MEMO

TO: SEC Issues Work Group

FROM: SC&A SEC Issues Team (Task Manager Arjun Makhijani; Members John Stiver, Joyce Lipsztein, Harry Chmelynski, John Mauro, Bob Barton, and Joe Fitzgerald)

SUBJECT: Status of Issues Relating to the Development of Coworker Models

DATE: September 5, 2014

This memorandum responds to the charge of the Special Exposure Cohort (SEC) Issues Work Group (WG) of the Advisory Board on Radiation and Worker Health to summarize the status of, and SC&A's current position on, general issues relating to coworker models in light of the discussion during, and materials presented at, the WG meeting on July 28, 2014. The meeting took place in Idaho Falls, Idaho. To produce this update and status memorandum, SC&A relied on the following materials:

(1) Jim Neton's June 17, 2014, paper (Neton 2014)

(2) Jim Neton and Daniel Stancescu's paper on time-weighted OPOS (Neton and Stancescu 2014

(3) SC&A's memorandum reviewing three NIOSH white papers (SC&A 2014)

(4) The transcript of the July 28, 2014, WG meeting (Transcript 2014)

NIOSH and SC&A appear to agree on various issues. These are catalogued below, along with issues that are outstanding and may need further work and/or review. The latter are also grouped at the end of the memorandum.

1. DATA ADEQUACY

NIOSH agreed that data adequacy is one of the first issues to address. This involves looking at data quality. Reference was made during the WG meeting to the problem of widely different results from two or more analytical measurements of the same aliquot. This was an example of concerns regarding data quality raised by SC&A with specific reference to the Savannah River Site (SRS), but which have general validity (Transcript 2014, pp. 9–16). In short, it is necessary (but not sufficient) to have data of adequate quality to construct a coworker model.

2. QUANTITY OF DATA:

NIOSH and SC&A agreed that 30 samples was only a guide to data sufficiency for comparing distributions and constructing coworker models. It was not a hard and fast rule. If there were, say, 15 workers involved in an operation and monitoring data were available, then that data would be sufficient to fill in gaps in monitoring for those workers. But the problem of applying the coworker model for such operations to other workers who may have accessed the work area

intermittently would still remain; it is a complex one. On the other hand, some of SC&A's analysis for SRS has shown that total samples much greater than 30 may not be enough for reliable comparison of distributions when the geometric means were very large (Transcript 2014, pp. 16–20). SC&A and NIOSH agree that it is important to consider the geometric standard deviation (GSD) as well as the geometric mean when considering whether the number of data points is adequate (Transcript 2014, p. 62).

3. WHO WAS MONITORED AND THE MONITORING PROTOCOL[1]

NIOSH and SC&A agreed that (1) it was important to characterize who was monitored and their exposure potential, and (2) there were different monitoring protocols at various sites or for different groups of workers at different times. One protocol is when the routinely monitored group is representative of all workers. A second would be when the group with routine monitoring is representative of the highest exposed group. That has to be analyzed and demonstrated. For instance, it cannot be assumed that just because a group was not monitored that the workers in it had no or low exposure potential.[2] A third type of monitoring was incident-based monitoring. It was agreed that it was important to maintain the distinctions between these types of monitoring protocols when comparing groups or constructing coworker models. It is especially important to distinguish between routine and incident-based monitoring *protocols*, though it was recognized that the routine monitoring would also include incident-related monitoring. Nevada Test Site (NTS) monitoring was discussed at some length. Rad Tech workers were monitored on a routine basis. Test site workers were monitored when there were tests, and these could be considered similar to incidents. It was agreed that one could not assume that workers with routine monitoring were among those with the highest exposure potential. That needs to be demonstrated:

> *MR. BARTON: I think that was really SC&A's main comment about this section was that we agree, for a coworker model to be valid, we sort of have to fit it into one these two –*
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> *DR. NETON: Right.*
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> *MR. BARTON: -- categories. And we just want to make sure, maybe just a little word tweaking would take care of it, that it was never assumed, a priori, that that's the case. But you have to sort of demonstrate it somehow.*
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> *DR. NETON: Yes, yes. I agree. And, you know, we've gone, lately it's been more of a standard mode of operation to go back and look at the procedures, and at Savannah River in particular, and say here're the sheets, the checklists that say who has to be on a monitoring program.*

[1] Refer to Transcript 2014, pp. 67–80 for details on the discussion on this topic during the July 28, 2014, WG meeting.

[2] "Dr. Neton: ….The question then is did they really need it? Then we have to get into that analysis. Because, just because they didn't have it doesn't mean it wasn't needed." (Transcript 2014, p. 73.)

And then not only is that sufficient in itself, but you've got to go back and say did they really take those samples.

MR. BARTON: Yes, did they do it?

