001
1961	1	1972	1	1983	1	1994	0.8	2005	0.001
1962	0.07	1973	1	1984	1	1995	0.8	2006	0.001

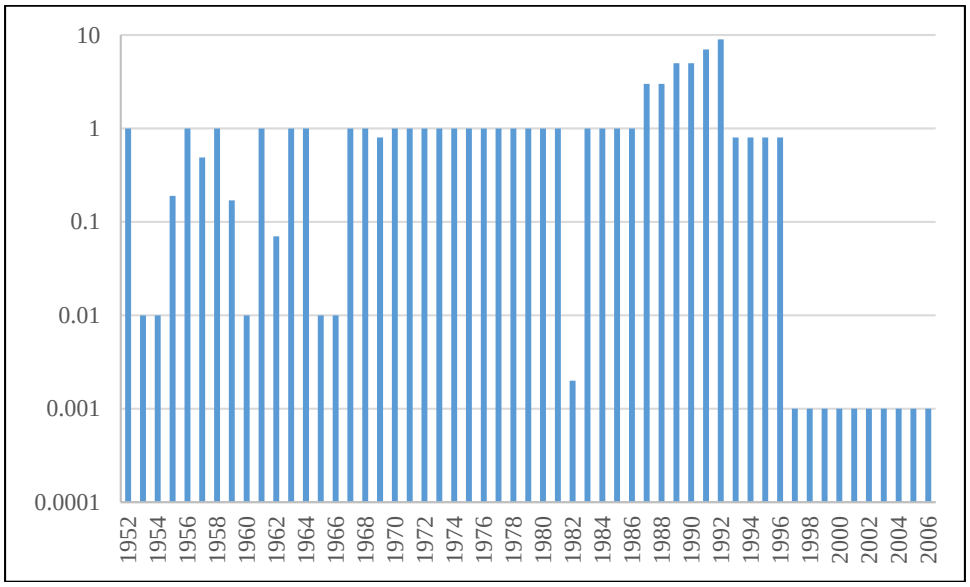

Figure 1. Censoring Level by Year Used to Modify Zero and Negative Bioassay Results

RPRT-0053, Revision 02 (ORAUT 2014) states the following about the treatment of negative values:

> *When negative results are present they are censored at 0 and the mean is calculated in a similar fashion (Examples D, E, F, and G).*

The examples identified in the quoted text are shown in Figure 2. It is clear that the effect of censoring negative and zero bioassay results at the minimum observed positive bioassay result for the year would result in a claimant-favorable TWOPOS value. Nonetheless, the practice appears to be inconsistent with guidance provided in RPRT-0053.

Finding #1: Although claimant favorable, the censoring of negative and zero bioassay results at the minimum observed positive value in a given year is inconsistent with the

guidance provided in ORAUT-RPRT-0053, Revision 2, *Analysis of Stratified Coworker Datasets* (ORAUT 2014), which specifies that all negative bioassay values be censored at zero. Note that the treatment of negative, zero, and results less than the MDA is an ongoing topic of discussion with the SEC Issues Work Group.

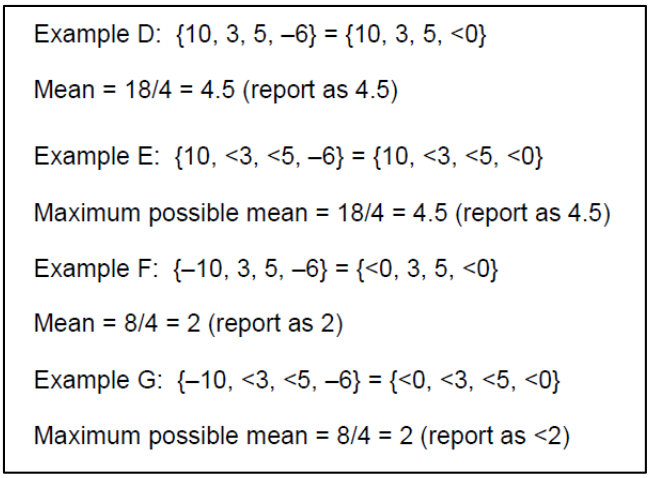

Figure 2. Screenshot from RPRT-0053 Providing Examples of How Negative Values Are Interpreted in the TWOPOS Calculation

In calculating the annual TWOPOS values, SC&A followed the guidance provided in RPRT-0053 and set all negative values to zero. This allows for an assessment of the effect that censoring negative and zero values at the minimum positive bioassay result has on the resulting annual TWOPOS values. Figure 3 shows a comparison of the TWOPOS values reported in OTIB-0078 with the values calculated by SC&A.

