MEMO

TO: SEC Issues Work Group

FROM: SC&A SEC Issues Team

SUBJECT: SC&A's Preliminary Review and Comments on Three NIOSH White Papers Related to Coworker Modeling

DATE: July 25, 2014

SECTION 1. EXECUTIVE SUMMARY

NIOSH has provided SC&A and the SEC Issues Work Group with three new white papers related to coworker modeling in an SEC context entitled:

(1) *Draft Criteria for the Evaluation and Use of Internal Exposure Coworker Datasets* (referred to as 'Draft Coworker Criteria' in this memo). Dated June 17, 2014 (NIOSH 2014a)

(2) *Evaluation of Differences between Strata Coworker Models*. Dated July 11, 2014 (NIOSH 2014b)

(3) *NIOSH's Reconsideration of the Application of the OPOS Methodology: Allowance for Time-Weighted Averaging*. Dated June 17, 2014 (NIOSH 2014c)

SC&A's evaluation of each of these white papers is discussed in Sections 2–4, and represents a preliminary review to facilitate discussion during the upcoming SEC Issues Work Group meeting on July 28, 2014.

It is SC&A's view that the overarching issues can be grouped into two separate topics of discussion:

- The ability to establish and compare different worker strata in order to evaluate the representativeness of a proposed coworker model(s) and its application to workers with varying exposure potential.
- The appropriateness of the mechanism by which resultant coworker intakes are calculated [One Person-One Sample (OPOS), Time-Weighted OPOS, "Pooled Data" approach]

It is SC&A's contention that the former topic is essential in order to demonstrate that a given coworker model will represent those workers who may have had higher exposure potential, and that any application of resultant coworker intakes will bound such exposures. In order to accomplish this comparison, NIOSH developed the OPOS statistic and related strata comparison methodologies as outlined in ORAUT 2012a. NIOSH then modified the process of calculating the OPOS statistic (NIOSH 2014b) in order to better account for the time weighting between a given sampling result and the subsequent observed sample. In this way, samples with long periods between the next sample would be given more “weight” in the OPOS calculation than samples with very short temporal duration to the next sample (such as would be expected for incident-based sampling).

SC&A acknowledges that utilizing a temporal weighting criteria represents a technical improvement over the original OPOS statistic, which gave equal weight to each sample in a given evaluation period. However, SC&A does not feel that this improvement obviates the concern over comparing two groups of worker strata that do not have sufficiently similar monitoring protocols. ***It is SC&A’s opinion that without a clear connection between the sampling protocol of two worker strata, then a scientifically accurate and defensible comparison is not feasible.*** SC&A further acknowledges that this important issue is independent of whether the comparative distributions are calculated using the original unweighted OPOS statistic, time-weighted OPOS statistic, or the “Pooled Data” approach.

The second main topic for discussion relates to how the coworker intake values are calculated, or more specifically, how the distribution of excreta values is obtained for a given time period. The OPOS mechanism (both unweighted and time-weighted) was mainly created to diminish the confounding factors of “data dominance” and “correlation.” The former term refers to situations where a single worker or small groups of workers have significantly more sampling results than the overall worker population. The latter term refers to the fact that many radionuclide intakes take significant time to clear the body and thus consecutive bioassay samples may reflect a single intake scenario and therefore are not independent. SC&A, in our February 2014 report on OPOS (SC&A 2014) notes that the problem of correlation is not obviated by OPOS. Furthermore, the OPOS mechanism represents a data reduction technique and thus reduces the number of data points available for comparison, which in turn reduces the power of the statistical tests employed to test for differences in strata. OPOS also removes an element of uncertainty when compared to the traditional pooled data models, which reduces the geometric standard deviation (GSD) of the OPOS distribution. While alleviating any observed issues with data dominance, this will likely result in lower calculated coworker intake values. ***Therefore, SC&A’s position remains that the OPOS mechanism (whether unweighted or time-weighted) for calculating coworker distributions should only be used in cases of clear data dominance***. A typical example would be a worker involved in an incident/accident for which many follow-up samples were taken over a short period of time. In such a case, it would be appropriate to average these results into a single value for inclusion in the overall coworker distribution.

SECTION 2. SC&A REVIEW COMMENTS FOR NIOSH WHITEPAPER ‘DRAFT COWORKER CRITERIA’ (NIOSH 2014a)

SC&A had the following seven specific review comments based on the noted sections of the NIOSH white paper ‘Draft Coworker Criteria (NIOSH 2014a).

SC&A Comment 1: Data Completeness and Representativeness

From the Introduction (page 1, paragraph 1):

> *While the use of individual personnel monitoring is preferred in the completion of dose reconstructions, these data are oftentimes not available because either the worker was monitored and the data have been lost or the worker was potentially exposed and not monitored. In the latter case, NIOSH has observed that, in accordance with the practices in effect at the time,* ***only workers with the highest exposure potential were monitored or, in some cases, monitoring was conducted on representative members of the exposed population***. [Emphasis added]

SC&A has found during previous coworker evaluations that it is not always the case that the highest exposed classes of worker were targeted by the bioassay program. One particularly notable example was the Nevada Test Site coworker evaluation in which it was found that health physics monitors and security guards comprised the majority of the sampled worker population, yet these workers often stayed at the radiological checkpoints and seldom entered the forward areas for any appreciable amount of time. Higher risk job types, such as miners and drillers, were not sampled nearly as often and thus were severely under-represented in the proposed coworker model.

