NIOSH Response to SC&A Review of ORAUT-OTIB-0081, Internal Coworker Dosimetry Data for the Savannah River Site

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SEC Issues and SRS Workgroup Meeting
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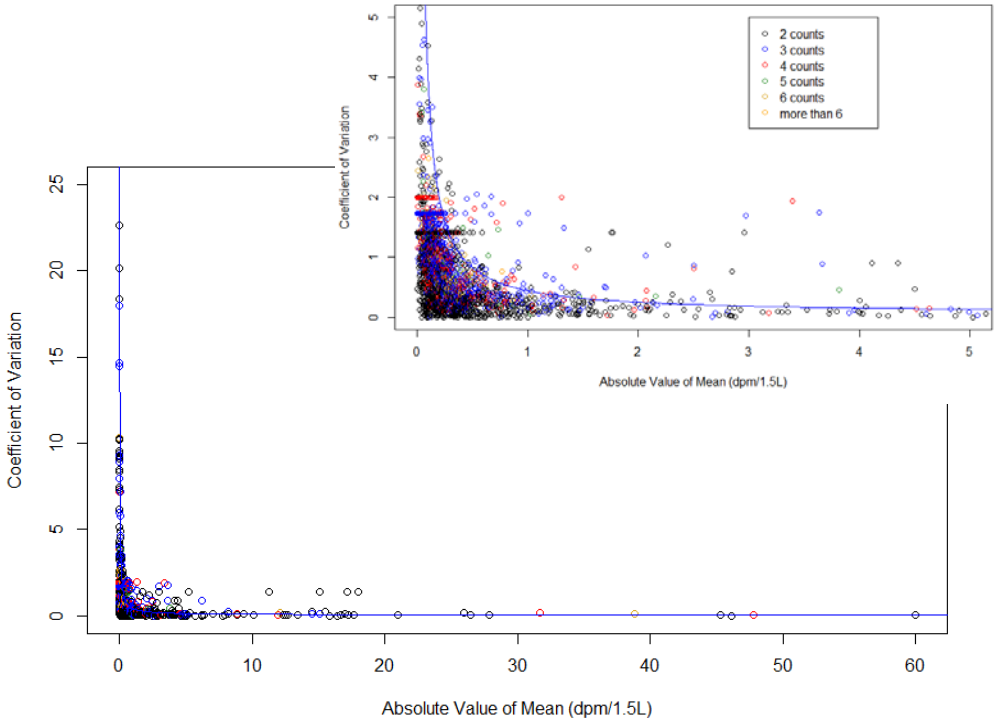
Overview

- SC&A review of ORAUT-OTIB-0081 (13 concerns)
  - 6 Findings
  - 7 Observations
- General Categories of Concern
  - Statistical Analysis – Multiple Imputation (4)
    - Findings 2,3 and Observations 1,2
  - Stratification (5)
    - Finding 5,6 and Observations 4,5,6

Finding 1 – Bioassay Variability

- Data Adequacy Issue
- NIOSH/ORAUT Response:
  - Concern originates from initial evaluation of trivalent actinides
  - Small number of variable samples once chelation removed from co-worker model



Finding 1 – Bioassay Variability – cont.

- NIOSH/ORAUT does not agree that the observed variability in repeated counts prohibits use of the bioassay data for developing coworker models, primarily because:
  - Analytical results can be the average of multiple counts of a planchet
  - Individual bioassay results are averaged into a Time-Weighted One Person One Statistic (TWOPOS)
  - TWOPOS values are fit to a lognormal distribution
  - 50^{th} and 84^{th} percentile are fit to a chronic intake rate over a number of years

Finding 2 – Multiple Imputation

- Statistical Analysis Issue
- **Related issues:** *Finding 3, Observations 1 and 2*
- *NIOSH/ORAUT Response:*
  - Multiple imputation is a better and more statistically appropriate method for estimating censored data compared to the MDA/2 method
  - As the Dose Reconstruction program evolves, new and more robust methods can and should be expected to replace initial methods and assumptions

Finding 2 – Multiple Imputation – cont.

