NIOSH Response to SC&A Review of ORAUT-OTIB-0081, Internal Coworker Dosimetry Data for the Savannah River Site

Response Paper

National Institute for Occupational Safety and Health

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This paper provides responses from the National Institute for Occupational Safety and Health (NIOSH) to the findings and observations in *Review of ORAUT-OTIB-0081, Revision 04, "Internal Coworker Dosimetry Data for the Savannah River Site"* [SC&A 2019]. ORAUT-OTIB-0081, *Internal Coworker Dosimetry Data for the Savannah River Site*, provides analysis of the Savannah River Site (SRS) internal dosimetry program and data as they apply to using these data to reconstruct doses to unmonitored workers [ORAUT 2019a]. For convenience, the document uses OTIB-0081 to refer to this technical information bulletin.

FINDING 1

> *Although SC&A recognizes that incident-based sampling involving chelation is not considered in final coworker modeling, the removal of* [diethylene triamine pentaacetic acid] *DTPA-influenced samples from consideration in the analysis of the high variability observed in trivalent actinide bioassay results has not been justified sufficiently. Evidence suggests the variation among DTPA and non-DTPA samples is nearly identical. Furthermore, OTIB-0081 has not provided any reference to justify the assumption that DTPA causes heterogeneity among a single urinalysis voiding. (See section 3.1.1.).*

NIOSH Response

The primary concern of SC&A appears to be that the repeated counts of a trivalent actinide planchet from a given urine sample can have "large variability" that can prevent it and other such samples from being used in a coworker model. NIOSH agrees with SC&A that chelation therapy is not a source of variability in repeated counts of a given planchet. However, we do not agree that the observed variability in repeated counts prohibits use of the bioassay data for developing coworker models, primarily because:

- As discussed, the analytical result for a given sample can be the average of multiple counts of its planchet,
- The bioassay results for a given person in a given year are averaged using the time-weighted one person–one statistic (TWOPOS) method,
- The TWOPOS bioassay results for all monitored workers in a given year are averaged (via the fit of a lognormal model to the data), and
- The 50th percentiles of the lognormal fits to the annual TWOPOS data are averaged [using the Interactive Modules for Bioassay Analysis (IMBA)] to come up with a 50th-percentile chronic intake rate over the range of years being modeled. The same process is repeated for the 84th percentile.

In summary, the repeated averaging of the bioassay results before they are used in the coworker model makes the variability observed in multiple counts of a given planchet of no practical significance with respect to the final coworker model.

In Section 3.1.1 of the comments, SC&A expresses concerns about the minimum detectable activity (MDA) of the trivalent actinide bioassay method at SRS during the 1970s being lower than those reported for similar analyses by Los Alamos National Laboratory and Rocky Flats Plant. Even today, in 2019, there is no universally accepted way of calculating or using an MDA in radiobioassay. Therefore, to make a meaningful comparison of MDAs from one laboratory with those from another requires detailed information on how the MDA was calculated. The situation was even more confusing in the 1970s, before the existence of standards like ANSI/HPS N13.30 [HPS 2011]. Any result reported as "less than something" is called a censored result, with the "something" being a censoring level. As discussed in OTIB-0081 and its supporting technical reports, sound statistical methods are available to model censored data and there is no need to know what the censoring level was based on or how it was calculated. Therefore, in the context of coworker modeling, the differences in the MDA of trivalent bioassay noted by SC&A are irrelevant.

FINDING 2

> *Use of imputed values that are less than one-half of the MDA raises a fundamental fairness issue in that monitored workers who have bioassay results that are less than the MDA are assigned a missed dose in accordance with ORAUT-OTIB-0060, "Internal Dose Reconstruction" (NIOSH, 2018). Per that guidance, bioassay values that are censored are assumed to be equal to one-half of the MDA rather than the use of an alternate imputed value (see section 3.2).*

NIOSH Response

NIOSH does not perceive any "fairness issue" resulting from the use of multiple imputation in the construction of coworker models versus the use of one-half the MDA for missed dose. Coworker models are used to assign intakes to individuals who were not monitored. Multiple imputation is used in the derivation of the coworker intake distribution when some of the data are censored. It is important to note that individuals are assigned percentiles (e.g., the 50th percentile) of the intake distribution, not any of the imputed bioassay values used to construct the intake distribution. Multiple imputation is used to construct coworker models because it results in unbiased estimates of the parameters of the coworker intake distribution, even for highly censored datasets. In contrast, substituting some constant value (like one-half the MDA) for censored results is well known to result in biased estimates of the coworker model parameters. If an individual was monitored, his bioassay data must be used for the dose reconstruction. Simple substitution (e.g., one-half the MDA) is used in this case because it is not feasible to derive a distribution for one or more specific reported results.

See also responses to Finding 3 and Observations 1 and 2.

FINDING 3

The sample comparison of coworker intakes to a missed dose method for uranium showed that the coworker model derived intakes were a factor of 4 or more higher than the missed dose approach. This illustrates the potential for inequity between the treatment of unmonitored workers assigned coworker intakes and monitored workers with results less than the detection limit in some situations (see section 3.3).

NIOSH Response

Coworker analyses are designed to provide intake rates for assignment to individuals who were not monitored for occupational intakes but possibly should have been. Included in that is the potential for those unmonitored workers to have had an actual intake. Therefore, the coworker intakes are based on data from coworkers, some of whom had positive bioassay results, indicative of intakes, and others for whom all the bioassay results were less than the MDA, indicative of a lack of, or minimal, intakes.