Therefore, SC&A believes that for each coworker model, the exposure potential of the monitored worker population must be evaluated to assure that the higher risk job types, temporal periods and areas are adequately represented in the resultant distribution. This can be accomplished by utilizing strata comparison techniques; secondary source term data, such as air and surface contamination monitoring; worker interviews; and campaign-specific information.

SC&A Comment 2: Data Completeness and Representativeness

From the Introduction (Page 1, Paragraph 2):

> *For dose reconstructions under EEOICPA, it is often difficult to locate a worker in a specific job at a specific location. Because of this, NIOSH has chosen to develop coworker models that cover a wide range of workers for a specific radionuclide at a specific time.*

SC&A acknowledges that often times the available datasets lack the granularity to identify and apply coworker intakes that are specific to an individual place, time, and job type, and more wide-ranging application of coworker intakes is necessitated. We also understand that in many cases (e.g., many AWEs) a single "all monitored worker" (AMW) distribution can be representative of all exposure categories. However, SC&A has also demonstrated instances where certain job types have a markedly different exposure potential than the general worker population (for example 'pipefitters,' who may have performed maintenance work on contaminated piping or ventilation equipment).

As a follow-on to SC&A comment 1, the exposure potential among different worker types must be carefully evaluated to assure that the application of a site-wide coworker model, or even a stratified model, adequately captures the intake potential to the highest exposed workers. One potential method would be to evaluate a subset of individual worker intakes for the highest exposed job types and compare those exposures to the recommended intakes based on the proposed coworker model.

SC&A Comment 3: Data Completeness and Representativeness

From Section 2.2 (Page 3, Paragraph 2):

> *It must be established who was monitored and why they were monitored. In this evaluation there must be some demonstration that the monitored population consisted of: 1) a representative sample of the exposed population or 2) the workers with the highest exposure potential. In these cases, the assignment of a coworker dose from the distribution of measured values would either be claimant favorable in the first case or representative of the worker's exposure in the second case.*

SC&A assumes that the third and final sentence shown above was an editorial error and the author intended to say that "case 2" would be claimant favorable, while "case 1" would be representative of the worker's exposure. Nonetheless, SC&A agrees that a positive review and finding that one of these two cases applies is essential for an acceptable coworker model. An explicit corollary is that one of these two should apply across all exposed job types. In other words, representativeness must be shown for job types when working conditions indicate that exposures differ by location. For instance, exposures to fission products are likely to be higher around a high-level waste tank farm than in a reactor building during normal operation.

SC&A Comment 4: Coworker Models based on Incident Sampling

From Section 2.2 (Page 3, Paragraph 3):

> *If one can demonstrate that the effectiveness of workplace administrative and/or engineering controls was adequate to prevent exposures, except during upset conditions, it may be possible to use incident-based sampling in a coworker model.*

SC&A questions the extent and feasibility to which such a concept could be adequately demonstrated. "Prevent[ing] exposures" is a pretty high bar to establish. It intimates that air contamination should be at background and not just below a given MDA that is above background. This would essentially be setting up to prove a negative—that there were no routine exposures. For instance, SC&A feels that definitive evidence would be needed that sources were sealed, etc. If such information is available and sufficient, SC&A could agree that exposures would be incident-related only.

However, an incident-related approach requires a demonstration that all incidents were actually documented, and that comprehensive and appropriate follow-up monitoring data (urinalysis/fecal/in-vivo sampling) was performed and is available. SC&A notes that interviewed workers have often stated that incidents were deliberately not documented or reported for various reasons. Additionally, construction of an incident-based coworker model is further complicated, because the line between "incidents" and recurring off-normal conditions is difficult to define and must be addressed on a case-by-case basis.

SC&A Comment 5: Strata Comparison Issues and Variability among SRS Trivalent Actinide Data

From Section 3.0 (Page 4, Paragraph 3):

> *NIOSH is considering a modification of the OPOS approach to include a time-weighted average analysis. We have conducted an analysis of the SRS americium coworker model using a time-weighted averaging technique and have determined that this method more appropriately accounts for the variability in excretion patterns, including this issue associated with carry-over from positive bioassay results in previous years.*

SC&A would like to note that the application of a time-weighted OPOS approach does not address the main concern that the ability to accurately compare different worker strata necessitates that the monitoring protocols for the two groups of workers be the same. The ability to accurately compare strata is essential to establish the representativeness of any proposed coworker model.

Furthermore, SC&A notes that the application of a time-weighted OPOS approach would not address the observed variation in measurement values among aliquots of the same trivalent bioassay sample at SRS. The observed variability, including samples indicating results both above and below the MDA, must be technically addressed to assure the accuracy and adequacy of the underlying dataset.

SC&A Comment 5: Combination of Multiple Exposure Periods into a Single Evaluation Regime

From Section 3.1 (Page 4, Paragraph 4):

> *If, because of data limitations, it is necessary to consider time intervals beyond one year in the coworker model, any changes in site practices or operations should be evaluated to ensure that the data can be validly combined.*

SC&A strongly agrees with this concept and notes that it is directly applicable to the thorium and trivalent coworker models at Savannah River Site (SRS). In those instances, the following years were combined: 1966–1968, 1981–1982, and 1987–1989. Based on RPRT-0055, it appears that these years were grouped together solely to gain the requisite number of samples for strata comparison. Specifically, RPRT-0055 states:

> *To have enough data to perform the comparisons, 1966 to 1968, 1981 to 1982, and 1987 to 1989 were combined to form three merged periods. This was necessary due to the small population size of the CTW stratum.* (ORAUT 2012a)

Therefore, a detailed investigation and analysis of exposure potential for these combined periods is warranted to establish that the year included in the combined grouping is sufficiently similar to enable the combination into a single evaluation period. This would be in accordance with the noted section from 'Draft Coworker Criteria' noted above.

