



Data Completeness and Co-Exposure Models

Brant Ulsh, Ph.D., Certified Health Physicist (CHP)

Lara Hughes, Ph.D., CHP

Research Health Scientists

Division of Compensation Analysis and Support (DCAS)

National Institute for Occupational Safety and Health (NIOSH)

A Discussion of Completeness in Co-Exposure Models

White Paper

**National Institute for Occupational
Safety and Health**

January 26, 2023

Thomas LaBone
Oak Ridge Associated Universities Team

Reviewed by Tim Taulbee, John Cardarelli, and Lara Hughes
Division of Compensation Analysis and Support

Outline

- Brief history – how did we get here?
- Co-exposure models (CX)
- Special Exposure Cohort (SEC) vs. CX models
- Data completeness
- Effects of incomplete data sets
- Regulatory compliance
- CX pipeline
- Priority list
- Conclusions





History

How did we get here?

Milestones

- DCAS-IG-006, Section 2.2
- 2022-04-11 Sandia National Laboratories Working Group requested NIOSH prepare report on data completeness
- 2023-01-26 NIOSH/Oak Ridge Associated Universities Team (ORAUT) issued white paper, “A Discussion of Completeness in Co-Exposure Models”
- 2023-10-17 SC&A issued memo, “SC&A Comments on NIOSH White Paper, “A Discussion of Completeness in Co-Exposure Models”
- 2026-02-11 discussed in SEC Issues Work Group meeting.

Division of Compensation Analysis and Support

Criteria for the Evaluation and Use of Co-Exposure Datasets

DCAS-IG-006, Rev 00

A Discussion of Completeness in Co-Exposure Models

White Paper

National Institute for Occupational
Safety and Health

January 26, 2023

 **SC&A 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

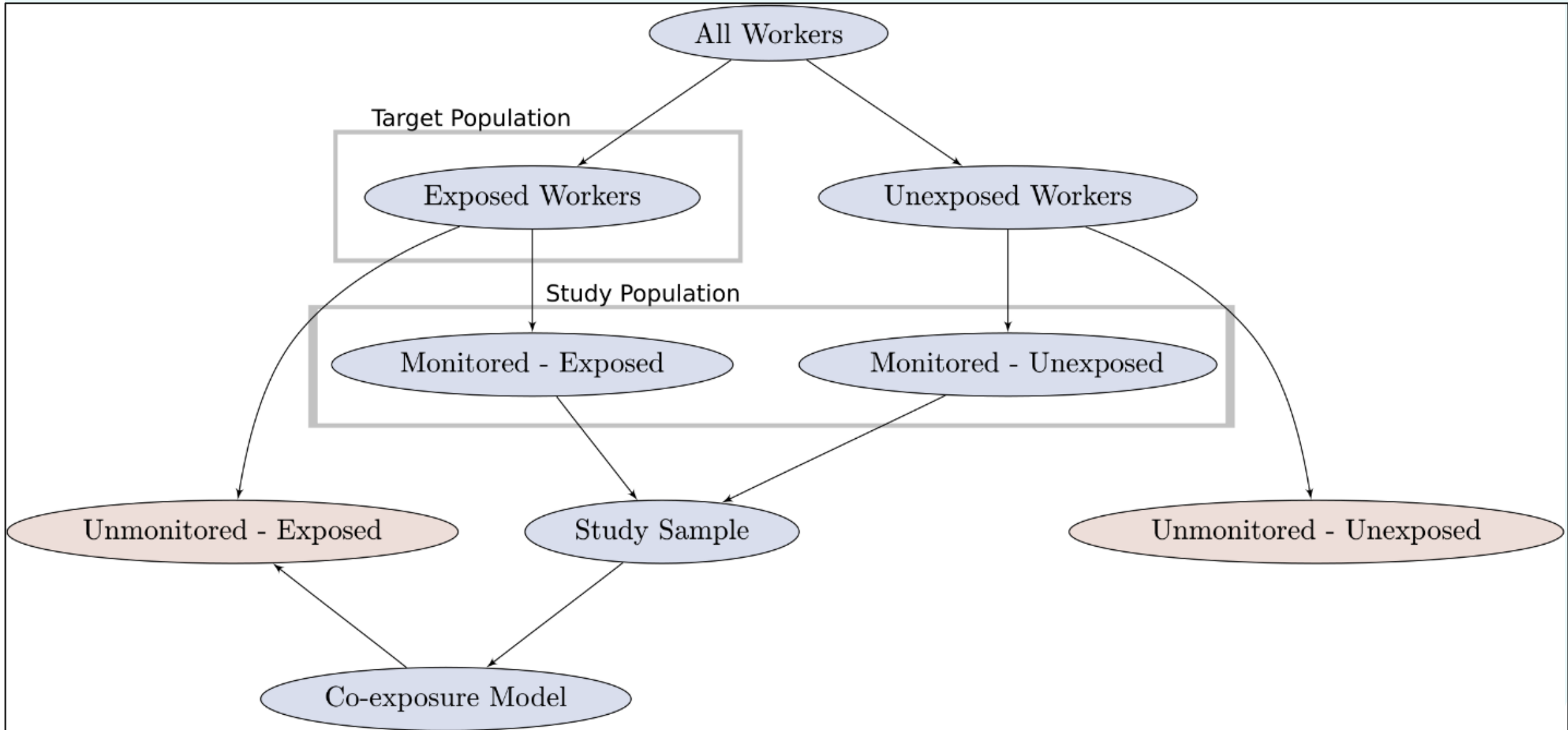
In March 2023, the National Institute for Occupational Safety and Health (NIOSH) issued a white paper, “A Discussion of Completeness in Co-Exposure Models” (NIOSH, 2023), to address comments by the Sandia National Laboratories Work Group during its April 2022 meeting. The discussion during that meeting 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,