In contrast, missed dose is based exclusively on data that are less than the MDA. The resulting intakes use a triangular distribution encompassing the full range of possible missed intakes from zero to the MDA. If a monitored worker had received a larger intake, then the worker would have a corresponding positive bioassay result, which could be evaluated. The lack of such a result indicates that the worker did not have an intake larger than the range assigned as missed dose. This is the best estimate of that individual worker's intake potential.

Because coworker data include positive results in the distribution of results included in the statistical analysis, the calculated intakes based on those results can be greater than a calculated missed intake based on bioassay results only equal to half the MDA. In the case of uranium, the coworker data are based on data reported both in units of activity, using some form of gross alpha counting, and in units of mass, based on fluorophotometric analysis. The fluorophotometric MDA used in the coworker study is 5 µg/L, which equates to 6.195 dpm/day, over 6 times higher than the gross alpha counting MDA. The use of both activity-based and mass-based uranium urinalysis data for the coworker study results in a comparison with "missed dose" for uranium that is different than for other radionuclides.

FINDING 4

The coworker analysis uses the internal monitoring for claimants for which data were available to NIOSH in approximately August 2011 (~4,000 claims). Since that time, approximately 2,000 additional claims have been submitted that could be used to augment the coworker dataset. Inclusion of these data would be especially important for the two contaminants that required a combination of multiple years for analysis due to lack of a sufficient number of data points (uranium and cesium) (see section 4.1).

NIOSH Response

In Section 4.1, SC&A provides a quote from OTIB-0081 that says that the NIOSH-Division of Compensation Analysis and Support Claims Tracking System (NOCTS) was "the best available compilation of data in a usable form (i.e., electronic spreadsheet or database)." This is a bit of a misleading carryover from earlier versions of the OTIB, where preceding paragraphs noted that bioassay data in NOCTS were used to develop a database. All in vitro (nontritium) and in vivo bioassay data from NOCTS that were used in the current revision of the coworker analysis required coding from the hard copy records provided by the U.S. Department of Energy (DOE). At the onset of this revision, an evaluation of the coded claim data revealed an inconsistent amount of claim data between the in vitro and in vivo bioassay datasets. The in vitro bioassay dataset contained partial data through Claim ID 27XXX [claim ID partially redacted], while the in vivo bioassay data included coding of claims thru 31XXX [claim ID partially redacted]. In order to provide a more consistent set of data and increase the amount of information available for analysis, a claim cap of 35000 was established by NIOSH in 2017. This included the coding of the new claim data added beyond the respective in vitro and in vivo caps noted above, as well as claim information in the original datasets that was not originally coded. An additional consideration for considering the claim limit was the amount of time it takes to code and review NOCTS data. The date through which data were available in NOCTS was not a significant contributor to the decision to cap at 35000. Any data from SRS claims greater than ID 35000 will need to be coded from hard copy documents and reviewed prior to inclusion in the study.

NIOSH can code additional NOCTS data beyond claim 35000 for use in the coworker study if it is deemed necessary. However, it will take a considerable amount of time and resources to code and peer review these new data. In addition to the coding effort, all relevant quality control (QC) [transcription and construction trade worker (CTW) designation] and completeness tests will need to be performed. NIOSH acknowledges the additional claim data may reduce the need to combine multiple years for select contaminants, primarily uranium for CTWs in the 1980s and cesium data in the late 1960s and early 1970s. While the preferred method for evaluating coworker data is on an annual basis, guidance allows for up to three years of data to be validly combined to obtain a sufficient number of workers. NIOSH feels the combination of years and resulting intake models for both of the noted contaminants is reasonable for use in the coworker study. Considering the large amount of data available for most radionuclides modeled in this revision, NIOSH questions the value of coding additional data at this time.

FINDING 5

> *Classification of a "Machinist" as a nonCTW* [non-construction trade worker] *in OTIB-0081 is inconsistent with its classification in OCAS-PER-014, "Construction Trades Workers" (see section 5.2).*

NIOSH Response

The list in OCAS-PER-0014 [NIOSH 2007] was used to screen previously assessed cases from across the complex to determine which ones should be reviewed and potentially reevaluated with

ORAUT-OTIB-0052, *Technical Information Bulletin: Parameters to Consider When Processing Claims for Construction Trade Workers* [ORAUT 2014]. Selected claims were then further reviewed to ensure they met specific criteria. Dose reconstructors refer to OTIB-0052 for guidance on CTW assignment, which does not include machinist in its list of example job titles.

Construction trade worker trades listed in OTIB-0081 are more specific to SRS than those given in OCAS-PER-0014. Construction type crafts and trades, regardless of employer, were evaluated as to whether the work at SRS was generally performed in one place versus across the site and whether normal tasks were process/production versus maintenance and/or construction involved in decommissioning, dismantling of facilities, and maintenance or repair activities. As expressed in OTIB-0081, NIOSH consulted Bingham [1997] for a list of CTWs evaluated for that report. Machinist was not reported as a job title used by Rust Construction, although Machinist was listed as a construction trade for early Hanford work [Bingham 1997]. In *Savannah River Building Trades Medical Screening Program A Needs Assessment*, the authors did not include Machinist as a construction trade for SRS [CPWR 1998].

As part of this response, NIOSH performed a review of NOCTS SRS claims where the claimant self-reported a job title as Machinist. Table 1 summarizes the CTW designations of the 31 SRS claims of interest.. Of the 31 claims, 19 represent prime contractor (DuPont or Westinghouse) workers and 12 represent subcontractor workers.