SC&A Comment 6: Application of Coworker Intakes to Different Worker Strata

From Section 4.0 (Page 5, Paragraph 2):

> *As described above, workers with a higher potential for exposure would be considered to have been exposed at the 95th percentile of the general worker distribution. Thus, the geometric mean and standard deviation of the stratified subset should be compared to the 95th percentile of the general distribution. If it can be shown that the use of the full distribution in the stratified subset is more favorable than using the 95th percentile of the general distribution, the full distribution of the stratified subset should be used for those workers that fall into this category.*

The above narrative appears to assume the following:

(1) A valid comparison among different strata is feasible

(2) There is sufficient data in the subsets (or worker strata) to construct a separate coworker model

These two conditions must be met in order to construct an acceptable coworker model, either stratified or site-wide.

Often times, the coworker model is based on a very large number of workers with little to no exposures and only a comparatively small subset of the population has bioassay results > MDA. Therefore, the 95th percentile can be very low (<MDA) if the number of unexposed monitored workers is very high. In these cases, significant care must be taken when comparing the results of a given subset of workers to the upper tail of a site-wide (all worker) model.

SC&A Comment 7: Comparison of the "Full Distribution" of Stratified Coworker Intakes to the Upper Percentiles of a Site-Wide Model

From Section 4.0 (Page 5, Paragraph 3):

> *Preliminary results seem to indicate that PC outcome associated with the full distribution can be generated by using a constant value that is around the 84th percentile. If this were true, then it would make sense to stratify distributions only if the ~84th percentile of the full distribution of the stratified dataset is larger than the 95th percentile of the general distribution of all monitored workers.*

There is a monotonic relationship between the expected value and the percentiles of a lognormal distribution. This relationship does not depend on the geometric mean (GM) of the distribution, only on the GSD = e^{σ}. Any percentile of a lognormal distribution may be expressed as $p = GM \cdot \exp(z_p \sigma)$, where z_p is the p^{th} percentile of the standard normal distribution. The expected value of the lognormal distribution is $E(X) = GM \cdot \exp(\sigma^2/2)$. By inspection, the expected value is equal to the percentile p* located at $z^* = \sigma/2$. The corresponding percentile is $p^* = 100\Phi(z^*)$, where $\Phi(z)$ is the value of the standard normal cumulative distribution function at z.

The percentile p* that equals the expected value at each value of the GSD is shown in the table below. For the typical GSDs encountered in exposure assessment, the expected value ranges from the 70th percentile to the 85th percentile, with a central value of approximately the 80th percentile at a GSD of 5. Hence, it is not unexpected that the PC obtained using a single intake near the 80th percentile will be nearly the same as the PC generated using the full distribution.

GSD	σ=ln(GSD)	$z^*=\sigma/2$	$p^*=100\Phi(z^*)$
2	0.69	0.35	64
3	1.10	0.55	71
4	1.39	0.69	76
5	1.61	0.80	79
6	1.79	0.90	81
7	1.95	0.97	83
8	2.08	1.04	85

What does this have to say about the comparison of the construction trades worker (CTW) 84th percentile with the all monitored worker (AMW) 95th percentile? It's much the same as saying that a subgroup (like CTW) will be treated differently if their mean value exceeds the AMW 95th percentile. The OPOS/ maximum possible mean (MPM) procedure could be used to calculate the mean value, so it would be as easy to implement. This appears less arbitrary than using a rule that the CTW 84th percentile exceeds the AMW 95th percentile. However, neither method for selecting who gets special treatment considers uncertainty in estimating the percentiles or the mean value. The paper is expressed in terms of point estimates of the 84th or 95th percentile. There are usually large uncertainties involved in the estimation of upper percentiles using a small sample size in one or both groups. Comparisons based on the difference between two point estimates will have large decision errors.

Given that the white paper 'Draft Coworker Criteria' focuses attention on point estimates for comparing the upper percentiles of two populations, other ways to look at this problem should be considered. Perhaps a better method would be to use a formal statistical test. Hypothesis tests explicitly account for uncertainty when making a decision of this type. For example, a non-parametric quantile test could be used here to test if a larger than expected proportion of CTW is found among the workers above the 84th percentile of the AMW distribution. If so, then the group should be treated differently. The quantile test is also easy to implement, and avoids many of the problems associated with evaluating the confidence intervals for comparing the estimated upper percentiles and/or expected values. The test may be used with up to 84% non-detects in the data.

In addition, looking only at the workers above the 84th percentile (top 1 out of 6) is somewhat arbitrary here. The 75th or 80th percentile would work as well, and would provide a larger sample size and greater power for the quantile test. But the 84th is at the "+1-sigma" mark on the normal distribution, and it seems to have some favor historically with NIOSH. To consider a percentile any higher than the 84th is likely infeasible, because the number of workers in the upper tail would be too small for evaluation.

SECTION 3. PRELIMINARY REVIEW OF THE WHITE PAPER "EVALUATION OF DIFFERENCES BETWEEN STRATA COWORKER MODELS"

3.1 Introduction

ORAUT-RPRT-0053 (ORAUT 2012b) provided a statistical approach for the evaluation of stratified coworker models. A two-tiered evaluation was proposed where the stratified distributions are first compared on a year-by-year basis to determine if any of the individual distributions are significantly different based on the Monte Carlo permutation test or the Peto-Prentice test. If a significant difference is observed in any time interval, then a test of practical significance was proposed to determine if there is a practical difference in these cases. This test compares the slopes of the chronic intake models in the time periods with a statistically significant difference. SC&A 2013 noted that these tests only detect relatively large differences in the GM, particularly when the small sample sizes in one or both strata are small and the distributions have large GSDs.