DR. NETON: And once you can make that case, then you're pretty far along saying I think we've got a fairly good situation. [Transcript 2014, pp. 78–79]

NIOSH appeared to agree that an exposure control program may not be sufficient for constructing a coworker model, notably in the early decades before the Department of Energy (DOE) promulgated 10 CFR 835 [in the 1990s] (Transcript 2014, pp. 73–77). It is also important to establish whether the monitored and unmonitored populations were part of the same exposure group or alternately that the "data reasonably represents the [unmonitored] workers" (Transcript 2014, pp. 96–97). Note: SC&A interprets the phrase "reasonably represents" to mean that the exposure potential of the monitored group adequately bounds the exposure potential of the unmonitored group. (See also the next item below.)

4. APPLICABILITY OF AVAILABLE DATA TO UNMONITORED WORKERS

SC&A has maintained that the applicability of available monitoring data to unmonitored workers needs to be established. SC&A agrees with the way in which the issue is characterized in Neton 2014:

The appropriateness of the application of the monitored population's data to those workers who were unmonitored should be evaluated. It is important to establish the exposure types and work activities of the unmonitored workers. A review of the job types and categories of the unmonitored workers should be conducted to determine if there are special exposure categories that might not be covered by the monitored population.

If the unmonitored population can be determined through a source term evaluation to have no potential for exposure, then it is not necessary to establish a coworker model. In this case, it might be sufficient to include ambient environmental dose in the dose reconstructions. [Neton 2014, pp. 3–4]

5. NEED FOR STRATIFICATION

SC&A and NIOSH agree that there might be identifiable strata of workers among the monitored workers who had higher exposure potential than others (Neton 2014, p. 5). It is necessary first to test whether an all-monitored worker model can be applied. NIOSH had proposed that the 95th percentile of the all-monitored worker distribution be applied in such cases. However, it must first be established that this is more claimant favorable than applying the full distribution of the stratified data subset:

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.* [Neton 2014, p. 5] [Emphasis added]

In other words, when exposure potential exists, it is essential to consider whether stratification is needed or whether an all-monitored worker model can be used for unmonitored workers belonging to a certain group, as for instance, construction workers (Transcript pp. 112–113). The issue of how the question of strata might be approached when adequate job classification data are not available has not yet been resolved (Transcript 2014, pp. 106–109).

NIOSH has not yet demonstrated the workability of the method of comparing a stratified dataset with a constant of the whole dataset:

> *NIOSH is working on the feasibility of such an evaluation and hopes to provide input on how this might be accomplished in the near future. Reliance on the probability of causation (PC) to make such a determination, although somewhat complicated, seems doable. If a predictable relationship between the PC generated for the full distribution and the use of the 95th percentile as a constant for the general distribution can be established, one might be able to establish a truly practically significant difference. 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.* [Neton 2014, p. 5]

SC&A believes that the proposal of establishing a general method by comparing the probabilities of causation that result from the application of the two datasets in the manner proposed could, in principle, provide a general method. However, in practice it is likely to be very difficult, perhaps impossible, to actually make valid comparisons much less establish a general result, which is the presumed goal. Based on the data SC&A has reviewed so far, most importantly at SRS where job classification data exist, there is insufficient basis to make comparisons in the datasets we have looked at where comparisons between all-monitored workers and construction workers have been attempted. For one thing, the monitoring protocols are different. And NIOSH has indicated that SRS is a best case when it comes to the availability of job classification data (Transcript 2014, p. 114). SC&A would recommend that NIOSH cite some specific cases where comparisons of stratified datasets with all-monitored-worker datasets are feasible in principle. These would have to meet the criteria of data adequacy (quality and quantity), representativeness, and monitoring protocol (i.e., the two groups should have the same monitoring protocol).

6. INCIDENT-BASED MONITORING

NIOSH and SC&A agree that one should only compare distributions with the same monitoring protocol. Strata formed by incident-based data should be looked at on a case-by-case basis before building a coworker model. It is not possible to say a priori whether such a dataset can be used to build a coworker model (SC&A 2014; Neton 2014, p. 3; and Transcript 2014, p. 121 and pp. 81–90).

7. ONE PERSON ONE STATISTIC (OPOS)

NIOSH and SC&A agree that the original One Person-One Sample (OPOS) method does not consider the time distribution of the exposures. There are still some outstanding issues in regard to OPOS. NIOSH has proposed that a time-weighted approach could be used in place of the earlier averaging of all bioassay sample results in a given time period. SC&A agreed that this method is an improvement over the prior one; in SC&A's analysis, the method of time-weighting is important. It is also very important for the time-weighting to be the product of the sample measurement with the number of days between that measurement and the *prior* sample. SC&A calls this the "pre-weighted" procedure (SC&A 2014).

The pre-weighted approach will give a reasonable approximation of the intakes, either routine or incident-related.

SC&A agrees with Dr. Neton that in reality, in the pre-weighted approach, we are integrating the bioassay results for a worker for a determined time period. For urine bioassay monitoring, this integration can be illustrated as a collection of all the urine excreted by a worker in a specific period of time in a bucket. The average excretion rate is just the division of all urine collected during the specific time period by the time period. As the worker did not collect all his excretions, the time pre-weighted approach assigns the same bioassay result for each day that elapsed since the previous result. This is the same as assigning to each bioassay result a weight equal to the number of days that elapsed since the previous result. ***Hence the correct use of the time-weighted approach is to use pre-weighting.*** NIOSH appears ready to accept this approach as noted by Dr. Neton during the July 28, 2014, WG meeting:

> *SC&A has suggested, and there's some basis for this, that you should integrate going backwards because the bioassay point is actually a measure of what happened before it not after it* [Transcript 2014, p. 197]

And

> *I'm not against going backwards, you know, backwards integration. That doesn't bother me. I mean, I'm totally willing to accept that* [Transcript 2014, p. 207].