Table 1. Analysis of NOCTS claims with position title Machinist.[a]

ID	NOCTS Position Title	Prime/Sub	Buildings	Initial Claim File/SRS Work Hx Cards/DOE Response	Assigned as CTW?
BB	Machinist Mechanic	Prime	C area, H area; worked on pumps, tanks, valves, equipment	Maintenance Mechanic	Yes
BC	Machinist	Prime	400 area, 700 area	Maintenance Mechanic	Yes
F	Machinist	Prime	773 "hot shop"	Maintenance Mechanic	Yes
BK	Machinist	Prime	773-A, 717A machine shop; could be assigned to other machine shops	Maintenance Mechanic	Yes
BM	Machinist	Prime	773, C machine shops	Maintenance Mechanic and Carpenter	Yes
BP	Machinist	Prime	Machine shop	Maintenance Mechanic	Yes

ID	NOCTS Position Title	Prime/Sub	Buildings	Initial Claim File/SRS Work Hx Cards/DOE Response	Assigned as CTW?
BR	Machinist	Prime	reactors, 700 area F/H area but months at a time; made new components for production	Maintenance Mechanic	Yes
BS	Machinist	Prime	Hot shop	Maintenance Mechanic	Yes
BT	Machinist	Prime	773 machine shop	Maintenance Mechanic	Yes
BW	Machinist	Prime	Unknown	Maintenance Mechanic	Yes
BY	Machinist	Prime	773 machine shop	Maintenance Mechanic	Yes
BZ	Mechanic/ Maintenance, Mechanic/ Machinist	Prime	Machine shop	Maintenance Mechanic	Yes
CC	Machinist	Prime	Unknown	Maintenance Mechanic	Yes
BJ	Millwright and Machinist	Sub	Unknown	Millwright, not monitored but would have been CTW	Yes
BV	Millwright/ Machinist	Sub	Central Shop; across the site (Millwright)	Millwright	Yes
BA	Machinist	Prime	Machined metals assigned to a maintenance group, 7/300 area	Maintenance Mechanic	Yes
BN	Machinist, Operator	Prime	320, 321 only	Operator; not a CTW	No
BU	Machinist	Prime	F Area	Operator; not a CTW	No
BG	Machinist	Prime	717A machine shop; could be assigned to other machine shops; work with contaminated materials	Shows exact job title	No

ID	NOCTS Position Title	Prime/Sub	Buildings	Initial Claim File/SRS Work Hx Cards/DOE Response	Assigned as CTW?
BO	Master Machinist	Prime	D area	Maintenance Mechanic	Yes
C	Machinist	Prime	R area	Maintenance Mechanic during the 1960s; Machinist during the 1950s	Yes (1960s) No (1950s)
BD	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on external dosimetry HP Dept	No
BE	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on NOCTS and CATI	No
BF	Construction Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on external dosimetry HP Dept	No
BI	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on CATI	No
BL	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on external dosimetry HP Dept	No
BX	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on external dosimetry HP Dept	No

ID	NOCTS Position Title	Prime/Sub	Buildings	Initial Claim File/SRS Work Hx Cards/DOE Response	Assigned as CTW?
CA	Machinist	Sub	Unknown	Job title based on external dosimetry HP Dept	No
CB	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on external dosimetry HP Dept	No
CD	Machinist	Sub	Central Shop; could be assigned to other machine shops; work with contaminated materials	Job title based on NOCTS	No
CE	Machinist	Sub	Unknown	Job title based on external dosimetry HP Dept	No

a. CATI = computer-assisted telephone interview.

SRS job history cards show the job title (craft) for 16 of the prime contractor claimants was Maintenance Mechanic. These are classified as CTWs in the OTIB-0081 Master Occupation Table (MOT). Information from computer-assisted telephone interviews (CATIs) and data supplied by DOE show these SRS employees primarily worked in machine shops fixed to certain areas and that these workers sometimes machined components and materials transferred from the reactors, SRS canyons, and research areas that could have been contaminated. The SRS job history for one claimant shows the actual job title Machinist. This claimant is classified as a non-CTW in the OTIB-0081 MOT. SRS job history cards show the job title for two of the 19 claimants was General Service Operator; as such, these are not CTWs (see response to Finding 6).

Of the reviewed subcontractors, two were actually Millwrights and are classified as CTWs in the OTIB-0081 MOT. Eight claimants have a payroll craft code "24" denoting Machinist as the craft. These claimants are classified as non-CTW in the OTIB-0081 MOT. NOCTS lacks sufficient data to state definitively that the remaining two subcontractor claimants were Machinists; however, CATI information for each support the assignment of the Machinist craft. These last two claimants are classified as non-CTW in the OTIB-0081 MOT. As with prime contractor workers, CATI information and data supplied by DOE show these SRS subcontractors mostly worked in machine shops fixed to certain areas but sometimes machined components and

materials transferred from the reactors, SRS canyons, and research areas that could have been contaminated.

In summary it was noted that subcontractor Machinists performed similar work as subcontractor Millwrights and prime contractor Maintenance Mechanics. While this type of work was at times performed in machine shops, it was generally more consistent with activities performed under non-routine exposure conditions. As both prime Maintenance Mechanics and subcontractor Millwrights are typically designated as CTWs in the coworker study, NIOSH would not object to re-classifying Machinist as a CTW. Based on the review of claims in Table 1, it appears at least eight workers from the coworker study would be impacted by this change in designation.