The recent NIOSH white paper titled, *Evaluation of Differences between Strata Coworker Models* (NIOSH 2014b) presents an alternative approach to coworker modeling based on the 95th percentile of the AMW distribution. In this approach, the 95th percentile of the full AMW distribution would be applied in IMBA for those "*unmonitored workers who are judged to have been highly exposed*."

Although the approach presented appears reasonable, a major short-coming is that the paper does not provide a specific method for determining which unmonitored workers meet the italicized criterion in the statement above. As noted by NIOSH, the statistical tests may fail to detect differences due to inadequate power with the small number of OPOS values available for some strata. If the statistical tests have inadequate power in these cases, what procedure will be used to "judge" which unmonitored workers require use of the AMW 95th percentile?

An example evaluation is provided in the white paper comparing the IMBA PC results obtained using either:

- The 95th percentile of the AMW lognormal distribution
- The full lognormal distribution observed for the stratum

In the selected example, the GM of the selected stratum is higher than that of the AMW distribution, so there is some reason to suspect that the stratum may require special attention. However, the GSD is lower than that of the AMW distribution, so this example does not provide a clear example of how to judge when to use the recommended procedure. Other general issues raised by the example evaluation are discussed in the following section.

3.2 Interpretation of the Results of the Example Evaluation

In the white paper, the AMW 95th percentile approach was applied to the example coworker models provided in Figures A-1 and A-3 of Attachment A to ORAUT-RPRT-0053 (ORAUT

2012b). In this example, the full distribution that includes AMWs has a GM of 0.7509 and a GSD of 4.055, while the stratified subset has a GM of 0.9306 and a GSD of 3.753. NIOSH provides the following motivation for this approach:

> *As described previously, the 95th percentile of the full distribution will be applied to those unmonitored workers who are judged to have been highly exposed. In this case, the 95th percentile of the distribution for all monitored workers is 0.7509 × (4.055$^{1.645}$) = 7.51. This value is used is to account for the fact that the full distribution may be comprised of several distributions and the most highly exposed unmonitored workers could fall into the upper tail of the all worker distribution.* ***In this way, there is less than a 5% chance that the unmonitored workers' exposure is greater than the value used in his or her dose reconstruction***. [Emphasis added.]

The example given in the paper shows that the AMW 95th percentile generates a higher probability of causation (PC) than when the full distribution of the stratified subset is used to generate a PC, and it is a factor of 1.6 times higher. However, it should be noted that the value of the 95th percentile of the AMW distribution (7.51) is equal to the 94.3 percentile of the stratified distribution. Thus, the example suggests an alternative explanation: that the increase in PC is systematic, i.e., when the 94th or 95th percentile of any distribution is used is used in IMBA, this will generate a PC that is approximately 1½ times higher than if the full distribution were used. Given this possible alternative explanation, it is not clear that the example provides a valid comparison of the AMW and stratified datasets. Unfortunately, the paper does not report what happens when the full AMW distribution is applied. Another IMBA run using the full AMW distribution may shed light on this issue.

The bolded section of the passage above also raises questions. In the example evaluation, we found that slightly over 5% of the stratified distribution exceeds the AMW 95th value of 7.51. Thus, it is approximately true (in that example only) that 5% of the unmonitored workers in the more highly exposed stratum would have exposures greater than the value used in his or her dose reconstruction. To determine if this statement is true in the general case, it is necessary to determine what fraction of the stratified dataset lies below the AMW 95th percentile. That issue is addressed in the following section.

3.3 Coverage of the All Monitored Worker 95th Percentile

NIOSH proposes that the 95th percentile of the AMW distribution is a claimant-favorable value to use in IMBA for unmonitored workers in a stratified subset of workers (say Group B) who may have been more highly exposed. If the AMW data follow a lognormal distribution with a geometric mean GM_{AMW} and geometric standard deviation GSD_{AMW}, then the 95th percentile of the AMW distribution is:

$$AMW_{95} = \exp(\mu_{AMW} + z_{.95}\sigma_{AMW})$$

Here μ_{AMW} = log(GM_{AMW}), σ_{AMW} = log(GSD_{AMW}) and $z_{.95}$ = 1.645 is the 95th percentile of the standard normal distribution.

The claimant favorability of this approach hinges on whether the AMW_{95} value will "cover" a high proportion of the Group B distribution. To measure the amount of coverage that the *AMW* 95th percentile value provides, we determine what fraction of Group B workers are at or below this value. Let μ_B = *log*(GM_B), σ_B = *log*(GSD_B) and z_c be the c^{th} percentile of the standard normal distribution. The coverage c is found at the point y_c =AMW_{95} on the Group B distribution function where:

$$y_c = \exp(\mu_B + z_c\sigma_B) = AMW_{95} = \exp(\mu_{AMW} + z_{.95}\sigma_{AMW})$$

To solve for c, we first obtain:

$$z_c = \frac{\mu_{AMW} - \mu_B + z_{.95}\sigma_{AMW}}{\sigma_B}$$

Then the coverage is:

$$c = \Phi(z_c)$$

The function Φ represents the cumulative distribution function of the standard normal distribution.

