Status Update on SC&A Comments on OTIB-0081, Revision 4

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SRS / SEC Work Group Meeting

November 20, 2020

Overview

- SC&A review of ORAUT-OTIB-0081, Rev 4. (13 concerns)
  - 6 Findings ➡ 5 Findings
    - F1 – OPEN
    - F2, F3 – RECOMMEND CLOSING
    - F4, F5 - CLOSED
  - 7 Observations ➡ 8 Observations
    - O7 – CLOSED
    - O1, O2, O3, O4, O5, O6, & O8 – RECOMMEND CLOSING

Finding 1: Bioassay Variability (1 of 2)

- **Finding 1:** *Although SC&A recognizes that incident-based sampling involving chelation is not considered in final coworker modeling, the removal of DTPA-influenced samples from consideration in the analysis of the <u>high variability observed in trivalent actinide bioassay results</u> has not been justified sufficiently. Evidence suggests the variation among DTPA and non-DTPA samples is nearly identical. Furthermore, OTIB-0081 has not provided any reference to justify the assumption that DTPA causes heterogeneity among a single urinalysis voiding.*

- **Status:** <u>OPEN</u>

Finding 1: Bioassay Variability (2 of 2)

- NIOSH agrees with SC&A that chelation therapy is not a source of variability in repeated counts of a given planchet. NIOSH does not agree with SC&A that the observed variability in repeated counts prohibits use of the bioassay data for developing co-exposure models. There is no definition for "high variability"; it is a subjective decision. Research on this issue is currently being performed by NIOSH and will be presented and discussed later during this WG meeting.

Finding 2: Multiple Imputation

- **Finding *2:*** *Use of* <u>imputed values</u> *that are less than one-half of the MDA raises a fundamental fairness issue in that monitored workers who have bioassay results that are less than the MDA are assigned a missed dose in accordance with ORAUT-OTIB-0060, "Internal Dose Reconstruction."*

- **Status:** <u>Recommend Closing</u>

- SC&A memo dated June 3, 2020 [SRDB 182225], *Review of Multiple Imputation Methods Applied to Censored Bioassay Datasets,* concluded "*…the use of multiple imputation in evaluation of bioassay datasets with censored results is technically appropriate, scientifically defensible, and likely of small practical significance when considering its effect on resulting POC calculations.*" Therefore, NIOSH recommends closing this observation.

Finding 3: Claimant Cutoff for Data

- **Finding 3** (originally Finding 4): *The coworker analysis uses the internal monitoring for claimants for which data were available to NIOSH in approximately August 2011 (~4,000 claims). Since that time, approximately 2,000 additional claims have been submitted that could be used to augment the coworker dataset. Inclusion of these data would be especially important for the two contaminants that required a combination of multiple years for analysis due to lack of a sufficient number of data points (uranium and cesium).*

- **Status:** Recommend Closing

- Per transcripts of the December 5, 2019 Workgroup meeting (page 165), it was decided not to pursue the inclusion of additional data, however we could not find in the transcripts where a vote was taken. Therefore, NIOSH believes this finding is closed but needs confirmation.

Finding 4: Machinist Classification as non-CTW

- **Finding 4** (originally Finding 5): *Classification of a "Machinist" as a nonCTW in OTIB-0081 is inconsistent with its classification in OCAS-PER-014, "Construction Trades Workers."*

- Status: <u>CLOSED</u>

- Workgroup discussed this issue at length and concluded that that since the misclassification rate is less than 5% it would have minor impact on the co-exposure models.

- The Special Exposure Cohort Workgroup voted to close this Finding on December 5, 2019 (pages 145-146).

Finding 5: CTW Misclassification Evaluation

- **Finding 5** (originally Finding 6): *A targeted sampling comparing the OTIB-0081 strata designation (CTW or nonCTW) against two alternate sources for identifying worker job classification indicated that just over 9 percent of the entries appear to be in conflict when comparing the NIOSH and SC&A analyses.*

- **Status:** CLOSED

- Discrepancies between the original CTW and nonCTW designations were less than 5%.

- The Special Exposure Cohort Workgroup voted to close this Finding on December 5, 2019 (pages 145-146).

Observation 1: Multiple Imputation

- **Observation 1:** *While the multiple imputation method is mathematically correct, it has the potential to result in biasing the simulated bioassay results unnecessarily low. Alternate approaches, such as the maximum possible mean method, which replaces censored data with the actual censoring limit (or alternately one-half the censoring limit), would solve the issues associated with datasets containing a large number of censored values in a claimant-favorable manner.*

- **Status:** Recommend Closing

- SC&A memo dated June 3, 2020 [SRDB 182225], Review of Multiple Imputation Methods Applied to Censored Bioassay Datasets, concluded the use of multiple imputation is technically appropriate.