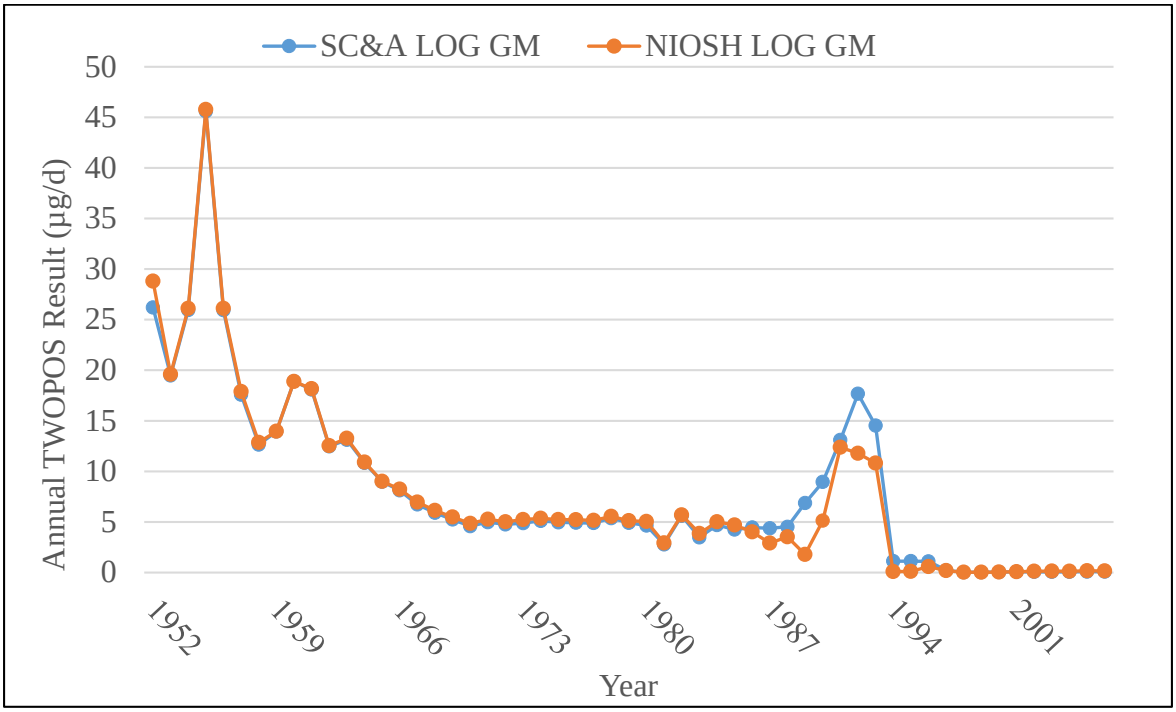

Figure 3. Comparison of the Calculated Logarithmic Geometric Mean TWOPOS Values from ORAUT 2015 and SC&A Evaluation

As seen in Figure 3, SC&A's calculated TWOPOS values closely mirror the values reported in OTIB-0078 for most years. As one would expect, the SC&A values are slightly lower in some years, which is likely due to the differences in treatment of negative and zero values. However, the differing treatment of negative and zero values does not appear to be a significant contributing factor to the calculated annual TWOPOS values.

There do appear to be significant differences in calculated values in the late 1980s and early-to-mid 1990s. Aside from the treatment of negative values and zeros, SC&A did not identify distinct differences in the treatment of the data for these years upon inspection of the calculation files provided by NIOSH. It is important to note that the treatment of negative and zero bioassay samples would logically result in an increase in calculated TWOPOS values results in OTIB-0078 when compared to the methods employed by SC&A. However, the opposite appears to be true for these years. Additionally, OTIB-0078 has adopted to exclude the data from 1991–1993 due to the increased censoring level and has adopted to apply the intakes derived from earlier years for this period. This issue is discussed in detail in Section 2.2 of OTIB-0078.

Nonetheless, the discrepancy in calculated values between NIOSH and SC&A for these years warrants further investigation. One possibility is that the data for these years were treated differently than for the other years due to the large number of results that appear to be censored at a certain level. Although not discussed (nor referenced) in OTIB-0078, the analysis may have employed methods described in ORAUT-RPRT-0044, *Analysis of Bioassay Data with a Significant Fraction of Less-Than Results* (ORAUT 2009a; hereafter referred to as "RPRT-0044").

Observation 1: SC&A was able to recreate the annual daily excretion rates reported in Table 2-3 of OTIB-0078 with a reasonable degree of accuracy for most years. However, SC&A was not able to recreate the values reported for the years 1986–1997. These years appear to contain large numbers of censored results, which may have resulted in the employment of alternate methods to arrive at the daily excretion rates reported. If an alternate calculation approach was, in fact, used, OTIB-0078 would benefit from a discussion of how annual excretion data were derived, the rationale behind the approach, and ultimate effect on derived intakes.

