

 **Memorandum**

To: SEC Issues Work Group
From: SC&A, Inc.
Date: October 17, 2023
Subject: SC&A Comments on NIOSH White Paper, “A Discussion of Completeness in Co-Exposure Models”

Background

In March 2023, the National Institute for Occupational Safety and Health (NIOSH) issued a white paper, “A Discussion of Completeness in Co-Exposure Models” (NIOSH, 2023), to address comments by the Sandia National Laboratories Work Group during its April 2022 meeting. The discussion during that meeting centered around the potential for creating a more quantitative framework for evaluating data completeness, as it is a near-universal issue for the majority of sites evaluated under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). As noted in appendix A of NIOSH (2023), a member of the Advisory Board on Radiation and Worker Health (ABRWH, Board) commented,

there’s this thing that’s always hanging over one of these discussions, and it’s the data completeness.

This kind of brings me then into my second comment. Bob mentioned that, I think expressed a desire for having a quantitative way to look at completeness, and boy that would really be helpful, because these discussions that take place in other, on other Sites too, are quite frustrating because SC&A will say well, we don’t feel that there’s data completeness, but it’s left sort of vague.

It’s very hard for NIOSH to answer that and to come back then without some specific direction on, as to how to answer that question. Of course quantitative, if there a quantitative way, then that would make it much easier. [ABRWH, 2022a, p. 49]

This potential line of inquiry was also discussed at the subsequent meeting of the ABRWH on April 28, 2022 (ABRWH, 2022b, pp, 40, 54-56), at which time NIOSH was tasked with evaluating the feasibility of a uniform quantitative approach to evaluating completeness. Approximately 1 year later, at the meeting of the ABRWH on April 20, 2023, SC&A was tasked to review the ensuing NIOSH white paper (NIOSH, 2023). This memorandum contains SC&A’s commentary on completeness as interpreted in NIOSH (2023).

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SC&A Comments on NIOSH 2023 Conclusions

Section 9 of NIOSH (2023) gives seven bulleted conclusion points (pp. 16–17). The following subsections discuss these seven conclusions.

NIOSH conclusion 1

Making a bounding co-exposure model does not require all the data, just a significant portion of the data from the most highly exposed workers. [NIOSH, 2023, p. 16]

SC&A agrees with this concept in principle. However, it also must be noted that establishing that the bounding co-exposure model *actually* contains a significant portion of the most highly exposed worker population is likely more difficult than it initially sounds. For example, how can we establish what the exposure potential for the missing portion of data (whether because the records are unavailable or the workers were not monitored) would have reflected? This is, and has always been, a professional judgment decision that resides with the Board. SC&A acknowledges that certain lines of inquiry can help inform that judgment, such as examining job titles, work areas, and specific work duties in the available dataset and making a qualitative determination if the dataset is representative of the different working conditions and/or clearly bounding of various exposure potentials experienced.

Furthermore, SC&A notes that “a significant portion” indicates a quantitative threshold when, in reality, a quantitative metric is simply not plausible for every site and situation. SC&A maintains a quantitative metric is not likely to be universally established, and this is acknowledged in NIOSH conclusion 5.

NIOSH conclusion 2

Even the best radiation protection monitoring programs are seldom 100% effective. However, if a radiation protection program is working properly, monitoring missingness is most likely to affect workers with low doses, whereas data missingness can exhibit practically any pattern. [NIOSH, 2023, p. 16]

SC&A agrees that as part of a weight-of-evidence evaluation, proper characterization of the monitoring program becomes paramount, including standard procedures, audit findings, and actual interviews with the workers both administering the monitoring program and those included (or should have been included) in the monitoring program. This type of evaluation is obviously subjective in determining whether the monitoring program would have included a “significant portion” of the most highly exposed workers. As this memo noted for NIOSH conclusion 1, a “significant portion” is not an established quantitative measure and thus will likely always be a subjective, qualitative judgment.

SC&A further cautions that it believes it is inappropriate to assume a priori that a given radiation protection program was “working properly.” Rather, it must be proven via the appropriate procedure reviews, available audits, and interviews with both the radiation protection staff and those included (or not included) in the monitoring program to affirm the efficacy of the program.

NIOSH conclusion 3

To demonstrate that the dataset is “complete enough” to construct a co-exposure model one must, to some degree, vet the radiation protection programs that generated the data and the recordkeeping systems that store and report the data. [NIOSH, 2023, p. 17]

SC&A agrees that such an analysis is a necessary aspect of evaluating whether the dataset underlying any subsequent co-exposure model is representative or bounding of the exposed population. Such analyses are already a standard part of Special Exposure Cohort (SEC) deliberations involving co-exposure modeling feasibility. That is, the dataset cannot be evaluated for completeness in a vacuum, and programmatic performance and administration issues must be carefully considered.