Review



Co-Exposure Models

Constructing Co-Exposure Models





Special Exposure Cohort vs. Co-Exposure Model Development

Special Exposure Cohort Petition Evaluation

- 42 CFR 83.13: Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?
- Information needs:
 - **Access** to sufficient information to estimate maximum radiation dose
 - **Access** to sufficient information to estimate radiation doses more precisely than maximum dose
 - Data hierarchy applies!
 - Identity of radionuclides and their maximum quantity or radiation generating equipment data
 - Process description
 - Personal dosimetry data and area monitoring data are **not** always necessary
- Evaluation report (ER) results in a Summary of findings and SEC recommendation
 - Adequacy of existing records and information
 - Estimate the radiation dose of members of the class with sufficient accuracy
 - Description of evaluation methods to be used and its information source
- Strict timeline: 180 days unless exception is granted

Co-Exposure Model Development

- 42 CFR 82.2: If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment.
- DCAS-IG-006 Rev 00: guidance for evaluation of personnel monitoring data used in dose reconstruction (DR) for unmonitored workers
 - Possible data sources: urine bioassay, but also in-vivo data or air data, external dosimetry
 - Data adequacy: are the techniques used to measure exposure capable of quantifying the exposure of interest?
 - Data completeness: Are there enough data to ensure data is bounding or representative for each exposure category?
 - Does the monitored cohort represent the workforce ?
 - Stratification needed ?
 - Data analysis
 - Data entry and quality control
 - Data cleanup (outliers)
 - Verification
 - Modeling and intake calculation
- Lengthy process requiring significant amount of labor in data entry and quality control

SEC Evaluation vs. Co-exposure Model Development

Co-Exposure Model:

- Co-exposure: Guidelines in IG-006
- Process has changed over time
- Each model focuses on single type of data (urine bioassay, dosimetry)
- Typically handled under Technical Basis Document Issues
- Detailed analysis and verification of data sets
- Lengthy due to required data entry and analysis requirements
- Time constraints presented by staffing availability