As an example of the use of coverage to assess claimant favorability of the AMW_{95} approach in specific applications, an assessment was conducted using the exotic trivalent radionuclide bioassay data for AMWs and CTWs at SRS reported in Appendix A of ORAUT-RPRT-0055 (ORAUT 2012a). Table 1 shows the coverage of the 95th percentile of the AMW distribution when applied for CTW at the SRS site from 1968 to 1988. In several time periods, the CTW distribution was estimated using more than one year of data. In these cases, a representative year was selected for the AMW distribution.

The coverage ranges from a minimum of 83.8% to a maximum of 99.6% with a mean of 93.3%. These data do not support the claim that the AMW 95th percentile is only exceeded by 5% of the unmonitored CTWs, but this may hold approximately on average for these specific datasets. The proportion of CTWs that exceed the AMW_{95} value ranges from approximately 16% down to 0.5%. On average over all years, 6.7% of the CTWs exceed the AMW 95th percentile for these SRS exotic trivalent radionuclide datasets.

Table 1. Coverage of the AMW 95th Percentile

AMW Period	CTW Period	μ=log(GM)*		σ=log(GSD)*		Coverage	
		AMW	CTW	AMW	CTW	z(c)	c (%)
1968	1966–1968	-1.4	-2.0	0.9	1.7	1.2	89
1969	1969	-1.2	-0.6	1.1	0.6	2.0	98
1970	1970	-1.5	-1.4	0.8	0.5	2.6	99.6
1971	1971	-1.8	-1.8	0.9	0.7	2.0	98
1972	1972	-2.6	-2.6	1.2	1.0	1.9	97
1973	1973	-4.8	-4.7	2.1	2.2	1.5	93
1974	1974	-4.7	-4.3	2.3	1.8	1.9	97
1975	1975	-4.6	-4.7	2.0	2.1	1.6	95
1976	1976	-4.3	-4.2	1.8	1.7	1.7	96
1977	1977	-5.6	-5.9	2.4	2.6	1.6	95
1978	1978	-3.7	-4.2	2.3	2.2	2.0	97
1979	1979	-3.7	-3.6	2.4	2.6	1.5	93
1980	1980	-4.7	-4.7	2.0	2.4	1.4	92
1981	1981–1982	-7.0	-5.8	3.2	4.0	1.0	85
1983	1983	-5.2	-4.4	2.1	2.0	1.3	91
1984	1984	-5.1	-5.3	2.4	4.2	1.0	84
1985	1985	-4.4	-3.0	2.3	1.7	1.3	91
1986	1986	-5.6	-6.5	2.4	4.1	1.2	88
1988	1987–1989	-4.0	-4.7	2.0	2.4	1.7	95
						Mean	93.3
						Minimum	83.8
						Maximum	99.6

*Source: ORAUT 2012b, GMs and GSDs reported in Figures A-39 to A-57 and A-72 to A-90.

SECTION 4. PRELIMINARY REVIEW OF THE WHITE PAPER "NIOSH'S RECONSIDERATION OF THE APPLICATION OF THE OPOS METHODOLOGY: ALLOWANCE FOR TIME-WEIGHTED AVERAGING

4.1 Summary

Although the best approach to coworker modeling would be to calculate actual intakes for all monitored workers in the intake regime, and to use that distribution for coworker modeling, NIOSH has stated they do not have the resources to do these calculations, and a more expedient approach is required based on excretion rates, not intakes. The concept of aggregating the bioassay data used for coworker modeling to create an OPOS statistic for each time period was proposed by NIOSH in the report, *Analysis of Stratified Coworker Datasets* (ORAUT 2012a). Current procedures fit a probability distribution to the full set of bioassay results from all workers with samples to derive the 50th and 84th percentile excretion rates used for coworker intake modeling.

The OPOS proposal was extensively discussed during the meeting of the Special Exposure Cohort (SEC) Work Group on September 26, 2013 (ABRWH 2013). SC&A was tasked at that meeting to review the various reports that have been prepared by NIOSH and SC&A on the topic, as well as the discussion during the Work Group meeting. SC&A findings (SC&A 2014) recommended a weighted approach to the mean value problem posed by OPOS. In this approach, the mean annual excretion rate is defined as a time-weighted average obtained by integrating excretion rates over the time period. This approach requires that a time-weighted average be used to estimate the mean excretion rate.

NIOSH recently proposed (NIOSH 2014c) a revised version of the OPOS procedure named Time-Weighted OPOS. Time-Weighted OPOS is the weighted average of the bioassay results using the number of days between the measurements as weights. If the samples were collected at equally spaced times, the Time-Weighted OPOS statistic reduces to the same result as the original un-weighted version of OPOS.

NIOSH applied the weighted OPOS methodology to the americium bioassay data collected at the SRS. The results of the comparison of the original OPOS to the Time-Weighted OPOS approach showed that the two statistics are the same in about 83% of the cases. In about 15% of the cases, the difference between the two statistics is less than 1 dpm/day in absolute value, and only 2% of the cases show differences between the two statistics of more than 1 dpm/day in absolute value, with some extreme cases where the two statistics are very far apart. NIOSH concluded that there is no evidence that one of the two methods is more claimant favorable than the other for americium at SRS.

Evidence should be provided to support this conclusion. While a difference of 1 dpm/d does not sound like much at face value, it could make a significant difference in the calculated intake. Considering that most measured urinalysis samples are below the detection limit of 0.3 dpm/d, a change of 1 dpm/d could have a large effect in some cases. For example, the difference in the calculated intake rate based on 0.3 dpm/d and 1.3 dpm/d is a roughly a factor of 4. If lower actual measurement values were used in calculating the OPOS result, this factor will be larger.