NIOSH conclusion 4

After vetting the programs and starting under the presumption that the data are complete, a limited number of internal and external checks of the datasets can be performed to look for signs of significant missingness or monitoring missingness. [NOISH, 2023, p. 17]

SC&A agrees that internal and external checks of the datasets should be performed. These include intercomparison of the full dataset provided by a given site to other data sources. These might include:

- dose tracking reports designed to demonstrate compliance
- periodic documentation of the health physics department activities (e.g., monthly/quarterly reports that include significant incidents and, where available, the number of workers and samples requested/submitted/and analyzed during the given timeframe)
- program performance assessments, both internal self-assessments and independent external reviews, that are directed at the effective and adequate implementation of site monitoring and recordkeeping in accordance with site procedures and departmental requirements
- comparison with the NIOSH DCAS Claims Tracking System (NOCTS) to assure that data transmitted for individual claims also appears in the full electronic dataset supplied by the site for co-exposure modeling

However, SC&A does not agree that after vetting appropriate documentation and interviews of the monitoring program that the available dataset should “start under the presumption that the data are complete.” SC&A notes that neither should it be assumed that the dataset is incomplete, SC&A believes the evaluation of a given dataset using “internal and external checks” should always start with the neutral assumption that it is not known whether the data are complete or incomplete until such checks are performed.

NIOSH conclusion 5

It may not be feasible to establish universally applicable, technically based quantitative limits for a dataset being complete enough. This is primarily a qualitative discussion based on the preponderance of evidence. [NIOSH, 2023, p. 17]

Per previous discussions, SC&A agrees that a universal quantitative measure is not plausible to develop and agrees that each situation must be evaluated individually on a subjective, qualitative basis. SC&A notes that evaluating the feasibility of a quantitative measure was the original purpose of the tasking by the ABRWH in April 2022.

NIOSH conclusion 6

Regulatory compliance with a monitoring program or lack thereof cannot be used by itself to decide if a dataset is complete enough to construct an acceptable co-exposure model. [NIOSH, 2023, p. 17]

SC&A agrees that regulatory compliance issues, by themselves, do not demonstrate the infeasibility of a co-exposure model. However, evaluating compliance issues is in the same vein as vetting the programmatic aspects of a given site's radiation protection program in that it provides weight-of-evidence indicators as to how effective and comprehensive the monitoring program is in practice. If any program assessment, whether performed internally or by an external independent source, establishes the incompleteness or inadequacy of a site monitoring program, that should be considered significant and require further review regarding the feasibility of co-exposure model development.

NIOSH conclusion 7

Stratification of datasets cannot be used to correct for data missingness or monitoring missingness and can be very time consuming and resource intensive to perform. Furthermore, stratification of the datasets will likely not provide any significant benefit to the unmonitored worker to whom the co-exposure model is applied. [NIOSH, 2023, p. 17]

NIOSH (2023) provides its justification to remove stratification from co-exposure formulation in Section 8. NIOSH postulates that stratification is ill-advised because:

- It is time consuming
- Workers would have to be appropriately categorized.
- It reduces the amount of data in each stratum (thus the co-exposure models are less accurate).
- Some workers would get more dose and some workers would get less dose when stratifying than with a single co-exposure model.
- It does not correct for data and monitoring missingness.

SC&A recognizes that the first three of these arguments are certainly aspects of stratification that should be considered. The fourth argument echoes the old adage, “robbing Peter to pay Paul”; SC&A finds this immaterial. If an unmonitored worker is indeed one of the higher exposed workers, then it only seems appropriate they would be assigned higher doses. Similarly, if a worker is a lesser exposed worker, then it seems appropriate they would get a lower dose assignment than the higher strata. In SC&A’s opinion, this is entirely the purpose of stratification, if needed and feasible, not a downfall.

SC&A dose agree with the fifth argument, that stratification alone would not solve potential completeness concerns. If there is a group of the most highly exposed workers who have significant data completeness issues from a qualitative standpoint (whether it is data missingness or monitoring missingness), then this is when questions of dose reconstruction feasibility are most poignant and an SEC should be considered by the Board.