SEC Evaluation:

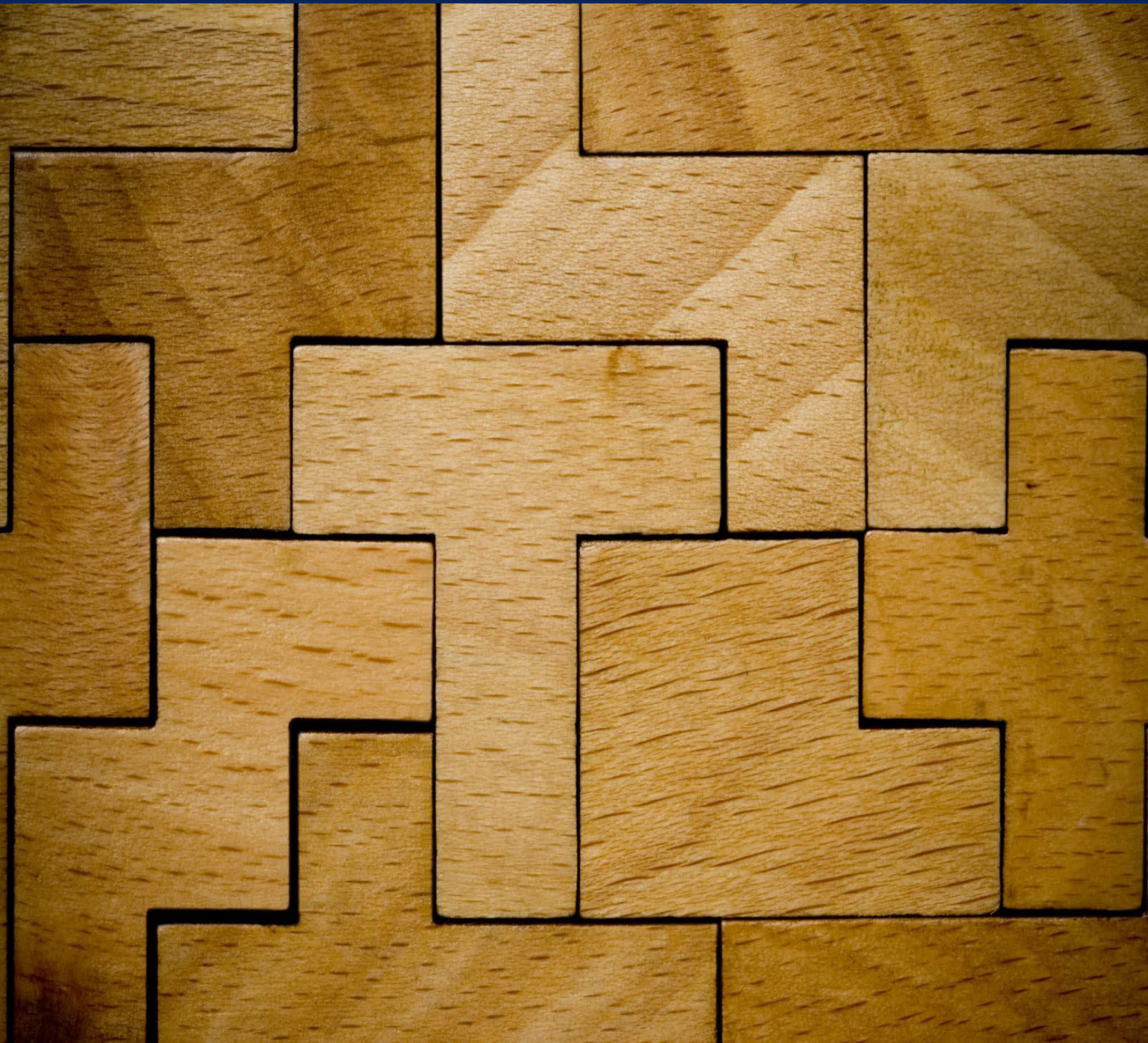
- Process is defined in regulation
- Timeliness constraints (180 days!)
- Ability to bound the dose ***based on current methods and available data***
- Includes all elements of data hierarchy
- Rarely contingent on the development of a future co-exposure model, but may include an already existing co-exposure model
- DR feasibility does not equal CX requirement (timeliness constraints of SEC process)
- Avenue of 42 CFR 83.14 process being considered?

