Response to SC&A Memorandum, "Summary Position on Trivalent Bioassay Variability"

Response Paper

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INTRODUCTION

SC&A raised the issue of excessive trivalent bioassay variability in 2014. Since that time, there have been three documents written by SC&A [2014, 2019, 2020] and two written responses from NIOSH [2019, 2020]. The issues discussed in the latest SC&A memorandum, "Summary Position on Trivalent Bioassay Variability" [SC&A 2020] can be distilled down into two primary issues:

1) **High Variability**: The americium data from Savannah River Site (SRS) are "highly variable" and this implies a fundamental deficiency in the data that makes it unsuitable for use in dose reconstructions, which includes the development of co-exposure models from the data.
2) **Procedures**: One should be able to obtain quality assurance and procedural records for americium analyses performed from 1963 to 1989 that provide enough detail for us (today) to judge the adequacy of the bioassay data for use in dose reconstructions. More specifically, these records should allow us to explain the "high variability" observed in the americium results.

HIGH VARIABILITY

In a previous National Institute for Occupational Safety and Health (NIOSH) response regarding the topic of high variability in SRS americium results, NIOSH pointed out (see Finding 1) that the variability in individual bioassay results is greatly reduced by the multiple averaging that takes place during the construction of a co-exposure model [NIOSH 2019, PDF p. 6]. Nevertheless, the beliefs persist that the perceived high variability is a symptom of an underlying problem with the americium analysis and that acceptable variability should be defined out of context (i.e., ignoring the multiple averaging used in co-exposure modeling). For example, SC&A states [SC&A 2020, PDF p. 9]:

> *It is SC&A's opinion that before applying the analysis steps described in NIOSH (2019) (and shown above), the Coworker Criteria regarding the adequacy of the data must be sufficiently established. If the bioassay data are not deemed adequate prior to application of the co-exposure methodology, then the resulting co-exposure results should likewise be deemed inadequate.*

SC&A was responding to the argument NIOSH made that after averaging four times in the process of generating a co-exposure model, the variability of the original bioassay data should be of little concern (i.e., the average of an average of an average of an average has much less variability than the original data). In their response, SC&A seems to be implying that the acceptability of the variation in the bioassay data should be judged without consideration of its ultimate use. Acceptable levels of uncertainty (variability is a component in the uncertainty associated with a measurement) are always defined in the context of the application — what the measurements are being used for. For example, the level of variability that is acceptable for an emergency analysis of americium in urine submitted after an incident is higher than the level of variability that is acceptable for the analysis of americium in urine submitted as part of a routine

monitoring program. NIOSH contends that the level of variability (uncertainty) that is acceptable for a measurement is tied to the use of the measurement.

An example of the difference in level of acceptable variability can be found by a simple analysis of Table 1 in SC&A's memo [SC&A 2020, PDF pp. 6-7]. The seven rows of the table were chosen subjectively and are not representative of the population of disc results. To draw any conclusion about the variability of the process from these seven results is inappropriate.

In SC&A's table, rows 1, 2, 5, 6, 7 are all data from one individual involved in an incident, and NIOSH would like to offer the following three observations:

1) These are small aliquots of the larger urine sample. Typically, a 300mL aliquot is analyzed by the laboratory. In each of these instances, a small 10 mL or 30 mL aliquot was analyzed. Thus, to compare the variability of these small aliquot samples to the whole dataset, for which the vast majority of samples are 300 mL, is not a straightforward analysis. In addition to the change in sample volume, the count time could also have been and was likely changed. This would likely have a much larger effect on the variability, but we do not know how long these samples were counted in an emergency scenario.

2) NIOSH would like to point out that even with this variability, the effect on the co-exposure model would be minimal. The five rows that are from one individual in the same year would only represent a single data point in a single year in the co-exposure model due to the use of the TWOPOS methodology. The same applies to the other two workers in that table.

3) The individual dominating SC&A's table was chelated, further complicating the small aliquot results and analysis. As NIOSH indicated in ORAUT-OTIB-0081 [NIOSH 2019], individuals who underwent chelation were removed from the co-exposure analysis. Thus, these data were not used in the co-exposure model. The reality of SC&A's example of *excessive variability* is that five of the seven rows have absolutely no impact on the co-exposure model.