SC&A notes that there are a variety of ways to assign the number of days used as weights. NIOSH currently uses a "post-weighted" procedure, where the weight for bioassay result *j* is the number of days that elapse after result *j* up to the time of the next result. The final result is then assigned the number of days up to the end of the year. This "post-weighted" procedure does not account for the period of time at the beginning of the year before the first excretion result. To account for this period, NIOSH introduces an initial term at *j* = 0, and specifies several rules to define the result used for the initial time period. If there is a sample in the previous year, it is used for the for the excretion rate in the initial period. If there is no sample in the previous year, then the first result of the year is used for the initial period (and the one following).

SC&A's original recommendation used the number of days in the period before the result *j* for its weight, reasoning that the intakes reflected in the excretion occurred before the sample was collected, not after. This "pre-weighted" procedure assigns the number of days in the initial period as the weight for the first excretion result, but does not account for the final period of time from the last sample to the end of the year. This period could be addressed by using the first excretion result in the following year, in mirror image to what is done with the NIOSH post-weighted procedure.

On the surface, the "pre-weighted" and "post-weighted" methods appear to be quite similar, but may lead to quite different results for years with an incident. If the incident occurs before any other results that year, then the first excretion result of the year is a very high number and the weight assigned to this initial will have a high degree of influence on the Time-Weighted OPOS result. Since incidents almost always include follow-up samples soon after the initial result, the time weight assigned to the high initial result will be very small, often only a day or two, if the post-weighted procedure recommended by NIOSH is used.

Since incidents are rare events, it is most likely that the excretion result for that worker in the previous year will be much lower than the initial incident result and will be applied to the entire initial period if post-weighting is used. If there is no result in the previous year, then the initial incident result will be assigned for the entire initial period. Thus, the first result may be assigned a relatively high weight or a very small weight, depending solely on whether an (unrelated) excretion result was or was not collected in the previous year. SC&A suggests that this arbitrary weighting outcome be avoided by using the "pre-weighted" approach.

4.2 Background

The concept of aggregating the bioassay data used for coworker modeling to create an OPOS statistic for each time period was proposed by NIOSH in the report, *Analysis of Stratified Coworker Datasets* (ORAUT 2012a). Although the best approach to coworker modeling would be to calculate actual intakes for AMWs in the intake regime and to use that distribution for coworker modeling, NIOSH stated they did not have the resources to do these calculations and a more expedient approach was required. Current procedures fit a probability distribution to the full set of bioassay results from all workers with samples in the time period to derive the 50th and

84th percentile excretion rates used for coworker modeling. These percentiles are used to calculate intakes corresponding to the 50th and 84th percentile excretion rates. This procedure uses the distribution of all bioassay results from all workers and is referred to as the pooled-data approach.

As an alternative to the pooled-data approach, the OPOS approach to coworker modeling was recommended by NIOSH as introducing a new scientific credibility to the intake modeling process that did not exist in the previous pooled-data approach. As originally proposed, the OPOS method calculates the arithmetic average of all urine samples for one individual in one year (or other specified time period). The resulting set of OPOS values is then used to calculate the percentiles needed for calculating intakes. NIOSH has argued that, under certain assumptions, the OPOS mean excretion rate will be proportional to the intake for that individual and thus serves as the best surrogate for the intakes of the individual worker.

The OPOS approach also was designed to address problems of data dependence and data dominance when statistical hypothesis tests are applied for comparing two strata of workers. In the former case, a number of bioassay samples following a single intake will be correlated if the radionuclide persists in the body; hence, the samples are not independent. Data dominance is when a few workers have provided such a large number of samples, as for instance following incidents, that those samples would skew the distributions used for coworker modeling. There is, of course, some overlap between data dependence and data domination, since samples following incidents are not independent.

The OPOS proposal was extensively discussed during the meeting of the SEC Work Group on September 26, 2013 (ABRWH 2013). SC&A was tasked at that meeting to review the various reports that have been prepared by NIOSH and SC&A on the topic, as well as the discussion during the Work Group meeting. SC&A was also asked (NIOSH 2013, p. 3) to be more explicit about its position on the use of the OPOS approach in coworker modeling and comparison of bioassay data of two worker strata.

SC&A presented its OPOS findings to the Work Group in the report *Draft Review of Proposed One Person-One Sample (OPOS) Approach to Coworker Modeling* (SC&A 2014). Section 7.4 of that report introduced a general approach to the mean value problem posed by OPOS. In this approach, the mean annual excretion rate is defined as a time-weighted average using integration over the year. A physical model of the integration process was proposed to motivate this approach. The true mean concentration is defined as the concentration obtained if all of the worker's excretions over the year were pooled together. If the volume excreted per day is roughly constant, then the mean concentration in the resulting mixture is the time-weighted average of all urine concentrations collected over the year.

4.3 Time-Weighted OPOS

In their most recent white paper on OPOS, NIOSH has suggested a revision to the approach for calculating the mean value of a worker's bioassay results (NIOSH 2014c). NIOSH proposes a new version of the OPOS procedure named Time-Weighted OPOS. Time-Weighted OPOS is the weighted average of the bioassay results using the number of days between the measurements as weights. If the samples were collected at equally spaced times, the Time-Weighted OPOS statistic reduces to the same result as the originally proposed un-weighted version of OPOS.

