RESPONSE TO SC&A MEMORANDUM: *Summary Position on Trivalent Bioassay Variability*

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Overview

- SC&A's Two Primary Issues
  - High Variability Context
  - Procedures
- Metric to Define Variability
- Conclusion
- New Data Issue and Path Forward
- Questions

SC&A Issue 1: High Variability

Variability – Discussion Timeline

- NIOSH Response, November 25, 2019
  - Americium results are averaged 4 times in co-exposure modeling
  - Variability of an average of an average of an average of an average is much smaller than variability of the original data
- SC&A Response June 3, 2020 :
  - Implies acceptability of variation should be judged without consideration of its use
- NIOSH Additional Response October 21, 2020
  - Focus of this presentation

High Variability - Context

- Context is crucial
  - Example: variability in emergency monitoring after an incident versus variability in routine monitoring
  - A measurement's acceptable variability is tied to its use

- Consider the seven examples in SC&A's Table 1

High Variability – SC&A's Examples (1 of 3)

- 5 of 7 examples are from one worker involved in an incident
  - These 5 examples were all small aliquots of 10mL or 30 mL compared to the routine 300mL
  - Samples were likely counted for different times
  - These 5 examples contribute to one TWOPOS result in the co-exposure model
  - Furthermore, the worker was chelated so these data were not used in the current Am co-exposure model

High Variability – SC&A's Examples (2 of 3)

- One of the remaining 2 examples involved a worker who was also chelated and should have been removed from our co-exposure model. A change of payroll ID resulted in the inadvertent inclusion
  - Fixed the coding error
  - Sample was also a non-standard small aliquot (210mL)
- The remaining "variable" example was flagged by the radiochemist for follow-up (SRDB 53283, PDF pg 99)
  - a subsequent sample was collected and analyzed
  - the follow-up result was below the reporting level

High Variability – SC&A's Examples (3 of 3)

- Not representative of the Americium co-exposure model
- Any conclusion about the variability of the process based on these 7 examples is inappropriate

High Variability - Criteria

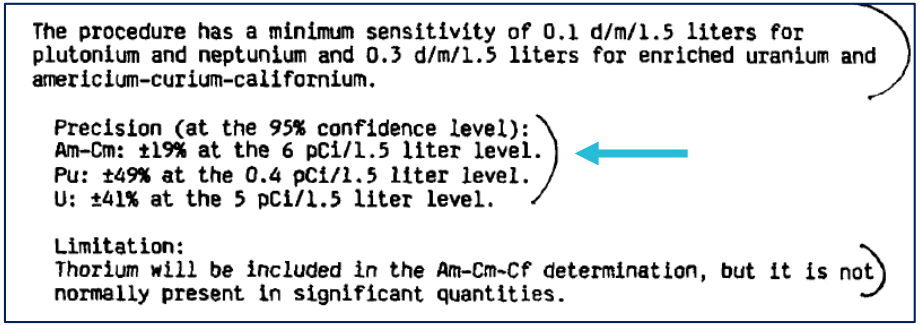
- SC&A May 2020 Response (SRDB 181759) attempted to define "excessive" variability
  - 2003 Optimization of Monitoring for Internal Exposure (OMINEX) bioassay survey
  - 1987 SRS DuPont Standard Operating Log (DPSOL) 47-206 (SRDB 45029, PDF pp. 60-65)
- Both documents reviewed in detail
  - See current NIOSH response (October 2020), Appendices A and B
  - Brief details given here

High Variability – Criteria – OMINEX

- SC&A references NCRP Report No. 164, *Uncertainties in Internal Radiation Dose Assessment* (SRDB 183179)
- Full OMINEX report (Hurtgen and Cossonnet 2003, SRDB 183168)
  - **"optimum condition"** of <25% uncertainty for a sample containing 1mBq is an arbitrary value established by the authors for state-of-the-art methods in 2003
  - Less than half the labs were able to meet this arbitrary standard using alpha spectrometry
  - Cannot be used to establish acceptable variability criteria for production labs in 2003, much less 1963 to 1989

High Variability – Criteria – DPSOL

- *DPSOL 47-206* (SRDB 45029)
- Precision criteria for Am-Cm
  - ±19% at the 6 pCi/1.5 L level
  - 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.