FINDING 6

> *A targeted sampling comparing the OTIB-0081 strata designation (CTW or nonCTW) against two alternate sources for identifying worker job classification indicated that just over 9 percent of the entries appear to be in conflict when comparing the NIOSH and SC&A analyses (see section 5.2).*

NIOSH Response

In an attempt to quantify CTW misclassification, SC&A checked a subset of "targeted" workers. Workers who were the most likely to be misclassified (ambiguous job titles, changing CTW status over time, etc.) were cherry-picked for this sample. In statistical terms, this is nonprobability sampling and more specifically called judgmental sampling. Because of the judgmental sampling, no confidence interval can be computed and the point estimate calculated is rather meaningless. The only statistically appropriate conclusion from SC&A's work is that 9.14% of the sample of targeted worker entries were (by their judgment) misclassified. That number cannot be generalized to the entire population of targeted worker entries because of the use of a judgment sampling technique.

In contrast, to quantify CTW misclassification, NIOSH performed probability sampling, more specifically simple random sampling (in accordance with ORAUT-RPRT-0078, *Technical Basis for Sampling Plan* [ORAUT 2016]) for the NOCTS in vitro bioassay dataset, NOCTS in vivo bioassay dataset, the neptunium logbook dataset, and the tritium dataset (tests 10, 9, 11, and 13 from SC&A Table 18, respectively). Each of these four tests presents a point estimate and 95% confidence interval for the classification error rate between the NIOSH CTW designation and the worker history cards (or CATI or personnel dosimetry quarterly reports). All four confidence intervals are entirely below 5%, which is the lot tolerance percent defective (LTPD) rate for these types of tests. ORAUT-RPRT-0078 has been approved, and the four tests mentioned here, done in accordance with that document, pass at the 5% LTPD.

NIOSH considers the worker history cards to be the best source for determining occupation and therefore non-CTW/CTW designation for those workers for whom the payroll identification (PRID) is not sufficient to make this determination. The worker history cards are contemporaneous records documenting the energy employee's (EE's) occupation and pay rate.

Other data sources are only used when worker history card information is not available. EE recollections in the CATI and U.S. Department of Labor sources are often long after the fact and can be uncertain about specific dates or completely lack dates to distinguish between multiple occupations while employed at SRS.

When assembling the MOT, no distinction was made between Operator and General Services Operator because both job titles were considered non-CTWs. Therefore, a General Services Operator might be identified in the MOT as an Operator.

The method used to construct the MOT is prone to error in close date proximity to when an EE changed occupation. However, the overall methodology was determined to be sufficiently accurate for the intended use in OTIB-0081. The fact that the error rate in the SC&A targeted sampling is only 9% is evidence of the overall acceptability of the method. Those entries not targeted by SC&A are much less likely to have CTW designation errors and make up the vast majority of the entries. SC&A checked only 15,244 entries. The MOT contains over 70,000 entries and there are 384,572 internal monitoring data points used in the coworker study. SC&A's 1,877 identified unadjusted conflicts make up less than 0.5% of all the internal monitoring data points.

The population of CTWs is based on workers who performed frequent, nonroutine tasks of generally short duration but which could present a potential for external or internal radiation exposure. SC&A presents General Services Operator, Supervisor, and Foreman as examples of job titles where some workers could be either non-CTW or CTW. None of those job titles are included as construction trades in OCAS-PER-014 [NIOSH 2007], Bingham [1997], or CPWR [1998]. At SRS, General Services Operators routinely operated production machinery. They also performed routine maintenance such as changing filters of production machinery and offgas ventilation systems in their assigned areas. A General Services Operator worked in an assigned area performing the same job duties routinely. They could also package and handle waste for disposal, but this was also routine work. Unlike CTWs who were assigned across the site working on varying exposure scenarios, these operators worked in routine exposure scenarios for which they were routinely monitored.

The Foreman job title at SRS spanned all technical, laboratory, maintenance, and construction departments. EE AP given in SC&A Table 17 was a salaried Technical Operations Foreman in A-Area in 773-A Laboratory Mechanical Services (based on external dosimetry Health Physics [HP] Department codes for the EE and DuPont [1977]). In relation to construction, Foreman is a position responsible for monitoring the progress and work done at the construction site by the workers to ensure that the work is being done on schedule and with the required quality. While foremen could visit a job site, they would not have the exposure scenario encountered by the task workers. Construction foreman job responsibilities included:

- Prioritization of the work to be done and assignment to the proper trades;
- Ensuring that all the tools, machineries, and equipment required for construction are available on the site;

- Ensuring that all the work on the construction site is done by following the necessary safety measures;
- Ensuring that the intermediate milestones in the construction work are completed within deadlines;
- Coordinating with site engineers, supervisors, and construction contractors to ensure smooth functioning at the construction site; and
- Maintenance of the inventory and inventory material.

Like the Foreman job title, the Supervisor title spanned all technical, laboratory, maintenance, and construction departments. Regardless of SRS department, supervisors were responsible for:

- Giving instructions or orders to subordinate employees;
- Ensuring that the work environment was safe, secure, and healthy;
- Meeting deadlines; and
- Making sure reporting employees met performance expectations.

NIOSH reviewed the seven examples presented in SC&A Table 17 (Illustrative examples of strata conflicts identified by SC&A analysis). NIOSH results are summarized in Table 2. NIOSH finds no discrepancies in the original CTW versus non-CTW assignments for the cases in question.