- It is well known that both external dosimetry data and bioassay data tend to follow lognormal distributions
- NIOSH/ORAUT have been using the multiple imputation method in external dosimetry co-worker models since 2015
  - ORAUT-RPRT-0071 External Dose Coworker Methodology
  - ORAUT-OTIB-0086 Pantex External Coworker Model
- SC&A has reviewed these models and has not critically commented on the methodology

Finding 2 – Multiple Imputation – cont.

- SC&A questions the deviation from the old method using LOD/2

Approaches to Censored Data

	External Dose	Internal Dose
Dose Reconstruction	Lognormal distribution GM = n*LOD/2 GSD = 1.52 95th Percentile = n*LOD	Triangular distribution Min = 0 Mode = LOD/2 Max = LOD
Old Coworker	LOD/2 of all censored dosimetry data	LOD/2 of all censored bioassay data
New Coworker	Multiple imputation of positive dose values to impute censored data to fit lognormal coworker (ORAUT-RPRT-0071)	Multiple imputation of positive bioassay to impute censored data For TWOPOS calculation (ORAUT-RPRT-0096)

Finding 2 – Multiple Imputation Summary

- NIOSH intends to use multiple imputation as the primary method for analysis of censored datasets

Finding 3 - Multiple Imputation: Uranium

- Statistical Analysis Issue
- **Related issues:** *Finding 2, Observations 1 and 2*
- *NIOSH/ORAUT Response:*
  - With multiple imputation, the censored values can either be higher or lower depending on the uncensored data
  - In the case of uranium, there are multiple censoring levels
  - The relatively high censoring level for some of the data is the primary reason for the increased TWOPOS results

Finding 3 – Multiple Imputation: Uranium

- NIOSH intends to use multiple imputation as the primary method for analysis of censored datasets

Finding 4 – Claimant Cutoff for Data

- Data Adequacy Issue
- *NIOSH/ORAUT Response:*
  - While we agree that additional data is usually better and improves statistical analysis, we do not believe this is necessary
  - The current coworker models do not appear to have a great deal of variability and are rather stable in the later years where additional data may improve the statistics

Finding 4 – Claimant Cutoff for Data Summary

- NIOSH does not intend to add additional claimant data unless there is a compelling reason to believe the coworker models will change significantly

Finding 5 – Machinist Classification as non-CTW

- Stratification Issue
- **Related Issue:** Finding 6, Observations 4, 5, and 6
- *NIOSH/ORAUT Response*
  - Basis for stratification was routine vs. non-routine work
  - Multiple documents were consulted as to whether or not to include machinist
    - Surveillance of former construction workers at Oak Ridge Reservation: a revised needs assessment (Bingham, 1997)
    - Savannah River Building Trades Medical Screening Program A Needs Assessment (CPWR, 1998)

Finding 5 – Machinist Classification as non-CTW -cont.

- Observed examples that can go both as CTW and non-CTW
- Many machinists (18/31) have already been designated as a CTW due to other information (Maintenance Mechanic, Millwright, etc)
- 31 Machinist (19 Prime Contractor, 12 subcontractor)
  - 18 – assigned CTW
  - 2 – non-CTWs (operators)
  - 1 – 700 area Machine Shop
  - 2 – Unknown location
  - 8 – Machine Shop in Central Shops Area

Finding 5 – Machinist Classification as non-CTW –cont.