NIOSH believes that SC&A has chosen non-representative examples that have very little effect on the co-exposure models.

However, the main problem with issue 1 from the Introduction is that an adequate definition of the level of variability that is considered "excessive" is never given. SC&A attempted to define acceptable variability for 1963 to 1989 SRS americium results using:

- Results of the 2003 Optimization of Monitoring for Internal Exposure (OMINEX) bioassay survey [Hurtgen and Cossonnet 2003b]
- Process precision criteria from the 1987 SRS procedure DuPont Standard Operating Log (DPSOL) 47-206 [SRS 1987].

Both documents were reviewed in detail (see Appendices A and B) and neither provides criteria that are useful to decide if specific SRS americium bioassay results reported from 1963 to 1989 have excessively high variability. A brief summary of the conclusions is given below.

Results of the 2003 OMINEX Bioassay Survey

SC&A states [SC&A 2020, PDF p. 8]:

> *Regarding other laboratories and standards of practice, National Council on Radiation Protection and Measurements (NCRP) Report No. 164, "Uncertainties in Internal Radiation Dose Assessment" (NCRP, 2009), provides some additional perspective. NCRP (2009) discusses the OMINEX Project, which conducted a survey of bioassay laboratories and compiled the results for 18 different laboratories included in the study. One goal of the study was to determine the optimum analytical conditions, with a focus on alpha-spectrometric measurements of actinides. The spectral measurements of actinides are considered to be among the most challenging analyses routinely conducted at radioanalytical labs. The optimum conditions determined by NCRP (2009) were based on an uncertainty of <25 percent when considering a total activity of 1 millibecquerel per day (mBq/day) sample (0.06 dpm/day) and considering an MDA of 0.1 mBq/day (0.006 dpm/day). The average uncertainty reported by the participating laboratories was ±30 percent (NCRP, 2009).*

The discussion in the National Council on Radiation Protection and Measurements (NCRP) report [NCRP 2009] is a summary of information in a 2003 paper [Hurtgen and Cossonnet 2003a], which, in turn, is a summary of the full report [Hurtgen and Cossonnet 2003b] referred to as the OMINEX report. Looking at the full OMINEX report, it is clear that the "optimum condition" of <25% uncertainty for a sample containing 1 mBq is an arbitrary value, established for the study by the authors, for methods that were state-of-the-art in 2003. Even in 2003, less than half of the labs that participated in the study were able to meet the arbitrary "optimum" standard using alpha spectrometry. In short, the OMINEX report has no regulatory or even good practice imperatives and cannot be used to establish acceptable uncertainty for production radiobioassay labs for any time period, much less 1963 to 1989.

Process Precision Criteria from the 1987 SRS Procedure DPSOL 47-206

SC&A states [SC&A 2020, PDF p. 8]:

> *SC&A was not able to find information on the precision of analytical methods related to trivalent actinides at SRS until a 1987 DuPont Standard Operating Procedure (DPSOL), which stated that the Am/Cm/Cf measurements in urine had a minimum sensitivity (also known as the minimum detectable activity or MDA) of 0.3 dpm/1.5 L and a precision at the 95 percent confidence level of ±19 percent at 6 picocuries per 1.5 L (~13.3 dpm/1.5 L) level (SRS 1987, PDF p. 60). This minimum sensitivity/MDA value is consistent with observed reporting levels in the*

> *captured Am/Cm/Cf bioassay records throughout the current period under evaluation (October 1, 1972–December 31, 1989). The maximum observed range of examples from SC&A (2014) that were greater than 13 dpm/1.5 L was 16–284 percent of the average/reported value.*

The 13.3 dpm/1.5L stated above is the minimum quantifiable value (MQV) (see Appendix B) for the sequential analysis of trivalent radionuclides described in the DPSOL [SRS 1987]. Quantities like the MQV describe the capabilities of a chemical measuring process and should not be applied to individual analytical results as a quality assurance (QA) criterion. For example, the DPSOL states that the process is capable of analyzing americium in urine at a level of 13.3 dpm/1.5L with a coefficient of variation (CV) of 10%. This should not be used as a criterion for "acceptable variation" to disqualify a specific sample at 13.3 dpm/1.5L having a CV of 20%, for example.