Table 2. NIOSH review of SC&A suggested strata conflicts

Case ID	Job Title	Comments
A	General Services Operator, Technician & Technical Assistant	The EE was identified as General Services Operator during the period of employment through [redacted], performing routine work. The EE job title changed to Technician in [redacted] and to Technical Assistant in [redacted]. NIOSH misidentified the EE as a Laborer and CTW for years 1989 and 1990 due to the NOCTS-listed position/title after the end of the worker history card data. There is no evidence the EE worked as a Laborer. The CATI-described Laborer work occurred while the EE was a general service operator. Appropriately assigned a non-CTW designation.

Case ID	Job Title	Comments
B	Construction Laborer & General Services Operator	Construction Laborer from [redacted] to [redacted]. No qualifying bioassay data were found for use in the coworker study during this employment period. Starting in [redacted], performed routine work at one area. Construction incorrect as stated in CATI, page 2; correctly stated as Operator on page 9. Worked in 313-M and 341-M, C and R. Appropriately assigned a non-CTW designation.
E	General Services Operator & Maintenance Mechanic	The EE worked in the Power Department from [redacted] through [redacted]. The EE then worked as a Maintenance Mechanic through end of employment as a CTW. While the EE has uranium bioassay starting in 1958, the first entry in the MOT is 1964 due to the first plutonium result. Uranium bioassay was not used to build the MOT. Appropriately assigned a CTW designation.
K	General Services Operator & Driver	The EE worked as a General Services Operator and Driver. NIOSH lacks sufficient information on specific duties EE performed as an Operator but would be a non-CTW. The EE's stated description of duties as a truck driver and CTW on Final CATI Page 7. NIOSH sees no conflict with identifications of both non-CTW and CTW based on the SRS job history cards.
W	General Services Operator	The EE was deceased before the CATI interview of survivor. NIOSH has insufficient data to show EE worked in construction or as a Laborer. The 1984 MOT entry showing Laborer is invalid as the bioassay date was "batch date" not "bottle date." The EE was a General Services Operator during the time of sampling. The NOCTS job title list does include Laborer, which is what led to Laborer being used for the 1984 sample. Appropriately assigned a non-CTW designation.
AE	Maintenance Mechanic	Work history card lists job as Maintenance Mechanic for entire employment period. EE not classified as Operator during employment. Appropriately assigned a CTW designation.

Case ID	Job Title	Comments
AP	Maintenance Mechanic, [redacted]	CTW while Maintenance Mechanic, [redacted] in [redacted]1976. Worked in A Area laboratory operations. Would be non-CTW from [redacted] 1976 forward. Appropriately assigned CTW designation prior to [redacted] 1976 and non-CTW designation from [redacted] 1976 forward.

The examples provided by SC&A do not show a systemic discrepancy in identifying job titles and for EEs who would perform frequent, nonroutine tasks of generally short duration and who could have a potential for external or internal radiation exposure. The selection of the crafts given in OTIB-0081 Table 3-2, with the possible addition of machinist, are consistent with trades published in CPWR [1998] and Bingham [1997]. NIOSH does not believe additional SRS sources need to be consulted.

OBSERVATION 1

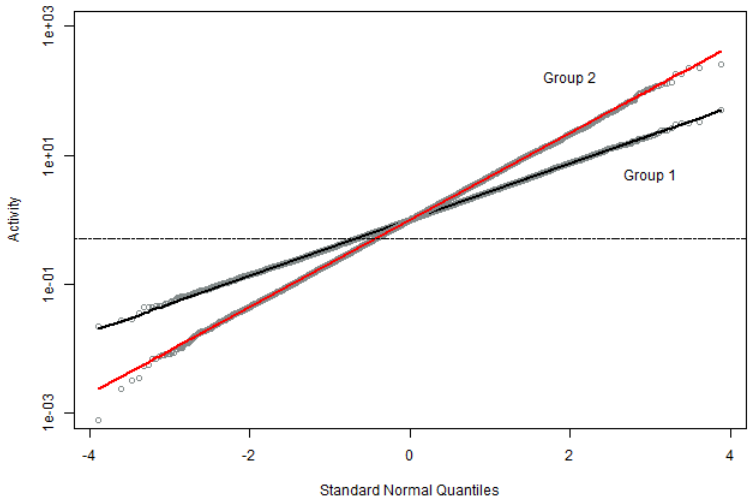
> *While the multiple imputation method is mathematically correct, it has the potential to result in biasing the simulated bioassay results unnecessarily low. Alternate approaches, such as the maximum possible mean method, which replaces censored data with the actual censoring limit (or alternately one-half the censoring limit), would solve the issues associated with datasets containing a large number of censored values in a claimant-favorable manner (see section 3.2).*

NIOSH Response

NIOSH considers multiple imputation to be a statistically sound approach to deriving unbiased parameter estimates of data distributions that contain censored data and is superior in all respects to the use of the maximum possible mean for such applications.

Consider the plot below, in which 10,000 random draws from a lognormal distribution LN(0,1) for Group 1 and 10,000 random draws from another lognormal distribution LN(0,1.545) for Group 2 are plotted against standard normal quantiles. This plot was constructed to mimic Figure 7 in the SC&A review, the main differences being that the data are not censored and there are a lot more data. As expected, both sets of data reveal their lognormality by being well fit with straight lines on this plot, albeit with different slopes and intercepts.