- NIOSH does not believe the 8 to 10 machinist who were classified as non-CTW will have a significant impact on the coworker models

Finding 6 – CTW Misclassification Evaluation

- Data Validation /Stratification Issue
- **Related Issue:** Finding 5, Observations 4, 5, and 6
- *NIOSH/ORAUT Response:*
  - Information from a targeted sampling also called nonprobability or judgmental sampling cannot be applied to the co-worker model as a whole
  - 9.14% of the sample of targeted worker entries were by SC&A's judgement misclassified

Finding 6 – CTW Designation Evaluation

- NIOSH/ORAUT conducted probability sampling to quantify the misclassification rate for the coworker models
- All four dataset passed the evaluation with less than 5% misclassification rate

Dataset CTW Determination	Dataset size (N)	Fields Checked (n)	# of Errors	Classification Error Rate
SRS In vivo	28026	847	25	2.95% (CI: 1.93% - 4.30%)
SRS In vitro	100952	873	16	1.83% (CI: 1.05% - 2.95%)
SRS Np Logbook	3620	709	8	1.13% (CI: 0.55% - 2.10%)
SRS Tritium	260278	874	6	0.69% (CI: 0.25% - 1.49%)

Finding 6 – CTW Designation Evaluation – cont.

- SC&A presented *General Service Operators, Supervisors, and Foreman* as examples where some workers could be either non-CTW or CTW
  - None of these are listed as CTWs in OCAS-PER-0014, Bingham (1997) and CPWR (1998)
- During the development of the Master Occupation Table (MOT), all operators were categorized as non-CTW
- At SRS the foreman job title was used in multiple departments including technical, laboratory, maintenance, and construction

Finding 6 – CTW Designation Evaluation – cont.

- NIOSH reviewed the seven examples presented by SC&A in Table 17 and found no discrepancies in the original CTW vs. non-CTW designation
- Questions for SC&A
  - Why is this a Finding and not an Observation?
  - What is SC&A's conclusion? How is this conclusion applicable to the current coworker models.?
  - What is the confidence interval about the 9.14% point estimate?

Observation 1 – Multiple Imputation

- Statistical Analysis Issue
- **Related issues:** *Finding 2 and 3, Observation 2*
- *NIOSH/ORAUT Response:*
  - Multiple imputation is a better and more statistically appropriate method for estimating censored data compared to the MDA/2 method
  - Multiple imputation method introduces less bias than other methods

Observation 1 – Multiple Imputation – cont.

- Maximum Possible Mean method was initially proposed and used because we had not developed a suitable alternative for use in TWOPOS
- The recommendation to intentionally use a biased, technically inferior method should not be based simply on the fact that it gives higher results
- NIOSH intends to use multiple imputation as the primary method for analysis of censored datasets

Observation 2 – Multiple Imputation: POC Scoping assessment

- Statistical Analysis Issue
- **Related issues:** *Finding 2 and 3, Observation 1*
- *NIOSH/ORAUT Response:*
  - Finding 2 and Observation 1: SC&A comment indicating the coworker doses will be “unfairly” low because multiple imputation is used to model censored data
  - Finding 3: SC&A provided an example where coworker intakes were higher using multiple imputation than those derived from an alternate censored data approach

Observation 2 – Multiple Imputation: POC Scoping assessment – cont.

- Observation 2: SC&A indicates that, although there can be some significant differences in the derived doses, *there is very little difference in the probabilities of causation between the two methods*, which is the quantity of interest in a compensation decision.

Observation 2 – Multiple Imputation: POC Scoping assessment – cont.

- The contradictory nature of the findings and observations demonstrates that there cannot be a direct, systematic comparison between missed dose, which is calculated from person-specific bioassay results and employment history, and coworker intake, which uses a compilation of many results from many workers to assemble a distribution for all potentially exposed individuals at a site.

- NIOSH intends to use multiple imputation as the primary method for analysis of censored datasets

Observation 3 – Difference in the # of Trivalent Samples

- Data Adequacy Issue
- *NIOSH/ORAUT Response:*
  - Year by year comparisons are difficult samples are not necessarily analyzed in the same month or year as they were collected
  - Over the entire period (1963-1987) there were 18,293 americium samples in the logbooks
  - Over the same period there were 18,153 americium samples noted in the bioassay summaries

Observation 3 – Difference in the # of Trivalent Samples – cont.