2.2 COMPARISON OF REVISION 01 AND REVISION 03 COWORKER DISTRIBUTION

The uranium urinalysis data in the HIS_20 ORAU database for Fernald were analyzed by NIOSH in 2007. The results of that analysis were reported in a draft white paper (ORAUT 2007) reviewed by SC&A. The same uranium coworker models were reported in OTIB-0078, Revision 01 (ORAUT 2010). The coworker model analyses reported in these documents follow the statistical procedure that was recommended at that time in ORAUT-OTIB-0019, Revision 01, *Analysis of Coworker Bioassay Data for Internal Dose Assignment* (ORAUT 2005). This procedure is commonly referred to as the "pooled" approach, as it fits each bioassay sample into the coworker distribution without any averaging or time-weighting steps.

The procedure for removing unwanted records from the HIS_20 ORAU database for the OTIB-0078, Revision 01 study was very similar to the OTIB-0078, Revision 03 procedure described above in Section 2.1. In Revision 01, coworker model distributions were developed by fitting a lognormal model to the individual urinalysis sample values for all workers in each quarter of each year, with a few exceptions noted below.

A comparison of the OTIB-0078, Revision 01 quarterly coworker models with the annual TWOPOS models presented in OTIB-0078, Revision 03 was conducted using simulation of the Revision 01 quarterly models. For each year, 5,000 random samples from each of the four quarterly lognormal distributions were combined into a single annual distribution. The 50th and 84th percentiles of the simulated annual distributions developed from the Revision 01 quarterly coworker models are listed in Table 4. The Revision 01 analysis developed only a single annual coworker model for the years 1952, 1953, 1994, 1995, and 1996, and the Revision 01 annual model percentiles are shown in Table 4 for these years. No models were reported in Revision 01 for the years 1991, 1992, and 1993. The analysis for the year 1997 included three models, one for the months January through May and the other two for the final two quarters of the year.

The plot in Figure 4 shows a comparison of the new TWOPOS Revision 03 84th percentiles with the annual 84th percentiles simulated using the Revision 01 quarterly models for the entire period 1952 through 2006. This plot uses a log scale for the vertical axis. A similar plot with a linear vertical scale is shown in Figure 5 for the years 1952 through 1990. The Revision 03 TWOPOS estimates fall below the Revision 01 84th percentile estimates, except in the early years 1952 and 1955 and in the period from 1987 through 1997, where the Revision 03 TWOPOS analysis yields higher estimates than Revision 01. The differences are more apparent in Figure 7, which contains plots of the 1952 through 1990 data using a linear scale.

The plots in Figures 6 and 7 show similar comparisons of the 50th percentiles (median). The 50th percentiles match very well in both figures, except in 1952 and in the late 1980s through mid-1990s, where the Revision 03 TWOPOS analysis yields higher results than Revision 01. As expected, the use of TWOPOS does not have an appreciable effect on the estimates of the median.

In Figure 8, the plots of the geometric standard deviations (GSDs) show larger differences between the two analyses. The TWOPOS procedure uses the average of all samples in a given year for each individual. As expected, the averaging process reduces the variability inherent in the individual sample values, resulting in the marked reduction in the coworker model GSD shown in this figure.

Observation 2: A comparison of the median urinary excretion rates derived in Revision 03 of OTIB-0078 (using the TWOPOS method) with the excretion rates calculated in Revision 01 of OTIB-0078 (using the pooled sample approach) showed very little difference. However, as expected, the use of TWOPOS methods results in a significant reduction in the variability of the derived distributions, and thus excretion rates at the 84th percentile were markedly lower using the TWOPOS method.

Table 4. Simulated Annual Percentiles for OTIB-0078 Revision 01 Quarterly Coworker Models