Figure 1



The dashed horizontal line on the plot is at an activity of 0.5, just like in SC&A Figure 7. If we take the mean $\overline{X_1}$ of the Group 1 data that are <0.5 and the mean $\overline{X_2}$ of the Group 2 data that are <0.5, by inspection it is obvious that $\overline{X_1} > \overline{X_2}$. This is a property of how the example was constructed. Now assume that the data that are <0.5 were not observed but were imputed. Once again $\overline{X_1} > \overline{X_2}$ because of the way the example was constructed, not because the data were imputed. Yet, using Figures 8 to 10 in their review, this is precisely the argument SC&A makes, i.e., because $\overline{X_1} > \overline{X_2}$ "... it [multiple imputation] has the potential to result in biasing the simulated bioassay results unnecessarily low." The conclusions based on the discussion on pages 26 to 28 are based entirely on the arbitrary choice of the two distributions and have nothing to do with imputation—everything said applies to the complete datasets as well, as we have shown. On page 28, it is recommended that maximum permissible mean (MPM) be used in TWOPOS calculations instead of a time-weighted average of uncensored and imputed results simply because it is "claimant favorable." The MPM is a statistically biased method that is technically wrong. The only reason MPM was used at all was because at the time there was no other method available to use in TWOPOS, the implementation of which was the primary objective. Multiple imputation is a technically correct, statistically unbiased method, which means that it can give lower values than MPM when used in a TWOPOS calculation. The recommendation to intentionally use a biased, technically inferior method should not be based simply on the fact that it gives higher results.

On the bottom of page 25 in the review, there is a discussion of "log-symmetry." All this means is that the log of the bioassay results are normally distributed (by construction) and that the normal distribution is symmetric. It is concluded that there "… is no obvious physical explanation of log-symmetry." Restated, they are saying that there is no obvious physical reason to use a lognormal distribution to model bioassay data. Indeed, there is no physical reason, but the lognormal distribution is widely used in health physics to model right-skewed distributions and has been the default distribution used successfully in coworker modeling on the project for over 15 years. We are not exactly clear as to what issue is being raised here.

On page 26 of the review, it is stated that:

Although the two groups of workers have the same median exposure, workers with censored data in Group 2 are assigned lower imputed values than workers with censored values in Group 1 simply because they worked with other workers who had high exposures.

Whether imputed bioassay values are higher or lower is of little use when trying to interpret a coworker intake model because some percentile of the distribution of chronic intake is assigned to the worker, not the imputed values of censored bioassay results used to construct the coworker model. For example, in a coworker model, workers are usually assigned the 50th or 95th percentile of the distribution. Thus, although Group 2 has lower imputed values than Group 1, they have similar 50th percentiles and Group 2 has higher 95th percentile doses than does Group 1.

At the bottom of page 23, SC&A states, "… to obtain *K* TWOPOS estimates. These estimates are averaged for each worker to obtain the final TWOPOS results for use in the next step of intake modeling." That is not how ORAUT-RPRT-0096 [ORAUT 2019c] describes the process and is not how imputation was done for OTIB-0081. For $K = 1$, the censored data are imputed, TWOPOS values are calculated, a lognormal model is fit, and the values for geometric mean and geometric standard deviation (GM_1 and GSD_1) are retained. For $K = 2$, the censored data are again imputed, TWOPOS values are calculated, a lognormal model is fit, and the GM_2 and GSD_2 are retained. This process is repeated *K* times, so that there are *K* GMs and *K* GSDs. These *K* GMs are averaged to come up with a final GM, and the *K* GSDs are averaged to come up with a final GSD. The final GM and GSD are used in the intake modeling step.

OBSERVATION 2

> *A scoping assessment of the use of coworker bioassay data that are significantly less than the MDA versus an alternate missed dose approach concluded that, while intakes and doses are significantly higher using a missed dose approach in most of the sample calculations, the overall effect on resulting probability of causation (POC) values was relatively minor, and, in most cases, the coworker-derived POC bounded the missed dose evaluation. This appears to be due to the effect the statistical distribution has on resulting POC values, namely, the use of a triangular distribution for missed dose evaluation versus a lognormal distribution for coworker data (see section 3.3).*

NIOSH Response

Finding 2 and Observation 1 imply that the coworker doses will be unfairly small because values less than the MDA are used in the distribution, while Finding 3 provides an example of the coworker intakes exceeding those derived from the missed dose approach and indicates that this is also unfair. Observation 2 then goes on to demonstrate that, although there can be some significant differences in the derived doses, there is very little difference in the probabilities of causation between the two methods, which is the quantity of interest in a compensation decision.

The contradictory nature of the findings and observations demonstrates that there cannot be a direct, systematic comparison between missed dose, which is calculated from person-specific bioassay results and employment history, and coworker intake, which uses a compilation of many results from many workers to assemble a distribution for all potentially exposed individuals at a site.

These two types of assessments are assigned for different purposes and therefore cannot be compared. This includes accounting for the uncertainty in the evaluation, which is a major component of 42 *Code of Federal Regulations* (CFR) Part 81, one of the guiding rules of this program [Guidelines for determining probability 2019]. In addition, 42 CFR Part 82 says, "When conducting dose reconstruction for a compensation program, our primary concern will be to ensure the assumptions used to estimate doses are fair, consistent, and well-grounded in the best available science" [Methods for conducting 2002]. In the case of missed dose, there is individual-specific information that brackets the intake and intake period so the use of the triangular distribution is therefore appropriate. Missed dose will vary from one person to the next because, in addition to dependency on the MDA, it is dependent on when bioassay was collected relative to the start of intake. For the unmonitored individual, there is more uncertainty, so the dose is assigned as a lognormal distribution with a minimum GSD of 3. The distribution is determined based on best statistical analysis practices. When assigning coworker intakes, the 50th or 95th percentile is assigned depending on the worker's potential for exposure based on a review of the worker's records. Given the same dose, the lognormal distribution will yield a larger probability of causation.