- This difference of 140 samples is considered a minor difference (<1%)

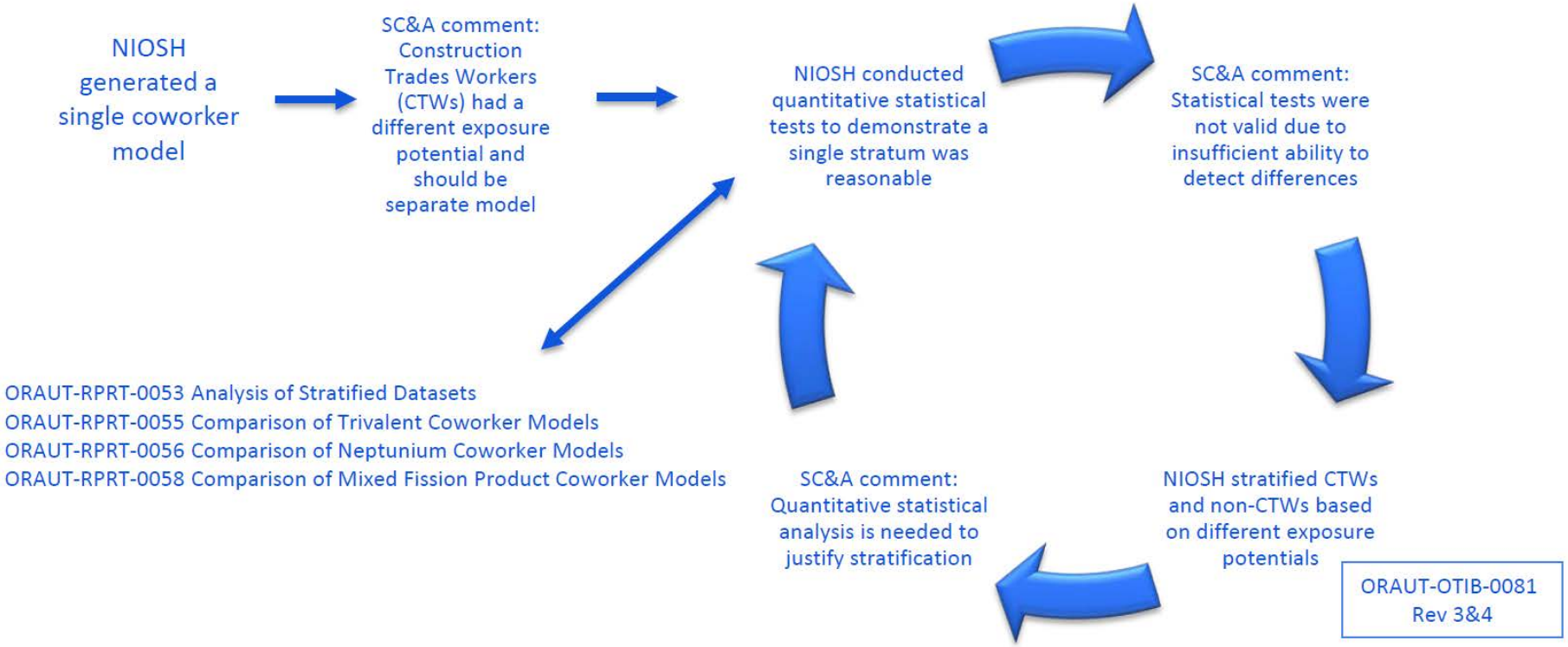
- NIOSH contends that the data used in the coworker model analysis is sufficiently complete

Observation 4 – Statistical Comparison of Stratified Groups

- Stratification Issue
- **Related Issues:** Finding 5 and 6, Observation 5
- *NIOSH/ORAUT Response:*
- *NIOSH conducted a priori* stratification based on differences in exposure potential between non-routine work and routine work *(professional judgement)*

non-routine work	Construction Trades Workers (CTWs)
routine work	Non-CTWs (all other workers)