The pre-weighted approach may be justified as an unbiased method to estimate the intake. When the time of intake is not known and it is necessary to estimate an intake from a measurement made at the end of a monitoring interval, the ICRP suggests it should be assumed that the intake occurred in the middle of the monitoring interval. Some authors, however, suggest that the ICRP

method is biased and the best unbiased estimate of the intake should be calculated assuming a chronic intake throughout the monitoring interval (Puncher et al. 2006). For example, if a monitoring result shows a high activity *A* excreted in urine on date "t2", characteristic of an incident, and the date of the intake is not known, the assignment of a continuous intake between the last monitoring result (on date "t1") and the date "t2" may be accepted as an unbiased method to estimate of the intake (Puncher et al. 2006). The assignment of a continuous activity excretion rate equal to *A* to the whole period of time t1 to t2 is thus reasonable for characterizing incidents, and more claimant favorable than the unbiased approach suggested by Puncher et al. 2006. For routine continuous excretion rates higher than the MDA, characteristic of chronic exposures, the integrated urine total excretion is also a reasonable representation of the excretion. NIOSH has been applying this methodology for many years in all coworker models. In this case, the assignment of the constant activity obtained at the end of the monitoring interval to every day during the entire interval since the last sample is claimant favorable. It is very important to note that the pre-weighted approach is the correct one, since it reflects the past exposures that are represented by the activity result from the monitoring sample.

SC&A still has some concerns around the use of zero and negative bioassay results; NIOSH has stated they are considering what approach they might adopt to deal with that (Transcript 2014, p. 214). SC&A notes that if we think of the time-weighted approach as representative of the total urine excreted by a worker during a time period, which is a function of the intakes during that period, negative bioassay results should not be used, as the minimum intake is zero or background.

SC&A would prefer time-weighting over shorter periods, such as a quarter, rather than a full year; NIOSH indicated that it is open to considering that (Transcript 2014, p. 212) and would adopt a quarterly averaging where the data are available (Transcript 2014, p. 221). In cases where there are specific and identifiable processes for defined periods of time, it would be preferable for the time-averaging to take place over the time of the operation, rather than a more arbitrary calendar quarter or calendar year. For instance, if a specific process operated from July 1967 to June 1968, SC&A would recommend averaging over the period of that specific process.

SC&A has some remaining concerns regarding OPOS, but recognizes that there are also deficiencies in the pooled-data approach. Our initial review of the "pre-weighted" OPOS approach indicates that it is worth establishing with sufficient example calculations with actual worker data how well the approach approximates intakes and whether it is systematically claimant favorable.

In addition, SC&A suggests that the 'pre-weighted OPOS' approach be tested using a sufficient random sample of real worker data to determine the extent to which the method approximates real 'best-estimate' intake values on an annual or other applicable basis. The purpose of such an analysis would be to determine:

- The accuracy and consistency with which a pre-weighted OPOS value reflects real worker intakes and exposure potential in a given analysis period

- To what extent pre-weighted OPOS values might consistently underestimate or overestimate the workers' real intake potential

In this context, the Advisory Board, NIOSH, and SC&A can make a more informed judgment as to the scientific accuracy and claimant favorability of the proposed coworker model approach.

SC&A notes in this context that all prior necessary conditions should have been met prior to the use of any method, including OPOS, for comparing data distributions or constructing coworker models. Specifically, the data must be of adequate quality, sufficient data must be available, and the monitoring protocols of the two groups being compared should be the same.

8. CONCLUSIONS AND RECOMMENDATIONS

(1) A confirmation from NIOSH of the above points of agreement as noted by SC&A in this memorandum is desirable.

(2) In SC&A's view, the comparison of the 95th percentile of all-monitored workers to the full distribution of a stratum of workers in order to derive a general conclusion would be very difficult. SC&A recommends that the WG ask NIOSH to specify the all-monitored worker datasets and the stratified data subsets they would use to show the feasibility of the approach. (See Section 6 above.)

(3) SC&A concludes that the time-weighted OPOS approach appears more promising than the un-weighted approach. However, the time-weighting *must be pre-weighted*, as described in SC&A 2014. SC&A's initial review of the "pre-weighted" OPOS approach indicates that it is worth establishing with sufficient example calculations with actual worker data how well the approach approximates intakes and whether it is systematically claimant favorable. In addition, SC&A suggests that the 'pre-weighted OPOS' approach be tested using a sufficient random sample of real worker data to determine the extent to which the method approximates real 'best-estimate' intake values on an annual or other applicable basis.

(4) SC&A reiterates that negative bioassay results should not be used.

REFERENCES

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