The difficulty in defining acceptable variability stems, in part, from the fact that today (much less in the 1963 to 1989 era in question) there are no national or international standards that define an acceptable level of variability for individual analyses performed as part of an operational radiation protection program. One might point to the 2011 version (and previous version) of American National Standards Institute/Health Physics Society (ANSI/HPS) N13.30 *Performance Criteria for Radiobioassay* [ANSI/HPS 2011] for definitions of acceptable variability, but those standards define acceptable variability only for high-level testing samples used in the Department of Energy Laboratory Accreditation Program (DOELAP) bioassay accreditation process. These criteria do not apply to results of analyses of specific samples from an occupational bioassay program. This leads to NIOSH's first major conclusion:

> *Today, there are no generally applicable quality criteria for variability that can be applied to individual analytical results generated in an occupational radiobioassay program. If there are no such criteria that can be applied to results generated today, then there were none in 1963-1989.*

PROCEDURES

The guidance in *Criteria for the Evaluation and Use of Co-Exposure Datasets* [NIOSH 2020] states in Section 2.1 that there "should be a review of the sample collection methods, any chemical processes employed, and the radiation counting equipment used." The Advisory Board approved this guidance on December 11, 2019. SC&A suggests a more comprehensive review is needed. NIOSH has reviewed the analytical methods used in this time period. SC&A has also reviewed them as noted in their summary [SC&A 2020]. The data present in the logbooks containing the americium bioassay data provide further evidence of the laboratory analytical process, such as the use of blanks and spikes. The historical documents referenced and discussed in NIOSH [2019] fulfill the level of review recommended by NIOSH [2020].

SC&A asserts that the level of review performed to date in accordance with NIOSH [2020] is inadequate [SC&A 2020, PDF p. 5]:

> *While the choice of analytical bioassay protocols is appropriate, the documentation provided regarding the bioassays performed by SRS for the determination of trivalent actinides is not adequate to support a determination of dose.*

SC&A [2020, PDF pp. 6–7] discusses in some detail the documentation they would like to see for the americium radiobioassay in order to help them determine that the americium results are acceptable for dose reconstruction. NIOSH acknowledges that access to this information would be helpful but disagrees that it is necessary and wishes to point out the difficulties with obtaining such information:

- Locating and vetting radiobioassay analytical results for a facility is in itself a difficult task. Locating all relevant procedures and QA records for those results is usually not feasible, especially in the pre-DOELAP era (i.e., before 1996).
- Considerable subject matter knowledge would be required to properly interpret procedures and QA records (especially for pre-DOELAP analyses) in any effort to verify what the cognizant technical authority (e.g., the radiochemist) approved at the time of the analysis (as indicated by his/her signature).

SC&A provided a discussion on the range of values of the Am-241 recovery and stated the following [SC&A 2020, PDF p. 8]:

> *Seeing this range of values and absent evidence that the laboratory had developed and actively applied acceptance criteria for spike recoveries, it is difficult to have confidence in the technical adequacy of the bioassay values.*

SC&A quoted heavily from one logbook [SRS 1981-1986] in developing their range of recovery values from 0% to 116%, focusing mainly on the extreme values, which are not representative of the population of recoveries. NIOSH analyzed all of the spike recoveries from this single logbook and plotted the results below in figure 1.