- Minimum Quantifiable Value (MQV)
  - Measure of process capability
    - 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%
  - Not appropriate as QA criterion for individual analytical results

High Variability – Criteria

- ANSI/HPS N13.30 *Performance Criteria for Radiobioassay (SRDB 168975)*
  - Defines acceptable variability only for high-level testing samples used in Department of Energy Laboratory Accreditation Program (DOELAP) process
  - Does not apply to results of specific samples from occupational bioassay program
- NIOSH's 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 no criteria for the 1963-1989.***

SC&A Issue 2: Procedures

Procedures

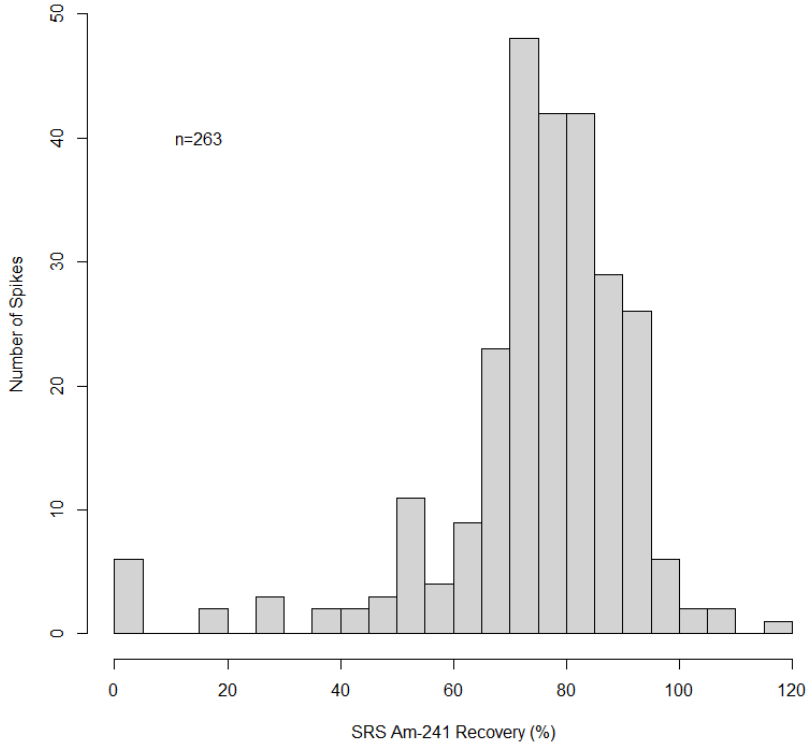
- *Criteria for the Evaluation and Use of Co-Exposure Datasets* (SRDB 179686, Co-Exposure Implementation Guide)
  - Approved by Advisory Board on December 11, 2019
  - "should be a review of the sample collection methods, any chemical processes employed, and the radiation counting equipment used"
  - NIOSH feels the level of review of historical documents referenced and discussed in OTIB-0081 fulfill Implementation Guide criteria
  - SC&A appears to suggest
    - A much higher level of scrutiny is required
    - Level of review performed to date is inadequate

Procedures (cont.)

- SC&A lists documentation they would like to see
- NIOSH acknowledges those documents would be helpful but are not necessary
- Difficulties with obtaining such information
  - Locating, vetting, and properly interpreting all analytical results
  - Locating and properly interpreting all relevant procedures and QA records (especially pre-DOELAP era)
- Radiochemist approval in logbooks means sample-specific criteria (variability included), if they existed, were met

Procedures – Am-241 Recovery

- SC&A commented on the range of Am-241 recovery values seeming to imply that the data are too variable for use
  - Range of 0% to 116%
- Considering all Am-241 recoveries in a 1981-1986 logbook (SRDB 53283)
  - Typical recovery range: 25% - 120%
  - 255/263 = 97% in typical range
  - 3/263 = 1% with 0% recovery



NIOSH's 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

Metric to Define Variability – History

- February 24, 2014 SC&A Response (SRDB 158936)
  - 188 values called out were “chosen subjectively”
  - Not a metric
- November 22, 2016 ORAUT-OTIB-0081 Rev 3
  - Proposes use of CV (also known as relative standard deviation)
  - CV is standard deviation divided by absolute value of average
  - Plot CV versus absolute value of average to assess variability

Metric to Define Variability – History (cont.)

- September 4, 2019 SC&A Review of ORAUT-OTIB-0081 (SRDB 178392)
  - log-log plot of CV versus average
    - Only for average values of 0.32 dpm/1.5L or greater
    - For proper assessment, all average values should be used
- November 25, 2019 NIOSH Response (SRDB 178696)
  - No new metric proposed
- June 3, 2020 SC&A Memo Response (SRDB 181759)
  - 145 samples had range greater than ±20% of average value
  - Not a well-known metric, no reference given

Metric to Define Variability

- Coefficient of Variation versus mean plot
  - NIOSH initially proposed plot
  - SC&A used an incomplete version of same plot
  - CV is a common, well-known metric
  - Plot can be used to assess variability
  - Eliminates the use of subjective and unjustifiable statistics

Conclusion

Conclusion

- SC&A Issue 1: High Variability
  - No generally applicable criteria for variability that can be applied to individual results today
  - If there are no such criteria today, then there were none in 1963-1989
- SC&A Issue 2: Procedures
  - Generally, the bioassay results of record used to demonstrate compliance are considered to be the best available data
  - Limited review of data performed as a confirmatory measure
- CV is the proper variability metric to be used moving forward