Observation 2: Multiple Imputation
(POC Scoping Assessment) (1 of 2)

- **Observation 2:** *A scoping assessment … concluded that, while intakes and doses are significantly higher using a missed dose approach in most of the sample calculations, the overall effect on resulting probability of causation (POC) values was relatively minor, and, in most cases, the coworker-derived POC bounded the missed dose evaluation. This appears to be due to the effect the statistical distribution has on resulting POC values, namely, the use of a triangular distribution for missed dose evaluation versus a lognormal distribution for coworker data.*

- **Status:** <u>Recommend Closing</u>

Observation 2: Multiple Imputation

(POC Scoping Assessment) (2 of 2)

- SC&A noted that the calculated intakes and doses differed between multiple imputation vs. LOD/2 methods but concluded that the overall effect on the probability of causation (POC) was relatively minor, and in most cases, the co-exposure derived POC bounded the missed dose evaluation.

- SC&A memo dated June 3, 2020 [SRDB 182225], Review of Multiple Imputation Methods Applied to Censored Bioassay Datasets, concluded the use of multiple imputation is technically appropriate.

Observation 3: Multiple Imputation: Uranium

- **Observation 3** (Originally Finding 3): *The sample comparison of co-exposure intakes to a missed dose method for uranium showed that the co-exposure model derived intakes were a factor of 4 or more higher than the missed dose approach. This illustrates the potential for inequity between the treatment of unmonitored workers assigned coworker intakes and monitored workers with results less than the detection limit in some situations.*

- **Status:** <u>Recommend Closing</u>

Observation 3: Multiple Imputation: Uranium (2 of 2)

- NIOSH acknowledges that in using the multiple imputation method, the censored values can be higher or lower depending on the uncensored data. Further, in the case of uranium, there are multiple censoring levels over time and that the relatively high censoring level for some data explain the increased intake results. In contrast, missed dose is based exclusively on data that are less than the MDA. The resulting intakes use a triangular distribution encompassing the full range of possible missed intakes from zero to the MDA.

- SC&A memo dated June 3, 2020 [SRDB 182225], Review of Multiple Imputation Methods Applied to Censored Bioassay Datasets, concluded the use of multiple imputation is technically appropriate.

# Observation 4: Difference in the # of Trivalent Samples
(1 of 2)

- **Observation 4** (Originally Observation 3)**:** *Available trivalent logbook data show notable differences with the number of reported samples taken in 1980 and 1982. These years, and any changes in operations, are not discussed specifically in OTIB-0081. However, it is noted that a future NIOSH report on americium exposure potential at SRS is pending that may address the apparent gaps in the data.*

- **Status:** *Recommend Closing*

- NIOSH provided a response [SRDB 182704] to the WG on 8/11/20 regarding the completeness of the trivalent logbooks.

Observation 4: Difference in the # of Trivalent Samples

(2 of 2)

- The difference of 140 samples (<1%) between HP Summary Reports and the Am logbooks over 15 years is considered a minor difference.