The mathematical details of the computation of the Time-Weighted OPOS are provided in Attachment A to NIOSH 2014c. To implement The Time-Weighted OPOS procedure, NIOSH has introduced three rules that apply in special circumstances:

(1) For an individual with more than one measurement in the same day, all the values (detects and non-detects) from the same day are averaged to arrive at an average daily excretion.

(2) For an individual that had a sample in the previous year, it is assumed that the last sample from the previous year is representative of the excretion from the beginning of the current year until the first sample in the current year.

(3) For an individual that had no sample in the previous year, it is assumed that the first sample from the current year is the exposure from the beginning of the current year until the first exposure observed in the current year.

The first rule addresses the problem of multiple bioassays on the same day, while the next two rules address "edge effects" that occur at the beginning and end of the time period in question, before the first sample and after the last sample. The effects of implementing these rules are discussed in the following section of the report.

NIOSH applied the weighted OPOS methodology to the americium bioassay data collected at the SRS. The results of the comparison of the original OPOS to the Time-Weighted OPOS approach showed that the two statistics are the same in about 83% of the cases. In about 15% of the cases, the difference between the two statistics is less than 1 dpm/day in absolute value, and only 2% of the cases show differences between the two statistics of more than 1 dpm/day in absolute value, with some extreme cases where the two statistics are very far apart. Overall, the average of the Time-Weighted OPOS values was about the same as the average of the OPOS values. NIOSH concludes that there is no evidence that one of the two methods is more claimant favorable than the other for americium at SRS.

4.4 Mathematical Details of Time-Weighted OPOS

Originally, the OPOS method was defined as the MPM. The formula given in the NIOSH paper for the original OPOS statistic contains an omission. The correct formula is:

$$\text{OPOS} = \sum_{i=1}^{n} x_i \,/n$$

where:

$n =$ Number of all excretion results for a person in a year

$x_i =$ Individual excretion result (can be either uncensored or censored)

NIOSH states that if there are censored excretion results, then the "face values" of these results are to be used in the formula above. No definition of the term "face value" is provided in the NIOSH paper. SC&A believes that the all measurements reported below the CL (or MDA) should be replaced by the CL (or MDA) as is done in the calculation of the MPM. In the examples in Attachment B to the paper, NIOSH does appear to use the CL for censored data, but the meaning of the term "face value" should be made clear.

The Time-Weighted OPOS method is weighted mean of the (censored and uncensored) excretion results in a year, where the results are weighted by the appropriate number of days between the measured values. The formula for the statistic computed using the Time-Weighted OPOS method is the following:

$$\text{Time-Weighted OPOS} = \sum_{j=0}^{m} y_j\, d_j \Big/ \sum_{j=0}^{m} d_j$$

Where m is the number of days when the person had excretion results in the year, y_j is the average excretion result on day j, and d_j is the umber of days assigned as the weight for the average result on day j. The use of an initial term at $j = 0$ in the equation above is one way to assign appropriate weights at the beginning and end of the year. The number of days associated with each result may be counted in many ways. If there are m days with excretion results, these days divide the year into m+1 time intervals, $j = 0, 1, \dots, m$. The sum of these intervals is the sum appearing in the denominator in equation above. Yet there are only m samples in the year which require weights.

This disparity introduces a variety of ways to assign the number of days used as weights. In Attachment B, NIOSH uses a "post-weighted" procedure, where the weight for result j is the number of days that elapse after result j up to the next result at time j+1. The final result is assigned the number of days up to the end of the year. The post-weighted procedure does not account for the period of time at the beginning of the year before the first excretion result. To resolve this, NIOSH introduces an initial term at $j = 0$, and specified two "Rules" to define the hypothetical bioassay result value used for the initial time period. The rules reduce to the choice of A or B:

A) If there is a sample in the previous year, it is used for the initial period

B) If there is no sample in the previous year, then the initial measured result at $j = 1$ is used for the initial period (and the one following)

Mathematically, these rules are implemented by defining y_0 as follows:

$$y_0 = \begin{cases} y_p, & \text{if the individual had a bioassay in the previous year} \\ y_1, & \text{if the individual had no bioassay in the previous year} \end{cases}$$

where:

y_p = last excretion result in the previous year.

The post-weighted OPOS procedure is depicted in Figure 1. Each bioassay result is assigned a weight equal to the number of days elapsed after the result until the next result. The length of the initial period (w_0 in the figure) is assigned as weight for either result A if there is a result in the previous time period, or result B if not. The contribution of the initial time period to the total integral can vary by a large amount, depending whether result A or result B is selected for this period.

SC&A originally used the number of days in the period <u>before</u> the result *j* for its weight, reasoning that the intakes reflected in the excretion occurred before the sample was collected, not after. This "pre-weighted" procedure assigns the number of days in the initial period as the weight for the first excretion result, but does not account for the final period of time from the last sample to the end of the year. This, of course, could be addressed by using the first excretion result in the following year, in mirror image to the NIOSH post-weighted procedure.

The pre-weighted OPOS procedure is depicted in Figure 2. Each bioassay result is assigned a weight equal to the number of days elapsed since the previous next result. The length of time in the final period (w_{n+1} in the figure) is assigned as weight for either result A if there is a result in the following time period (y_p^* in the figure), or result B if not. The contribution of the final time period to the total integral under these two alternative choices does not vary by as large of an amount as in Figure 1 with post-weighted OPOS.

