SC&A Comments on NIOSH White Paper, "A Discussion of Completeness in Co-Exposure Models"

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Background

- NIOSH white paper initiated by discussions during an April 2022 meeting of the Sandia National Laboratory Work Group (ABRWH, 2022)
- Question: Is there a quantitative method to evaluate “Completeness” in the formulation of co-exposure models?
- Universal issue across multiple sites
- NIOSH white paper issued in March 2023 to address issue (NIOSH, 2023)
- SC&A tasked in April 2023 with reviewing the NIOSH white paper

NIOSH conclusion 1

- **NIOSH conclusion 1:** All data is not required, only a significant portion of the most highly exposed workers.
- **SC&A response:**
  - SC&A agrees, in principle, that if you capture the highest exposed workers, then a co-exposure model is feasible.
  - Establishing that the highest exposed workers have been captured can be difficult (e.g., what would the missing data inform regarding exposure potential).
  - Qualitative information may be useful in forming a “weight of evidence” basis: job titles, work areas, specific duties, etc.

NIOSH conclusion 2

- **NIOSH conclusion 2:** Radiation protection programs (RPPs) are not likely to be 100% effective; however, data "missingness" is likely to affect workers with low potential for exposure.
- **SC&A response:**
  - Agrees that evaluation of the radiation protection program is an important qualitative (not quantitative) measure.
  - Lines of inquiry should include: established procedures, audits (external and internal), interview statements, etc.
  - SC&A does not believe any particular program should a priori be assumed to be functioning properly.

NIOSH conclusion 3

- **NIOSH conclusion 3:** To demonstrate that the dataset is "complete enough," the RPP that generated the data and the recordkeeping systems that store and report the data must be vetted.
- **SC&A response:**
  - Similar line of reasoning as NIOSH conclusion 2.
  - SC&A agrees that such evaluation is an important facet in establishing the feasibility of the co-exposure model.

NIOSH conclusion 4

- **NIOSH conclusion 4:** Under the presumption the RPP generated data is “complete,” external and internal checks should be performed.
- **SC&A response:**
  - SC&A agrees such checks provide value in a weight-of-evidence argument.
    - Dose tracking reports to demonstrate compliance
    - Regular reports from the Health Physics Department documenting activities and exposures
    - Program performance assessments documenting adequate implementation of RPP
    - Comparison with alternate datasets such as those generated from the NIOSH Claims Tracking System (NOCTS)
  - Does not agree that the RPP should be presumed to be complete.

NIOSH conclusion 5

- **NIOSH conclusion 5:** Universally applicable, technically based quantitative limits for a dataset being complete enough may not be feasible.
- **SC&A response:**
  - Agrees generic quantitative criteria are not attainable for EEOICPA.
  - Each individual co-exposure model must be evaluated on a subjective and qualitative basis.

NIOSH conclusion 6

- **NIOSH conclusion 6:** Regulatory compliance of the RPP, by itself, should not be used to determine completeness.
- **SC&A response:**
  - SC&A agrees that regulatory compliance, or lack thereof, cannot solely be used to determine completeness.
  - Regulatory compliance determinations are part of a weight-of-evidence argument that ultimately forms a subjective decision to be made by the Advisory Board.

NIOSH conclusion 7

- **NIOSH conclusion 7:** Stratification of datasets is time consuming, would not answer "data missingness" issues, and would not benefit unmonitored workers.
- **SC&A response:**
  - SC&A agrees stratification would result in lower unmonitored doses to some workers and higher doses to others.
  - SC&A agrees that stratification does not solve "data missingness."
  - If there is a group or strata of workers who qualitatively appear to have higher exposure potential and also data completeness issues, then co-exposure models may not be appropriate.
  - The overall functionality of an RPP is generally based on qualitative information and thus is a professional judgment.

NIOSH implementation guide on stratification

- DCAS-IG-006 ("Criteria for the Evaluation and Use of Co-Exposure Datasets") 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).

NIOSH implementation guide on completeness (general guidance)

"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" (NIOSH, 2020, p. 6).

NIOSH implementation guide on completeness (example in practice)

"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 overall conclusions

- Agrees with the overall logic and principles discussed in the NIOSH white paper with the following exceptions:
  - Presumption of a priori completeness
  - Removal of stratification when qualitatively warranted from consideration
- Each EEOICPA site is unique and must be evaluated separately.
- A quantitative approach is not plausible.
- DCAS-IG-006 should be the guiding document when evaluating completeness.

References

Advisory Board on Radiation and Worker Health (ABRWH). (2022). Sandia National Laboratories Working Group Monday, April 11, 2022 [Transcript of teleconference meeting]. https://www.cdc.gov/niosh/ocas/pdfs/abrwh/2022/wgtr041122-508.pdf

National Institute for Occupational Safety and Health. (2020). *Criteria for the evaluation and use of co-exposure datasets* (DCAS-IG-006, rev. 00). https://www.cdc.gov/niosh/ocas/pdfs/dr/dc-ig-006-r0-508.pdf

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