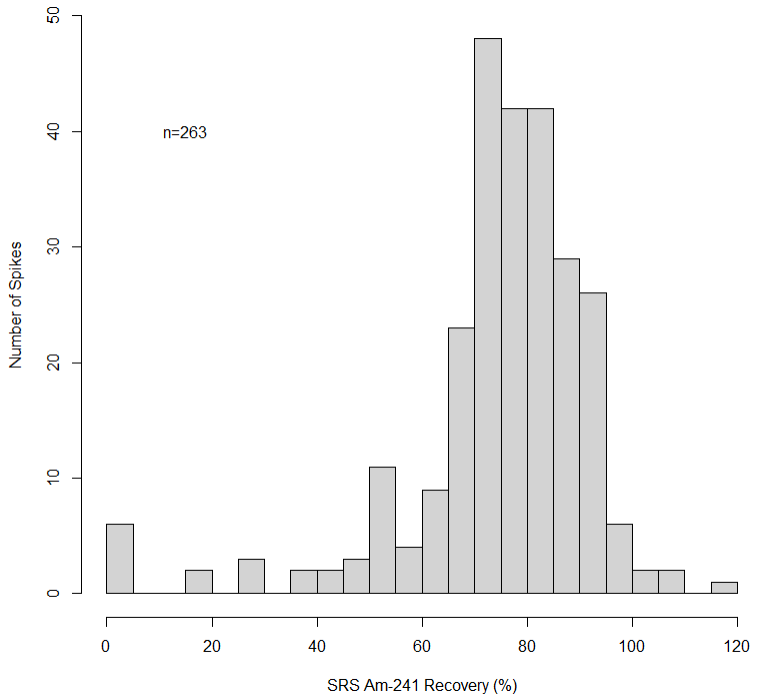

Figure 1: Histogram of SRS spike recoveries of Am-241 from 1981 to 1986.

While the range of recovery is from 0% to 116%, the vast majority of samples had a reasonable recovery. A typical acceptable recovery range is 25% to 120%, and 255 of 263 (97%) samples fell within that range. Only three of 263 (1%) spikes had a 0% recovery. These data were circled on the page indicating that they were flagged, however, the result for the samples were reported. In this particular case, the effect on the co-exposure model as a whole is negligible. SC&A implies that the range of recoveries calls the whole dataset into question, despite the fact that their main focus was extreme recovery values, not the population of values.

The fact that the radiochemist signed off on the analyses in the SRS americium logbooks indicates that sample-specific variability criteria in particular and acceptance criteria in general, whatever they may have been, were met for those analyses. Second-guessing the SRS radiochemist decades after the original analysis, in any meaningful way, is difficult at best. NIOSH [2020] requires a review of the methods used, not a full independent verification. The fundamental assumption is that the available data are usable.

There are a few important caveats to this, including:

- Data that were falsified (e.g., analytical results from Controls for Environmental Pollution) should not be used as reported.
- If data are reanalyzed after being reported (e.g., Mound Po-210 urine bioassay results), the reanalyzed results should be used.
- Data that contain typographical errors as reported by the site to NIOSH should not be used until the errors are corrected.

The level of effort required to reanalyze the data reported by the site is worth noting. The reanalysis of the Mound Po-210 data was a major scientific effort that resulted in several Ph.D. dissertations and is beyond the scope of this project. SC&A's requested level of review would match that done for the Mound Po-210 data with no reason to believe that there is a need for that level of review or that significant changes to the reported results would occur after the review.

This leads to NIOSH's second major conclusion:

> *In general, the original bioassay results of record at a site that were used to demonstrate compliance with the DOE regulations in place at the time of the analyses are considered to be the best available data to use for dose reconstruction and generation of co-exposure models. Limited review of that data is performed as a confirmatory measure.*

METRIC TO DEFINE VARIABILITY

In order to discuss excessive variability, one must define a statistic to measure variability. In SC&A's original memo [SC&A 2014, PDF pp. 7–8], they state (see Finding 18) that the 188 values they called out were "chosen subjectively," which is obviously not a statistic or a metric. In the most recent SC&A memo [SC&A 2020, PDF pp. 4–5], SC&A is counting the number of samples that had ranges of individual disc results greater than plus or minus some percentage of the average value of the sample (i.e., 145 samples had range greater than ±20% of the average value). This is neither a common nor well-known statistic to measure variability, and no reference is given to justify using this statistic.

NIOSH's response to SC&A's 2014 memo [Oak Ridge Associated Universities Team (ORAUT) 2019, PDF pp. 153–157] proposes the use of the CV, also known as the relative standard deviation in some fields, which is the standard deviation of the results divided by the absolute value of the average of the results. Those CV values, plotted as a function of the absolute value of the average values, provide a plot that can be used to assess variability. The CV of a sample should decrease as the absolute value of the average value increases.