Year	50th Percentile (µg/d)	84th Percentile (µg/d)	Year	50th Percentile (µg/d)	84th Percentile (µg/d)
1952	15.84	61.41	1978	5.94	13.08
1953	21.75	68.86	1979	6.05	14.08
1954	26.93	82.41	1980	5.90	14.16
1955	40.87	113.45	1981	3.75	9.58
1956	32.87	85.86	1982	4.89	11.62
1957	21.67	64.08	1983	4.83	12.37
1958	14.28	39.35	1984	5.18	12.60
1959	14.64	37.66	1985	5.01	10.86
1960	20.71	45.74	1986	3.13	7.36
1961	19.40	38.35	1987	1.89	5.20
1962	13.64	31.19	1988	1.88	4.27
1963	14.10	32.11	1989	0.35	1.52
1964	12.72	32.27	1990	0.48	2.06
1965	9.10	25.81	1994	0.01	0.06
1966	6.58	25.49	1995	0.01	0.07
1967	7.41	19.34	1996	0.01	0.04
1968	6.43	17.14	1997	0.01	0.04
1969	5.84	14.98	1998	0.02	0.08
1970	4.70	11.34	1999	0.02	0.08
1971	6.21	15.91	2000	0.02	0.10
1972	5.89	16.34	2001	0.05	0.17
1973	7.00	19.34	2002	0.05	0.14
1974	6.65	16.79	2003	0.05	0.14
1975	7.14	17.34	2004	0.05	0.13
1976	6.68	15.87	2005	0.07	0.18
1977	5.72	13.18	2006	0.07	0.17

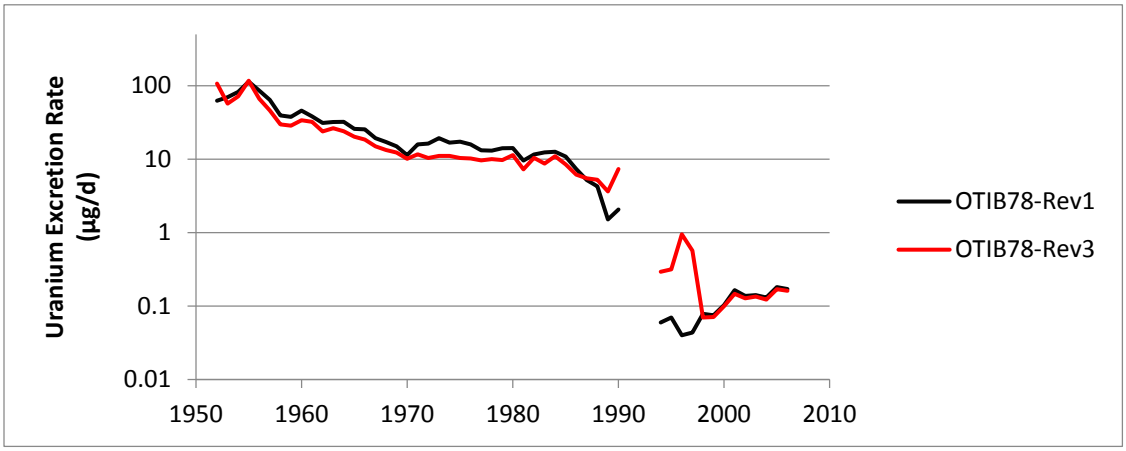

Figure 4. Comparison of 84th Percentiles 1952 to 2006 (log scale)

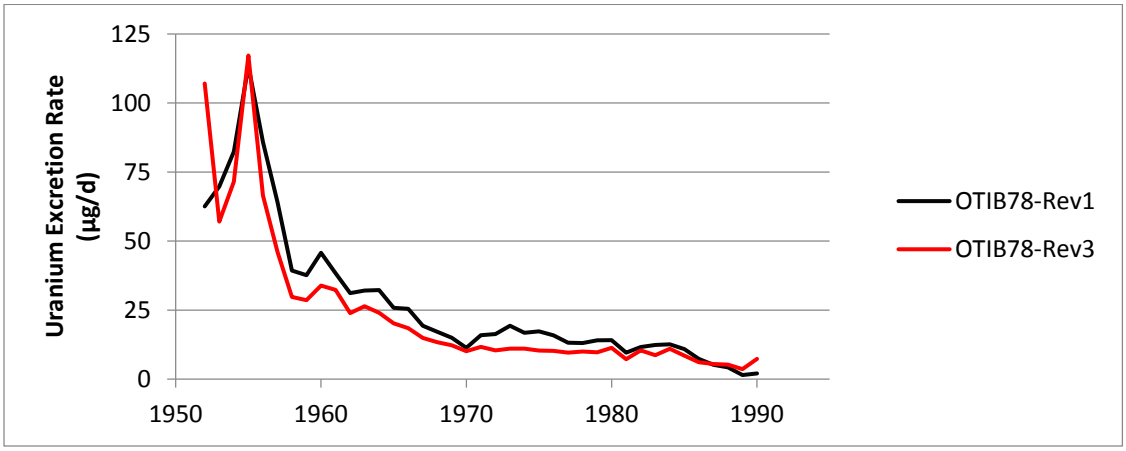

Figure 5. Comparison of 84th Percentiles 1952 to 1990 (linear scale)