SRS Americium Bioassay
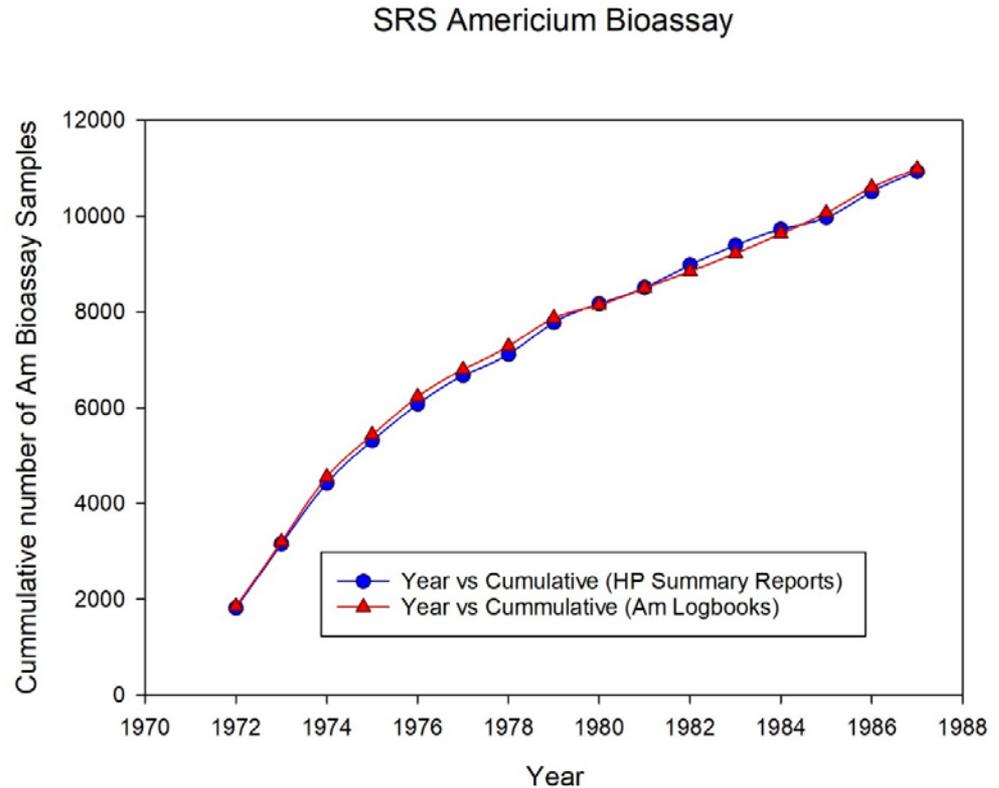
Observation 5: Statistical Comparison of Stratified Groups

- **Observation 5** (Originally Observation 3): OTIB-0081 does not provide a statistical comparison of the two stratified groups as prescribed in the coworker implementation guide. The various coworker models were stratified based on the a priori assumption that exposure potential between CTWs and nonCTWs was different.

- **Status:** Recommend Closing

- Transcript from the December 11 meeting, page 129, shows SC&A states *"And so the status of this is there's really no action required. It's just, it's there to note the fact that the coworker guidelines say that you should perform a statistical analysis after you stratify the groups to see if they're truly different."*

Observation 6: Quantitative Assessment of Job Plans

- **Observation 6** (Originally Observation 5): *SC&A acknowledges that there are inherent difficulties in correctly associating individual workers with the correct CTW/nonCTW strata. This is particularly true for job titles that could potentially be included in either stratum…. SC&A suggests a scoping analysis in which such borderline job titles are removed to ascertain the effect on the resulting distributions. Such an analysis would help determine whether current strata designations are sufficient or a more rigorous approach to individual job classification is warranted.*

- **Status:** Recommend Closing

Observation 6: Quantitative Assessment of Job Plans

(2 of 2)

- NIOSH White Paper entitled "Savannah River Site Plutonium Construction Trade Worker Stratification Refinement" dated May 28, 2019 stated that *"…NIOSH believes it is reasonable to combine all CTWs into a single stratum for assignment of intakes in the SRS internal dose coworker study."* SC&A disagreed in their review (dated November 12, 2019) and suggested additional analyses. NIOSH's responses to SC&A comments, dated March 4, 2020 [SRDB 179903] concluded that *"…the final conclusions that sub-stratification is not necessary remains unchanged…"* and notes that *"…additional coding and analysis would take many months, if not years to complete."*

Observation 7: Sensitivity Analysis of Misclassification

- **Observation 7** (Originally Observation 6): *The results shown in attachment A of OTIB-0081 demonstrate a high degree of confidence that the acceptable error rates are within the goals established for each test. However, this conclusion is dependent on the assumption that payroll ID issues identified would not affect the resulting coworker distributions.*

- **Status:** <u>CLOSED</u>

- The Special Exposure Cohort Workgroup voted to close this Finding on December 5, 2019 (pages 145-146).

Observation 8: Error rates dependent on Payroll ID

- **Observation 8** (Originally Observation 7): *The results shown in attachment A of OTIB-0081 demonstrate a high degree of confidence that the acceptable error rates are within the goals established for each test. However, this conclusion is dependent on the assumption that payroll ID issues identified would not affect the resulting coworker distributions (refer to section 6.5).*

- **Status:** Recommend Closing

- This was a data validation issue. The Payroll prefix issues have no effect on the CTW/non-CTW coworker distributions. The Workgroup discussion on pages 146 through 150 of the December 5 transcript indicate there was agreement by all this was a non-issue. Although no vote was taken, page 134 of the December 11 transcript has SC&A considering this observation closed and therefore NIOSH recommends closing this observation.