Section 8 concludes:

if the radiation protection program at a facility was mature and functional, stratification is not needed to construct a bounding co-exposure model and can result in less accurate predictions of dose compared to unstratified co-exposure models. [NIOSH, 2023, p. 16]

Whether a particular radiation protection program is mature and functional is often a matter of professional judgment and should not be presumed a priori. Whether or not stratification may be warranted in a given situation is a site-specific issue, and SC&A does not believe the future application of the stratification concept should be discarded out of hand. SC&A notes that the concept of stratification was developed by NIOSH in concert with SC&A and the SEC Issues Work Group, discussed, and accepted by the Board as documented in DCAS-IG-006, revision 00, “Criteria for the Evaluation and Use of Co-Exposure Datasets” (NIOSH, 2020). This document discusses stratification as follows:

The distribution of a potentially more highly exposed population should be evaluated as a separate standalone distribution in situations where: 1) accurate job categories and/or descriptions can be obtained for all workers making up the general co-exposure dataset; 2) there is reason to believe that one of the job categories is more highly exposed; and, 3) there were unmonitored workers in this job category. If it can be demonstrated, however, that there were no unmonitored workers with the potential for exposure in this more highly exposed population, then stratification would not be necessary. [NIOSH, 2020, p. 11]

SC&A believes this is the correct and appropriate approach to handling potential stratification, and its stance remains unchanged as that documented in DCAS-IG-006 and approved by the Board.

SC&A Conclusion

SC&A notes that data completeness has been an oft-discussed topic with the general concept clearly defined in DCAS-IG-006 (NIOSH, 2020). That document states the following concerning data completeness:

the amount of available monitoring data must be evaluated to determine if there are sufficient measurements to ensure that the data are either bounding or representative of the exposure potential for each job/exposure category at the facility. . . .

If the number of potentially exposed workers in each category is unknown, a useful starting point is to look at the distribution of samples among the various categories of workers represented in the claimant population at that site. . . . In [the analysis of workers at the Nevada Test Site], the radiation safety staff was monitored to a larger extent than workers directly involved in site activities. Thus, a co-exposure model based on these data would not necessarily reflect the exposure conditions of the unmonitored production/process workers. If, in fact, it can be established that the categories of workers were potentially exposed, yet inadequately monitored, it could preclude the development of a sufficiently accurate co-exposure model, unless it can be established that the exposures to another, adequately monitored category of workers reliably bounds the initial category's exposures." [NIOSH, 2020, pp. 6–7]

SC&A is including this information because it maintains that this is the correct interpretation of data completeness under EEOICPA as developed in concert with NIOSH, the SEC Issues Work Group, and SC&A and that was unanimously approved by the full Board on December 11, 2019 (ABRWH, 2019, pp. 145–147).

With this in mind, SC&A does not materially disagree with the general logic and philosophical content of NIOSH (2023), with the noted exceptions of presuming completeness a priori and removing potential stratification from consideration. SC&A also believes that each site is distinctly different regarding the implications of incomplete datasets used in co-exposure modeling. As such, SC&A agrees with NIOSH that an actual quantitative uniform approach would be inappropriate and likely not plausible. SC&A continues to assert that each site must be taken individually and that the only way to evaluate completeness is to apply qualitative weight-of-evidence arguments to determine whether a co-exposure model can be constructed that is reasonably bounding for *all* affected energy employees.

It is SC&A's interpretation of NIOSH (2023) that NIOSH appears to agree with this position. In fact, most of the concepts discussed in NIOSH (2023) have already been introduced to varying degrees in SEC discussions and co-exposure model development and so do not necessarily present a novel approach to completeness evaluations. For example, programmatic documentation is already reviewed to determine the efficacy of the radiation protection program (refer to NIOSH conclusion 3). This includes relevant information on regulatory compliance audits and citations that serve to illustrate the efficacy of the program, though SC&A recognizes that these indicators alone do not serve to inform data completeness (refer to NIOSH conclusion 6). Sources such as NOCTS and alternate datasets are already considered when evaluating full datasets for co-exposure feasibility and appropriateness (refer to NIOSH conclusion 4).

Regarding the NIOSH (2023) objections concerning stratification, SC&A maintains that the concept has merit and should continue to be a consideration when evaluating co-exposure model feasibility and applicability as was outlined in DCAS-IG-006 (refer to NIOSH conclusion 7).

Finally, and perhaps most importantly, SC&A and NIOSH are in agreement that a quantitative threshold or metric is not possible to develop. Answering this question was the whole purpose of this investigation at the outset (refer to NIOSH conclusion 5).

References

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