Current SEC Evaluations awaiting decision (1/2)

SEC Petition	Site	SEC ER recommends CX ?	ABRWH waiting for CX completion?
SEC-00057	Hanford	Yes	Yes (Underway)
SEC-00103	Savannah River Site	Yes	No (CX model completed)
SEC-00109	Los Alamos National Lab	No (but Pu CX feasible in RPRT 102)	No
SEC-00219	Idaho National Lab	Yes	No (CX model completed)
SEC-00221	Lawrence Livermore National Lab	No	No

Current SEC Evaluations awaiting decision (2/2)

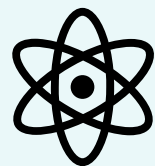
SEC Petition	Site	SEC ER recommends CX ?	ABRWH waiting for CX completion?
SEC-00224	Argonne National Lab, West	No	No
SEC-00235	Area IV, Santa Susana Field Lab	No	No, but requires proof that it is bounding using breathing zone (BZ) data
SEC-00246	De Soto Avenue Facility	No	No
SEC-00250	Y-12	No	Yes (Th)
SEC-00256	Pinellas Plant	No	No



Data Completeness

Data Completeness Basics

- Co-exposure data sets are **ALWAYS** incomplete. If we had data on every worker, we wouldn't need CX models.
- Is there enough data from the most highly exposed workers to create a (1) representative, **OR** (2) bounding model [identifies the maximum plausible dose]?
 - Model doesn't have to be representative if it is bounding.
 - Model doesn't have to be bounding if it is representative.
- The NIOSH/ORAUT white paper introduced the term “missingness” (i.e. opposite of completeness).
- Data sets could be incomplete either because:
 - Workers were monitored, but records are unavailable (i.e. “missing”).
 - Workers who may have had an exposure potential were not monitored.

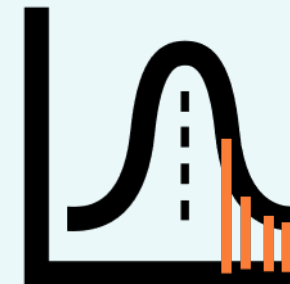
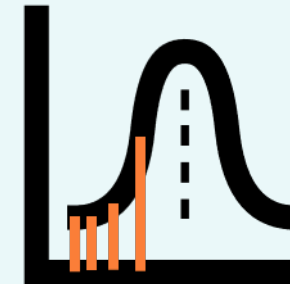
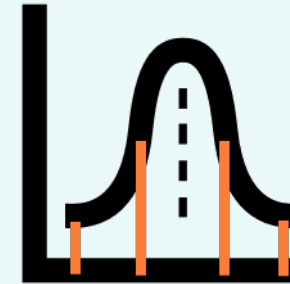




Effects of Incomplete Data Sets

Incompleteness

- Is incompleteness a problem?
 - If the data set does not include randomly distributed records, the model is representative – it accurately estimates worker exposures.
 - NOT a problem!
 - If the data set does not include records from low exposed workers, the model is biased high – it overestimates worker exposures.
 - NOT a problem! *(provided model is sufficiently accurate)*
 - If the data set does not include records from high exposed workers, the model is biased low – it underestimates worker exposures.
 - PROBLEM!