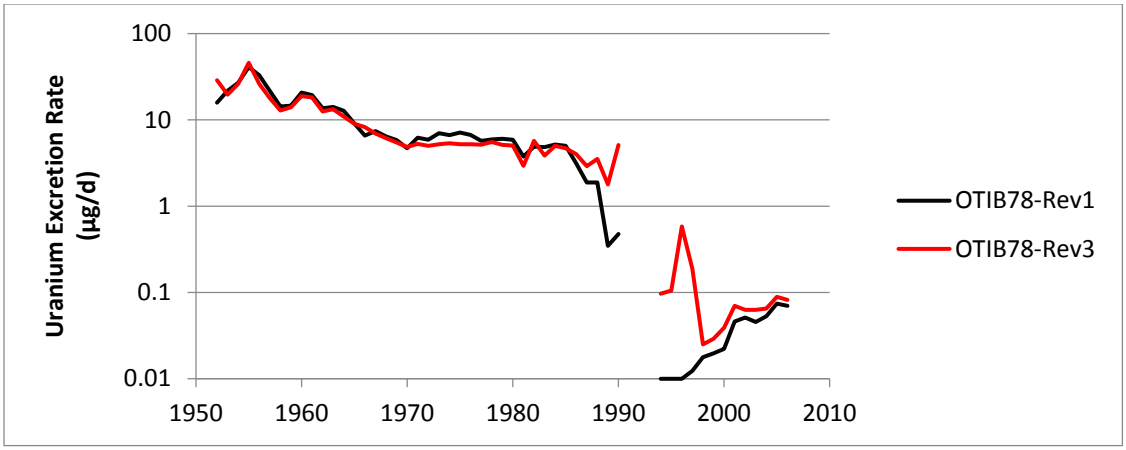

Figure 6. Comparison of 50th Percentiles 1952 to 2006 (log scale)

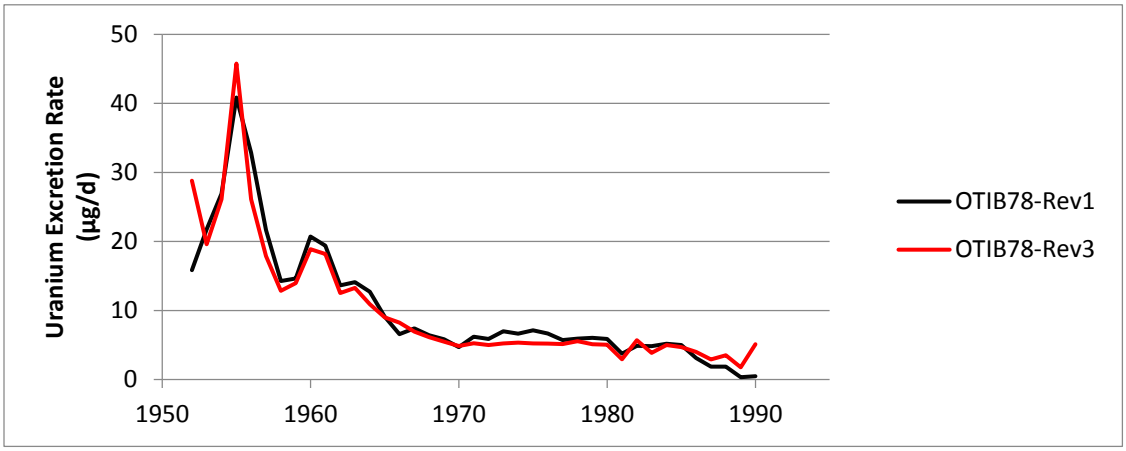

Figure 7. Comparison of 50th Percentiles 1952 to 1990 (linear scale)