The mathematical form of the pre-weighted OPOS estimate is similar to that of the post-weighted OPOS estimate:

$$\text{Time-Weighted OPOS } = \sum_{j=1}^{m+1} y_j\, d_j \Big/ \sum_{j=1}^{m+1} d_j$$

The weight terms d_j are defined as the number of days from result *j-1* to result *j*. For y_1, the count of days starts at the beginning of the year. The rules A and B for the pre-weighted OPOS estimate are:

A) If there is a sample in the following year, it is used for the final period

B) If there is no sample in the following year, then the final result at *j*=*m* is used for the final period (and the one before)

For pre-weighted OPOS the term y_{m+1} is defined as:

$$y_{m+1} = \begin{cases} y_{p*}, & \text{if the individual has a bioassay in the following year} \\ y_m, & \text{if the individual has no bioassay in the following year} \end{cases}$$

Where

y_{p*} = first excretion result in the following year.

On the surface, the "pre-weighted" and "post-weighted" methods appear to be quite similar, but may lead to quite different results for years with an incident. If the incident occurs before any other results that year, then the first excretion result of the year is a very high number and the weight assigned to this initial result will have a high degree of influence on the Time-Weighted OPOS result. Since incidents almost always include follow-up samples soon after the initial result, the time weight assigned to the high initial result will be very small, often only a day or two.

Since incidents are rare events, it is most likely that y_p, the excretion result in the previous year, will be much lower than the initial incident result y_1 and y_p will be used for the entire initial period. If there is no result in the previous year, then the initial incident result will be assigned for the entire initial period. Thus, the first result may be assigned a relatively high weight or a very small weight, depending solely on whether an (unrelated) excretion result was or was not collected in the previous year. SC&A suggests that this arbitrary weighting outcome be avoided by using the "pre-weighted" approach.

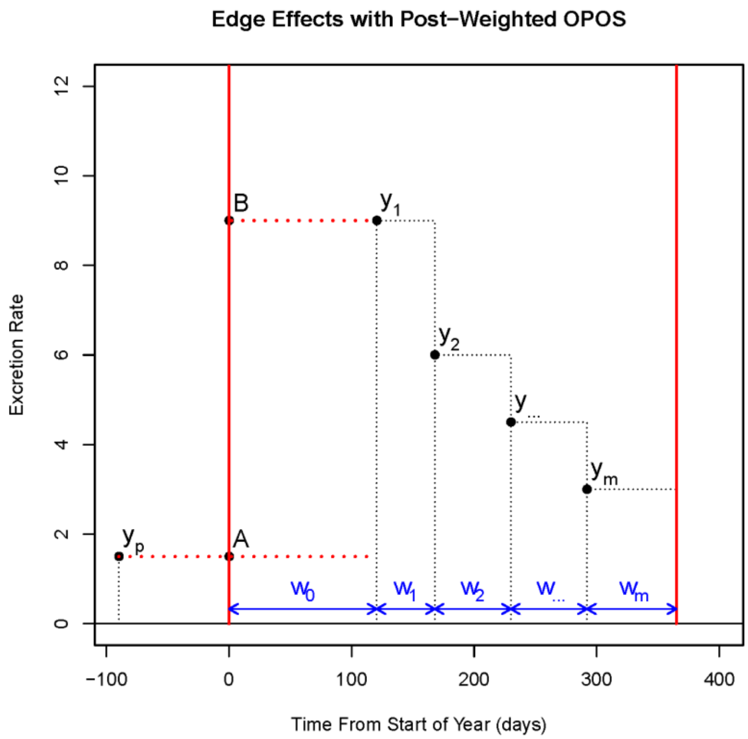

Figure 1. Alternatives A and B at Start of Year for Post-Weighted OPOS

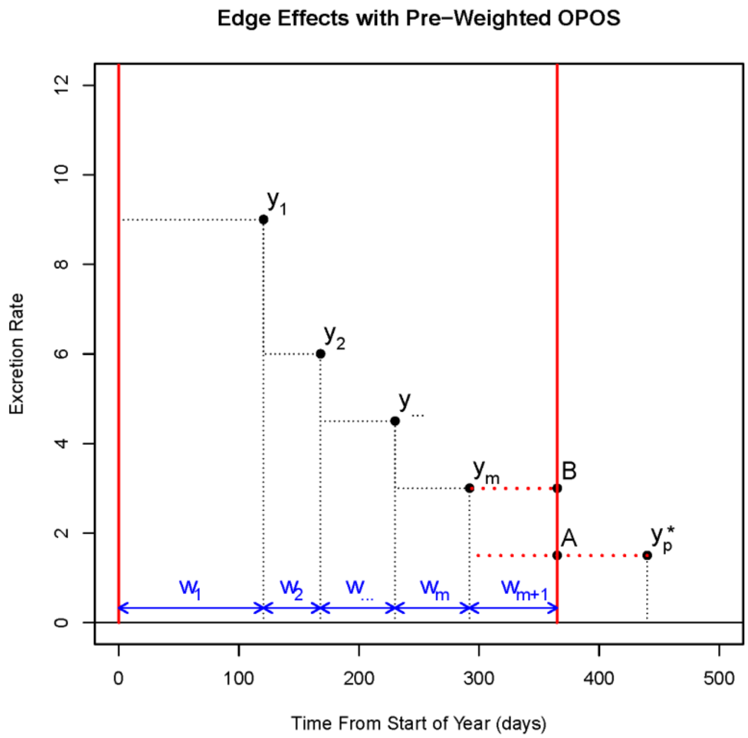

Figure 2. Alternatives A and B at End of Year for Post-Weighted OPOS

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