In another SC&A [2019, PDF p. 17] response to this issue, their Figure 1 shows a log-log plot of the CV versus the average result, only for average values of 0.32 dpm/1.5L or greater. To do a proper assessment, all average values should be considered. Based on the fact that NIOSH and SC&A have used the CV versus average value plots to assess variability, the CV should be the metric used to define variability, so that subjective and unjustifiable statistics are not used.

CONCLUSION

NIOSH concludes that the SRS americium bioassay data of record were fit to be used to determine compliance with the regulations in place at the time the analyses were performed. The required level of review of that data and the underlying methods were performed. In the absence of contradicting information, the fitness of the analytical results for the original intended purpose implies fitness for use in dose reconstructions in a compensation program.

There are no generally accepted and applicable quality criteria for variability that can be applied to individual analytical results generated in an occupational radiobioassay program to determine if the variability is excessive. The CV is the proper metric to assess variability and should be used moving forward.

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APPENDIX A: 2003 OMINEX BIOASSAY SURVEY

The European Union project OMINEX conducted a survey of radiobioassay labs in the early 2000s to identify the capabilities of these labs for performing alpha and mass spectrometry based radiobioassay. In Report 164, the NCRP [2009] cited a summary [Hurtgen and Cossonnet 2003a] of the full report [Hurtgen and Cossonnet 2003b] describing the survey. In the introduction to the full report, the authors stated the following [Hurtgen and Cossonnet 2003b, PDF pp. 9–10]:

> *This report presents the results of the survey on bioassay measurement performed by the different EU laboratories involved in the monitoring of nuclear workers. In particular:*
>
> - *information was collected from the laboratories on the measurement parameters influencing the uncertainty on the measured quantity.*
> - *the effect of these parameters on total uncertainty on the measured quantity was investigated.*
> - *recommendations are made on the optimization of the values of these parameters to reduce as much as possible the uncertainty on the measured activity and to obtain MDAs as low as possible.*
> - *recommendations are made on the exploitation of the different analytical techniques to achieve these targets.*

Some of the text has been underlined to emphasize that the main purpose of this survey was to define the value of process parameters in an analytical procedure that would lead to optimal detection capability (which is discussed below). In this discussion, it is important to make the distinction between process-specific criteria and sample-specific criteria. For example, the minimum detectable amount (MDA) is used to characterize the detection capability of an analytical process, whereas the decision level (DL) is applied to a specific result to decide if the sample contains the analyte [United States Environmental Protection Agency (US EPA) 2004, PDF pp. 12]. Thus, the criteria presented in the OMINEX report cannot be applied directly to a specific analytical result. The authors of the report were more explicit about what they meant by "as low as possible" later in the document [Hurtgen and Cossonnet 2003b, PDF p. 16]:

> *Our aim is to find the optimum analytical conditions such that for urine analysis, the relative uncertainty is less than 25 % for a measured activity of 1 mBq/24h and an MDA of less than 0.1 mBq/24h. An activity of 0.1 mBq/24h for a routine monitoring of Pu-239 Type S compound with a 6-month monitoring interval would correspond to a dose of 5 mSv.*

The authors are to be commended for stating the ultimate criterion (i.e., a committed effective dose of 500 mrem from an inhalation intake of insoluble Pu-239) they used for selecting their optimal analytical conditions. However, detecting such an intake by a single urine bioassay is a very aggressive goal (even today) and is orders of magnitude lower than what SRS was trying to detect (or needed to detect) in the time period of interest. A summary of the relative uncertainty (precision/variability is one component of uncertainty) achieved by the labs was summarized in

Table 3 of the report, and is reproduced below as Table 1 [Hurtgen and Cossonnet 2003b, PDF p. 32].