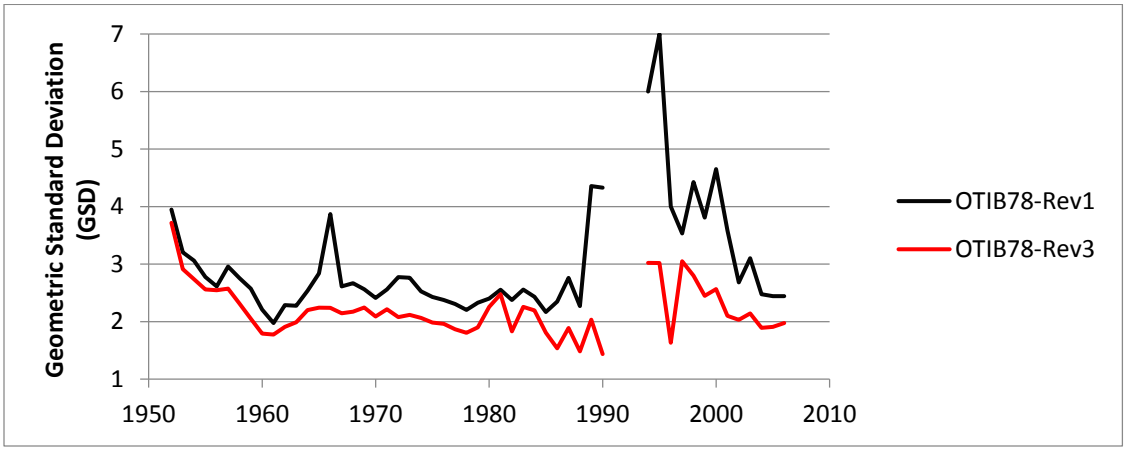

Figure 8. Comparison of Geometric Standard Deviations (GSDs) 1952 to 2006

2.3 EXAMINATION OF COMMENTS COLUMN IN HIS_20 ORAU DATABASE

The HIS_20 ORAU database contains a "comments column" that contained a non-blank entry in approximately one-third of samples used in building the uranium coworker model (130,203 of 403,016 usable samples). In the vast majority of these cases, the entry would simply contain a sample number or other notation that does not affect the actual numerical result. However, a few of the comment entries had information that was relevant to the actual use of the sample itself. These comment entries fell into the categories listed in Table 5.

Table 5. Description and Number of Observed Comments That Are Relevant to the Use of the Reported Sample Result

Comment Description	Sample Result Reported	Count
Comment indicates "below detection limit"	"MDA/CL" listed as the sample result	1,699
Comment indicates "below detection limit"	"Zero" listed as the sample result	1,525
Comment indicates an actual numerical sample result below the MDA/CL	"MDA/CL" listed as the sample result	715
Pre-Employment or Re-employment	Not relevant to discussion	142
Visitor	Not relevant to discussion	2
Possibly Invalid Sample	Not relevant to discussion	169

As seen in the first three entries of Table 5, samples that were less than the MDA/CL or below the detection limit were not always treated in the same manner in the HIS_20 ORAU database. For example, the first two categories contained notations in the comments column that indicated the individual sample was below the detection limit. However, in some of these cases, the MDA/CL was used as the reported numerical result, while in others the sample was entered as zero. This inconsistent characterization of samples that were below the MDA in HIS_20 ORAU is somewhat obviated by the fact that OTIB-0078 treated all negative and zero entries at the minimum observed positive result for that year.

A third variation on the treatment of values that appear to be less than the MDA/CL was observed in which the comments column contains an individual numerical result that was less than the assumed MDA/CL; however, the MDA/CL was entered as the sample result. SC&A's review of calculation files provided by NIOSH indicates that, in these cases, the MDA/CL value was used as is and no adjustment appears to have been made using the sample result provided in the comments column. This treatment would result in higher TWOPOS values and thus is claimant favorable.

Observation 3: Sample results that were below the detection limit were not reported in a consistent fashion in the HIS_20 ORAU database. NIOSH has elected to treat negative and zero results by censoring the value at the lowest observed positive result by year. This approach is claimant favorable compared to using the negative and zero values as is although not consistent with the methodology in RPRT-0053 (see Finding 1).

Observation 4: NIOSH appears to have used reported values at the MDA/CL in situations where a lower numerical result was provided in the comments section of the bioassay entry. This is a claimant favorable interpretation of these records.

It can be seen in Table 5 that 142 samples contained a notation indicating it was a pre-employment or re-employment sample. In addition, two samples had comments indicating the worker was a visitor from the Mound Plant. Per the instructions contained in Section 2.1 of OTIB-0078, these samples should likely have been removed prior to the TWOPOS analysis.

Finally, 169 samples contained comments that indicate the sample result is likely invalid. For example, a notation might indicate that a sample was lost or not submitted; however, the result

was still reported as zero. This type of invalid result would bias the calculated TWOPOS values low. On the other hand, sample results were observed in which the comment entry indicated the result was a false positive. Inclusion of these samples would logically bias the calculated TWOPOS result high. Given the relatively small number of such observations, the cumulative effect of excluding these results is assumed to be insignificant.

Observation 5: SC&A observed 313 sample entries that should likely have been removed from the coworker model due to comments indicating the sample was an invalid result or the sample was for pre-employment/re-employment purposes. Given the relatively small incidence of such samples, the cumulative effect of excluding those results is likely to be insignificant.