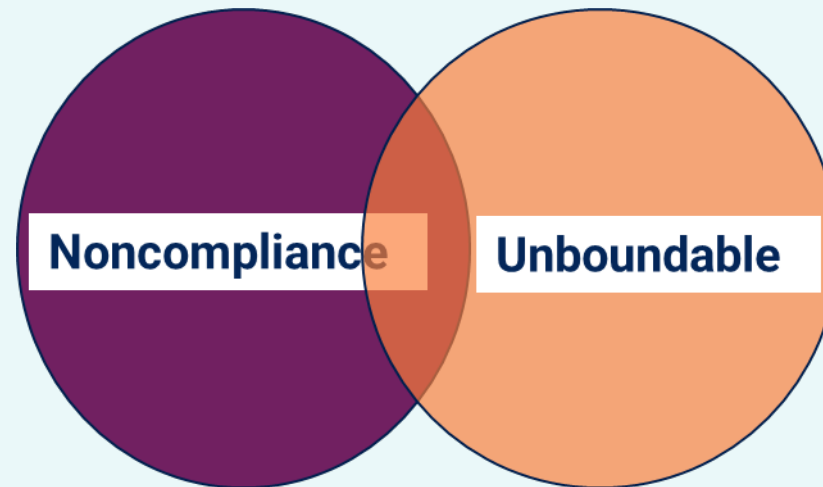




Regulatory Compliance

Regulatory Compliance and Completeness

- Regulatory compliance is not necessarily related to the ability to construct co-exposure models.
 - Following the regulations does not by itself prove that one can construct a co-exposure model.
 - Not following the regulations by itself does not prove that one cannot construct a co-exposure model.
 - Following the regulations cannot be used by itself to judge the monitoring completeness of a dataset.
 - Following the regulations can add to the weight of the evidence, with further evaluation for relevance.





CX Models in the Pipeline

CX Pipeline

Co-Exposure Models in Development

1) Hanford internal (1984-1993)	8) Los Alamos internal	15) K-25 external
2) Santa Susanna internal	9) Sandia external	16) W.R. Grace internal
3) West Valley internal	10) Pacific Northwest external	17) Lawrence Livermore internal
4) BWX Technologies (BWXT) external	11) K-25 internal	18) Kansas City Plant internal
5) Y-12 external	12) X-10 internal	19) Savannah River external
6) Rocky Flats internal	13) Y-12 internal	20) Mound
7) Grand Junction external	14) Portsmouth internal	

- Hanford (1984-93) and West Valley expected to be complete by the end of 2026.
- NIOSH is waiting on West Valley SEC conclusion before proceeding with CX model.
- NIOSH is waiting on BWXT documents from the site.
- NIOSH expects development of the Y-12 external CX model to take a couple years due to magnitude of the effort.
- The rest will follow – no completion date set yet.



Conclusions

Conclusion

- If individual monitoring data are not available, NIOSH can use monitoring results for groups of co-workers for dose reconstructions.
- SEC evaluations rarely depend on the development of a future co-exposure model.
 - NIOSH has a 180 day time limit to complete SEC evaluations.
 - The ABRWH has no similar time limit to complete their evaluation of a SEC petition.
 - There is no similar time limit for NIOSH to develop CX model for DR.
- Co-exposure model development is a lengthy process requiring significant amount of labor in data entry and quality control.
- Internal and external checks of the datasets are performed to look for signs of significantly incomplete data or incomplete monitoring.
- A co-exposure model does not require all the data, just a significant portion of the data from the most highly exposed workers.
- Regulatory compliance with a monitoring program or lack thereof cannot be used by itself to decide if a dataset is complete enough.

Contact Info:

Brant Ulsh, Ph.D., CHP

Research Health Scientist

Division of Compensation Analysis and Support

National Institute for Occupational Safety and Health

Email: bau6@cdc.gov

Lara Hughes, Ph.D., CHP

Research Health Scientist

Division of Compensation Analysis and Support

National Institute for Occupational Safety and Health

Email: fum7@cdc.gov



Thank you.

For more information, contact CDC

1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 <https://www.cdc.gov/> | <https://www.cdc.gov/niosh>

Follow us on social **@CDCgov**

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention or the National Institute for Occupational Safety and Health.