Observation 4 – Stratification Evolution



Observation 4 – Decision to Stratify

- Again, we decided on a qualitative exposure potential difference as the basis for stratification
  - We found it difficult to argue that the exposure potential was similar between routine operations and non-routine operations
  - For example, consider when a glovebox is purposely breached
    - Loss of engineering control used to protect operations workers vs. after breach respiratory protection used to protect non-routine workers

Observation 4 – Quantitative Stratification Method

- Previous statistical comparison methods were critiqued
  - Workgroup members opined

    "I think it's going to be hard to generalize on that [statistical analysis] *because there are just so many different situations that might change our evaluation of that statistical analysis" (Melius 2015)*
  - No single statistical analysis (quantitative analysis) that we could identify and use *a priori*
  - In reality, the initial CTW vs. non-CTW stratification of the co-worker model was the hard part

Observation 4 – Quantitative Stratification Method – cont.

- If the SRS and SEC Issues Workgroups disagree with stratification
  - Fairly easy to put the groups back together and would result in better statistical analysis if the two groups are the same potentially worse if they are different
- What remains unclear, based on the mixed comments, is the recommendation of the respective Workgroups
  - No Stratification needed
  - CTWs and non-CTWs
  - Subcontractors vs. non-Subcontractors (all DuPont)

Observation 4 – Workgroup Stratification Advice

- We have demonstrated that we can stratify the workforce with a low misclassification rate
  - *Do we need to stratify?*
    - *Please note, NIOSH's preference is to not stratify*
  - *If we do need to stratify, are there strata that the Workgroups prefer?*
    - *What quantitative analysis do you want us to use?*

Observation 5 – Quantitative Assessment of Job Plans

- Stratification Issue
- **Related Issues:** Finding 5 and 6, Observations 4 and 6
- *NIOSH/ORAUT Response:*
  - SCA recommends a quantitative assessment to determine whether Dupont CTW and Subcontractor CTWs are part of the same strata
  - A separate White Paper discussing this issue was submitted to the Workgroup
  - In November 2019, SC&A commented on this White Paper

Observation 5 – Quantitative Assessment of Job Plans – cont.

- NIOSH is currently reviewing and developing responses to SC&A Comments in a separate response

Observation 6 – Sensitivity Analysis of Misclassification

- Stratification Issue
- **Related Issues:** Finding 5 and 6, Observation 4 and 5
- *NIOSH/ORAUT Response:*
  - SCA recommends a sensitivity analysis be conducted to assess effect of misclassification of borderline job titles
  - While this can be done, NIOSH does not see the value of this sensitivity analysis considering
    - NIOSH's probability sampling indicates misclassification of less than 5%
    - Similarities between the final CTW and non-CTW coworker models

Observation 7 – Error rates dependent on Payroll ID

- Data Validation Issue
- **Related Issues:**
- *NIOSH/ORAUT Response:*
  - Much work was done to ensure that all of the payroll prefix issues not counted in the transcription tests would not place the worker in the wrong CTW/non-CTW category and therefore have no effect on the coworker distributions

Observation 7 – Error rates dependent on Payroll ID – cont.

Table 3. Numbered tests from SC&A review

Test Type	Rev 4 In Vitro	Rev 4 In Vivo	Rev 4 Np Logbook	Rev 3 Am Logbook	Rev 3 Tritium	MOT MFPG[a]
Completeness	Sequential 1	CF=1, CF=5 2	Census 3	Pre-dated RPRT-0086	Pre-dated RPRT-0086	Pre-dated RPRT-0086
Transcription	4	7 PR	6 PR	5	12	8 PR
CTW Designation	10	9	11	Not tested	13	Not tested

a. MFPG = Mixed fission product gamma