2.4 INTAKE AND SOLUBILITY CLASS INFORMATION

The HIS_20 ORAU database contains two columns that often indicate a specific type of intake (inhalation or ingestion[3]) and/or the solubility class (days, weeks, or years) associated with a given sample. Approximately 81.5% of the observed samples indicated the exposure was from an inhalation compared to 5.5% reported as ingestion. The remaining 13% did not indicate an intake pathway. All 403,016 samples listed a solubility type, with the vast majority indicating solubility type W (weeks). Less than 0.002% were reported as solubility type D (days), with the remaining indicating solubility type Y (years).

SC&A is unaware of the pedigree or accuracy of this additional intake information associated with the available bioassay data. OTIB-0078 would benefit from a discussion of this information and whether adjustments to the coworker model, such as separating samples based on the intake pathway indicated and/or calculating separate TWOPOS distributions based on solubility type, would be appropriate.

Observation 6: OTIB-0078 would benefit from a discussion of the additional intake information (intake pathway and solubility type) available in the HIS_20 ORAU database. Neither the pedigree and accuracy of such indicators, nor whether appropriate adjustments to the intake model may be warranted, are not known at this time.

2.5 QUESTIONABLE SAMPLE PAIRS OBSERVED

SC&A observed situations where two distinct sample entries are available for a single worker on the same day with results that are exactly two orders of magnitude different. One such example is given below for a worker in 1965 (see Table 6). It is not uncommon at a site such as Fernald for a worker to have multiple samples taken on the same day and for the results to be somewhat different. For example, a worker may have submitted a sample right at the start of the shift and then again at the end of a shift. However, consistently different by two orders of magnitude may indicate one of the entries is questionable.

Another example of this type of record is provided in Table 7. In this case the worker had three bioassay results per day for three consecutive days. The three samples on the first day vary from

[3] The database actually labels such results as “injestion” [sic] and so could alternately represent an injection or puncture wound-type dose.

0.01 to 11 µg/l (over three orders of magnitude). It is also worth noting that the higher sample is also marked as an "injestion" intake of solubility type Y. For the other two days, the samples marked as an "injestion" intake of solubility type Y was identical to the inhalation intake of solubility type W when also identified as sample type "3R." The results that are labelled as sample type "XX" were two orders of magnitude lower. This highlights the need to understand and correctly interpret the numerical bioassay results contained in HIS_20 ORAU.

It is especially important to evaluate the questionable bioassay pairs for their validity in light of the use of the minimum positive value observed by year to adjust negative and zero results. For example, the lowest positive value observed in 1965 and 1966 was 0.01 µg/l (see Table 3, Section 2.1). Each observed sample at this magnitude during those years was also paired with a result a factor of 100 higher (1.0 µg/l) on the same day.

Finding 2: NIOSH should closely examine questionable bioassay pairs that demonstrate differences of exactly two orders of magnitude on the same day for the same worker to assure that all of the numerical results used in OTIB-0078 accurately reflect the daily excretion rates for monitored workers at Fernald and are being interpreted correctly.

Table 6. First Example of a Worker with Multiple Bioassay Results on the Same Day that Are Two Orders of Magnitude Different

TYPE_ BIOASSAY	ACT_ UNITS _SU	NUC_NA ME	SAMPLE_ DATE	SAMPLE _TYPE	SAMPLE_ NUMBER	ACTIVITY	COMMENTS	INTAKE	NUC_ CLASS	TYPE_INTAKE	DATE_I NTAKE
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	XX		0.01			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	5B		1			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	XX		0.09			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	5B		9			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	XX		0.21			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	50		21			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	XX		0.36			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	5H		36			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	XX		1			W	INHALATION	01-Dec-65
URINALYSIS	ug/l	U-TOTAL	01-Dec-65	5H		100			W	INHALATION	01-Dec-65

Source: Reproduced from ORAUT n.d.

Table 7. Second Example of Worker with Multiple Bioassay Results on the Same Day that Are Two to Three Orders of Magnitude Different

TYPE_ BIOASSAY	ACT_ UNITS _SU	NUC_NA ME	SAMPLE_ DATE	SAMPLE _TYPE	SAMPLE_ NUMBER	ACTIVITY	COMMENTS	INTAKE	NUC_ CLASS	TYPE_INTAKE	DATE_I NTAKE
URINALYSIS	ug/l	U-TOTAL	14-Dec-65	XX		0.01			W	INHALATION	14-Dec-65
URINALYSIS	ug/l	U-TOTAL	14-Dec-65	3R		1			W	INHALATION	14-Dec-65
URINALYSIS	ug/l	U-TOTAL	14-Dec-65	00		11			Y	INJESTION	14-Dec-65
URINALYSIS	ug/l	U-TOTAL	15-Dec-65	XX		0.04			W	INHALATION	15-Dec-65
URINALYSIS	ug/l	U-TOTAL	15-Dec-65	00		4			Y	INJESTION	15-Dec-65
URINALYSIS	ug/l	U-TOTAL	15-Dec-65	3R		4			W	INHALATION	15-Dec-65
URINALYSIS	ug/l	U-TOTAL	16-Dec-65	XX		0.02			W	INHALATION	16-Dec-65
URINALYSIS	ug/l	U-TOTAL	16-Dec-65	00		2			Y	INJESTION	16-Dec-65
URINALYSIS	ug/l	U-TOTAL	16-Dec-65	3R		2			W	INHALATION	16-Dec-65

Source: Reproduced from ORAUT n.d.