Table 1: Relative uncertainty on 1 mBq/24h in urine sample (reproduced from Table 3 of OMINEX report)

Isotope	Average Relative Uncertainty (%)	Minimum Relative Uncertainty (%)	Maximum Relative Uncertainty (%)	Number of Laboratories
^{239}Pu	30	14	68	14
^{238}Pu	31	14	68	14
^{241}Am	31	15	71	14
^{243}Cm	31	15	71	14
^{234}U	37	21	77	14
^{235}U	34	21	77	13
^{238}U	37	21	77	14
^{228}Th	44	20	96	9
^{230}Th	38	18	85	9
^{232}Th	37	18	76	9

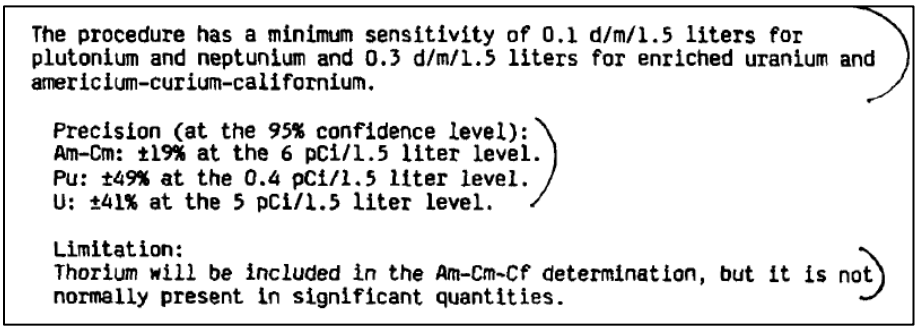
The NCRP [2009] report stated that the average uncertainty was ±30%,[1] which was quoted in the latest SC&A memo [SC&A 2020]. Note that the uncertainties for some labs are quite a bit higher than 30% — averages work that way and can, as a result, be misleading. Remember that these results were achieved in modern labs using state-of-the-art alpha spectrometers, software, chemical procedures (including internal tracers), and counting samples for an average of 4 days (versus less than 1 day at SRS).

All of this leads to the conclusion that one cannot, in good faith, use the average relative uncertainty of ±30% at an activity of 1 mBq from this modern-day study to judge whether or not specific results from the 1963 to 1989 SRS americium data have excessively high variability. In fact, this criterion cannot even be used to judge whether specific samples from the labs participating in the OMINEX study were excessively variable.

[1] Note that the average uncertainty for ^{241}Am was 31%, not 30%.

APPENDIX B: MQV FOR SRS Am-Cm ANALYSIS

SRS DPSOL 47-206 [SRS 1987] states that the precision for the Am-Cm urine bioassay analytical method is 19% at a concentration of 6 pCi/1.5L (at the 95% confidence level).


The procedure has a minimum sensitivity of 0.1 d/m/1.5 liters for plutonium and neptunium and 0.3 d/m/1.5 liters for enriched uranium and americium-curium-californium.

Precision (at the 95% confidence level):
Am-Cm: ±19% at the 6 pCi/1.5 liter level.
Pu: ±49% at the 0.4 pCi/1.5 liter level.
U: ±41% at the 5 pCi/1.5 liter level.

Limitation:
Thorium will be included in the Am-Cm-Cf determination, but it is not normally present in significant quantities.

Figure 2: Excerpt from DPSOL 47-206

Given that the two-sided 95% confidence level is 1.96σ, the standard deviation is therefore

$$\sigma = \frac{(0.19)(6\ \text{pCi/1.5L})}{1.96} = 0.582\ \text{pCi/1.5L}.$$

The CV at a concentration of 6 pCi/1.5L is thus

$$\text{CV} = \frac{0.582}{6} = 0.097 \approx 0.1,$$

which is the CV that defines the MQV[2] for this analysis [Currie 1995, PDF p. 18]. Thus, the MQV for the Am-Cm analytical process is approximately

$$\text{MQV} = 6\,\text{pCi/1.5L} = 13.3\,\text{dpm/1.5L} = 8.9\,\text{dpm/L}.$$

In analytical chemistry, this is usually accepted as the lowest concentration that can be quantified with an acceptable level of certainty [Ellison et al. 2009, PDF p. 170]. According to the DPSOL, Am-Cm can be reliably detected in urine down to a level of 0.3 dpm/1.5L, but the associated CV will be much larger than 0.1, because the CV increases as the mean decreases. It is important to remember that the MQV and MDA are process-specific parameters and should not be applied to a result for a specific sample to render judgments concerning that sample [US EPA 2004, PDF p. 12]. For example, if a specific americium result is 8.9 dpm/L, it can still be deemed acceptable even if the variability as measured by the CV is 0.2.

[2] Also known as the *limit of quantification* or the *quantification limit*.