OBSERVATION 3

> *Available trivalent logbook data show notable differences with the number of reported samples taken in 1980 and 1982. These years, and any changes in operations, are not discussed specifically in OTIB-0081. However, it is noted that a future NIOSH report on americium exposure potential at SRS is pending that may address the apparent gaps in the data (see section 4.2).*

NIOSH Response

Figures 16 and 17 are deceptive in their presentation format due to the truncation of the *y*-axis above zero; no year falls below 70%. Reporting the relative number of samples annually as a percentage likewise does not present an accurate picture. Samples are not necessarily analyzed in the same month or even year as when they are collected, which makes year-by-year comparisons difficult. It is more informative to compare the total number of samples collected or analyzed with the summary reports over a longer time interval.

Over the entire period from 1963 through 1987 provided in OTIB-0081 Table 4-1, there were 18,293 americium samples in the logbooks. Over the same period, the bioassay summaries reported 18,153 americium samples, 140 less. During the 1980s, there were 3,111 americium samples in the logbooks and 3,148 reported in the summaries, a difference of only 37 samples, 1.2% of the total samples reported in the summaries. Given the minor difference in the number

of samples reported in the summaries and those actually found in the logbooks, there is no apparent data gap.

OBSERVATION 4

> *OTIB-0081 does not provide a statistical comparison of the two stratified groups as prescribed in the coworker implementation guide. The various coworker models were stratified based on the a priori assumption that exposure potential between CTWs and nonCTWs was different (see section 5.1).*

NIOSH Response

As noted, NIOSH made the a priori decision to stratify the dataset based primarily on the difference in exposure potential between the two groups due to the nature of the work typically conducted by each strata. The coworker implementation guide does recommend a statistical analysis be performed to determine if the two datasets should actually be modeled separately. There have been discussions on the topic of stratifying using an a priori decision and/or a statistical analysis by the Advisory Board on Radiation Workers and Health Special Exposure Cohort issues workgroup, SC&A, and NIOSH. This issue was also raised during the SC&A review of Revision 03 of OTIB-0081.

As noted in previous responses, the a priori decision was aided by the fact that there is an abundance of bioassay data and worker classification information for both strata for most radionuclides. Additionally, proceeding with this process was viewed as more timely than performing the additional statistical analysis for the SRS coworker effort.

OBSERVATION 5

> *SC&A believes a quantitative assessment of available job plans, rather than a qualitative basis, is appropriate to determine that prime contractor and subcontractor CTWs are part of the same exposure strata. Such an assessment has been performed by NIOSH, and a report of their findings has recently been issued (NIOSH, 2019d) (see section 5.1).*

NIOSH Response

ORAUT-RPRT-0092, *Evaluation of Bioassay Data for Subcontracted Construction Trade Workers at the Savannah River Site*, was published on 6/14/2019 [ORAUT 2019b]. The chief conclusion of this report indicates that sub-CTWs without internal monitoring through 1989 can be assigned coworker excretion rates from ORAUT-OTIB-0081 Revision 04.

Additionally, a white paper was issued by NIOSH that developed and compared example intake models for prime versus subcontracted CTWs for selected years at SRS. The *Savannah River Site Plutonium Construction Trade Worker Stratification Refinement* white paper based this exercise on uncensored (via NOCTS and SRS laboratory books) plutonium bioassay data from

1974, 1977, 1980, 1983, and 1986 [NIOSH 2019]. Only CTW data were used and stratified by prime versus subcontracted workers. As a result of this limited exercise, NIOSH believes it is reasonable to combine all CTWs into a single stratum for the assignment of intakes.

As noted in the SC&A review, the former document was not available at the time of the OTIB-0081 Revision 04 review; therefore, no additional analysis is warranted at this time.

OBSERVATION 6

> *SC&A acknowledges that there are inherent difficulties in correctly associating individual workers with the correct CTW/nonCTW strata. This is particularly true for job titles that could potentially be included in either stratum (e.g., General Service Operators, Assistants/Helpers, Foremen). SC&A suggests a scoping analysis in which such borderline job titles are removed to ascertain the effect on the resulting distributions. Such an analysis would help determine whether current strata designations are sufficient or a more rigorous approach to individual job classification is warranted (see section 5.2).*

NIOSH Response

SC&A suggests what they call a scoping analysis. The correct term for this is a sensitivity analysis. A sensitivity analysis is used to determine how sensitive the final results are to changes in the input parameters (like CTW designation). NIOSH would suggest such an analysis only be done if the CTW designation issues in Section 5.2 cannot be resolved by other means.

If a sensitivity analysis is then required, there should be one sensitivity study done, where all interested parties agree on the details. SC&A suggests removing borderline job titles to attempt to determine the effect on the final results. Removing borderline job titles would probably lead to having to combine more years than was done in OTIB-0081. Removing borderline job titles would also only answer the question of whether borderline job titles should be included in coworker modeling, not the effect that they have on the final distributions.