2.6 CONSIDERATION OF IMPLEMENTATION GUIDELINES

SC&A acknowledges that at the time OTIB-0078 was drafted, Revision 4.1 of the *Draft Criteria for the Evaluation and Use of Coworker Datasets*[4] (NIOSH 2015) had not yet been accepted by the ABRWH for widespread use. Subsequently, the Board has tasked NIOSH/Oak Ridge Associated Universities (ORAU) with utilizing the implementation guideline on a trial basis for coworker modeling at Savannah River Site and Idaho National Laboratory. Should the Board ultimately accept the implementation guideline for widespread use, OTIB-0078 may have to be revised to reflect the new coworker requirements/criteria.

These criteria include, but are not necessarily limited to:

- Data adequacy and completeness
- Evaluation of stratification
- Appropriate time intervals for evaluation (e.g., quarterly versus annual)
- Applicability of available monitoring data to unmonitored workers

Given the large number of samples and coverage of workers monitored for uranium at Fernald, SC&A feels it is very unlikely that a legitimate data completeness or applicability of modeled doses to unmonitored workers issue (criteria bullets 1 and 4) would arise going forward. It should be noted, however, that there is currently an approved SEC that includes all subcontractors at Fernald from 1953 to 1983, due to the inability to reconstruct intakes of uranium for that individual subgroup of workers.

Stratification considerations could become important to the higher exposure job types, such as chemical operators and other radiation workers who were consistently exposed at a higher level. However, often times these concerns are alleviated by specifying what types of workers should be assigned the 95th percentile intake rates versus the 50th percentile rates, which utilize an associated GSD.

Finally, it was noted that Revision 01 of OTIB-0078 (ORAUT 2010) was evaluated on a quarterly basis instead of an annual basis. Revisions 02 and 03 of OTIB-0078 (ORAUT 2012 and 2015, respectively) expanded the evaluation period to an annual basis. Given the large amount of data available for analysis, Fernald may be one of the few sites able to evaluate excretion data for intervals smaller than a year.

[4] Also commonly referred to as the "Coworker Implementation Guidelines."

3.0 SUMMARY CONCLUSION

Based on its review of Revision 03 of OTIB-0078, SC&A identified two findings and six observations. The first finding identified apparent inconsistencies in the methods outlined in RPRT-0053 and those described in OTIB-0078. The second finding related to questionable sample results in which samples on the same day were observed to be different by a factor of exactly 100. The validity and interpretation of these results should be clarified.

The first observation describes the results of SC&A's reconstruction of values reported in OTIB-0078 according to the TWOPOS methodology. Although SC&A was able to match the annual excretion values shown in OTIB-0078 for most years, several years in the late 1980s and 1990s were not able to be recreated by SC&A. The source of this discrepancy has not been definitely established at this time; however, one likely possibility is the use of alternate methods such as those presented in RPRT-0044.

Observation 2 compared the derived urinary excreta distributions between Revision 01 and Revision 03 of OTIB-0078. Interestingly, the use of TWOPOS methods did not appear to have a significant effect on the median urinary excretion rates. Not surprisingly, use of the TWOPOS methods resulted in a marked decrease in the variability of the derived excreta distributions, and thus observed 84th percentile values were lower in Revision 03.

Observations 3–5 describe information contained in the comments column associated with each bioassay sample, including:

- Inconsistent reporting/treatment of values below the detection limit in the HIS_20 ORAU database (see Observations 3 and 4)
- Entries that are likely inappropriate for use in a coworker model due to indications of an invalid result or association with pre-employment or re-employment (see Observation 5)

The last observation noted that the HIS_20 ORAU database contains additional intake information, beyond the individual sample result, including solubility type and intake pathway. This information should be explored to determine if it can be used to produce a more scientifically accurate and defensible coworker model (see Observation 6).

The final section provides some general commentary about ongoing discussions and developments in coworker implementation policy. However, as these policies and guidelines have not yet been accepted by the ABRWH for universal application, the discussion is provided for informational purposes only.

4.0 REFERENCES

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