NIOSH suggests putting job titles into three categories: definitely CTW, definitely non-CTW, and questionable, and performing the analysis first with the questionable job titles in the CTW group and then with the questionable job titles in the non-CTW group. Those two analyses could then be compared to determine the effect of the borderline job titles. All interested parties would also need to discuss, a priori, how these analyses would be compared and examine such issues as:

- Should the annual GMs and GSDs from TWOPOS fits be compared, or should the intake rates be compared?
- Is the concern statistical significance or practical significance?
- What constitutes a practically significant difference for this comparison?

OBSERVATION 7

The results shown in attachment A of OTIB-0081 demonstrate a high degree of confidence that the acceptable error rates are within the goals established for each test. However, this conclusion is dependent on the assumption that payroll ID issues identified would not affect the resulting coworker distributions (see Section 6.5).

NIOSH Response

In several places in Section 6 of the SC&A document, there seems to be some confusion over the types of test results included in Attachment A of OTIB-0081. They are not all completeness tests, which is mentioned throughout Section 6. There are completeness tests, transcription tests, and CTW designation tests. In an attempt to avoid confusion, the numbered tests from SC&A Table 18 are reorganized in Table 3 below (numbers shown in bold red text), along with some notes.

Note that the entry in SC&A Table 19 for Test 2a is incorrect (also described in Section 6.1.2). Test 2a was not done using sequential sampling; it was done using the method described in ORAUT-RPRT-0086, *Internal Dosimetry Coworker Data Completeness Test* [ORAUT 2017], with a compression factor (CF) of 1. After it failed, Test 2b was done using that method with a CF of 5.

Table 3. Numbered tests from SC&A review.

Test Type	Rev. 4 In Vitro	Rev. 4 In Vivo	Rev. 4 Np Logbook	Rev. 3 Am Logbook	Rev. 3 Tritium	MOT MFPG[a]
Completeness	sequential **1**	CF=1, CF=5 **2**	census **3**	Pre-dated RPRT-0086	Pre-dated RPRT-0086	Pre-dated RPRT-0086
Transcription	**4**	PR **7**	PR **6**	**5**	**12**	PR **8**
CTW Designation	**10**	**9**	**11**	Not tested	**13**	Not tested

a. MFPG = mixed fission product-gamma.

Because there are three different types of tests included in the SC&A summary in Table 19, it should be noted that the "Number of misses" column means different things for each type of test. It is the number of missing results for completeness testing, the number of typographical errors for transcription testing, and the number of misclassified results for CTW designation testing. Similarly, the "Error rate (%)" column means missing rate for completeness testing, typo rate for transcription testing, and misclassification rate for CTW designation testing.

In the last paragraph of Section 6.1.1, SC&A states, "Despite the problems of unequal weighting, the very low estimated error rate (less than 1 percent) for the in vitro completeness test makes it unlikely that the 95 percent [upper confidence limit] would exceed the 5 percent success

criterion." Despite the sample size being chosen by other methods (test 1), the 95% confidence interval was calculated in accordance with ORAUT-RPRT-0086 [ORAUT 2017] (as SC&A notes in the previous paragraph), so the interval is sound and is less than 5%.

There are paragraphs in Section 6.5 that describe the calculation used to come up with the values in the "Total" row of Table 19. Because there are three very different types of tests being done among the 13 numbered tests (some with a 1% criterion, some with 5%), it is inappropriate to calculate one final interval to describe the entire group of quality assurance (QA) tests done for the various datasets used in OTIB-0081. Each individual test was a success, so the entire group of QA tests for OTIB-0081 should be considered successful. There is no need for a final interval to reach this conclusion.

SC&A states:

> *In conclusion, the results shown in attachment A of OTIB-0081 demonstrate a high degree of confidence that the acceptable error rates are within the goals established for each test. This conclusion is based on the presumption that the large number of payroll prefix-matching errors and other PRID issues encountered in the noted rows of table 19 would not affect the outcome of coworker modeling or the CTW/nonCTW classification of workers. Were this presumption not true, the favorable conclusion reached here would be reversed.*

Much work was done to ensure that all of the payroll prefix issues not counted in the transcription tests would not place the worker in the wrong CTW/non-CTW category and therefore have no effect on the coworker distributions. If the payroll prefix presumption was not true, it would only affect the three transcription tests (tests 6, 7, and 8, marked with a blue "PR" in Table 3) for which payroll prefix was an issue. The other transcription tests and all of the completeness and CTW tests are unaffected by the payroll presumption.

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ATTACHMENT A: NOCTS CLAIM NUMBERS ASSOCIATED WITH CASE IDS USED IN RESPONSE TO FINDING 5

NOCTS Claim Numbers Associated with Case IDs Used in Response to Finding 5

NIOSH Claim ID	ID
[redacted]	BA
[redacted]	BB
[redacted]	BC
[redacted]	BD
[redacted]	BE
[redacted]	BF
[redacted]	BG
[redacted]	F
[redacted]	BI
[redacted]	BJ
[redacted]	BK
[redacted]	BL
[redacted]	BM
[redacted]	BN
[redacted]	BO
[redacted]	BP
[redacted]	C
[redacted]	BR
[redacted]	BS
[redacted]	BT
[redacted]	BU
[redacted]	BV
[redacted]	BW
[redacted]	BX
[redacted]	BY
[redacted]	BZ
[redacted]	CA
[redacted]	CB
[redacted]	CC
[redacted]	CD
[redacted]	CE