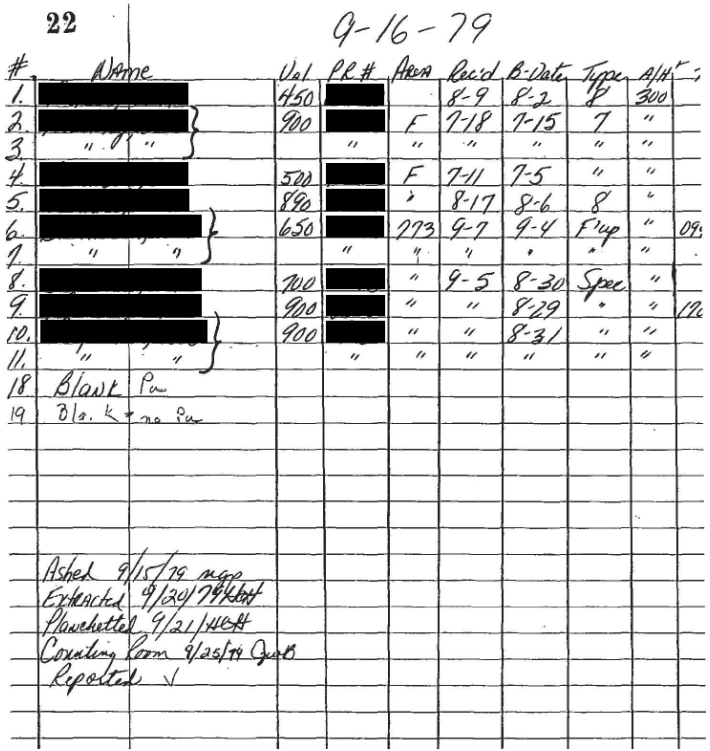
New Data Issue and Path Forward

Previously Unidentified Data Issue

- During our review, several new concerns were identified that prompted further evaluation
- Evaluation found that many of the high variability results were not necessarily variable but had some undesirable characteristics that unfortunately could impact co-exposure model
- Examples
  - Spike samples inadvertently included in results
  - Extreme typos
  - Misinterpretation of logbook data

Spike samples inadvertently included in results

SRDB 52019, pages 24-25



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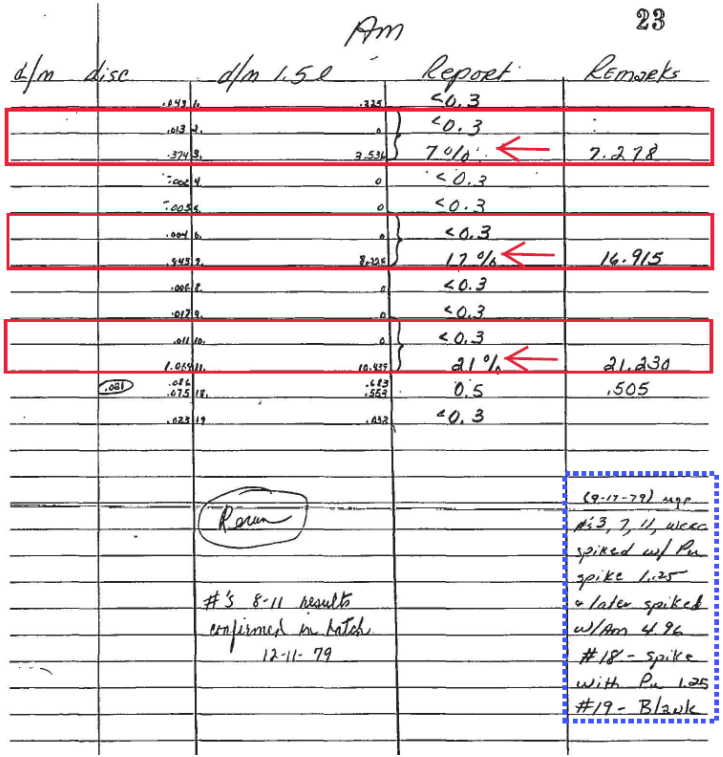
9-16-79

#	Name	Vol	PR #	Area	Rec'd	B-Date	Type	A/H
1.	[redacted]	450	[redacted]		8-9	8-2	8	300
2.	[redacted]	900	[redacted]	F	7-18	7-15	7	"
3.	" "	"	"	"	"	"	"	"
4.	[redacted]	500	[redacted]	F	7-11	7-5	"	"
5.	[redacted]	890	[redacted]	"	8-17	8-6	8	"
6.	[redacted]	650	[redacted]	273	9-7	9-4	F'up	"
7	" "		"	"	"	"	"	"
8.	[redacted]	700	[redacted]	"	9-5	8-30	Spec	"
9.	[redacted]	900	[redacted]	"	"	8-29	"	"
10.	[redacted]	900	[redacted]	"	"	8-31	"	"
11.	" "		"	"	"	"	"	"
18	Blank Pu							
19	Blk. K + no Pu							

Ashed 9/15/79 mgp
Extracted 9/20/79 HeH
Flowchatted 9/21/HeH
Counting room 9/25/79 JoB
Reported ✓



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Am

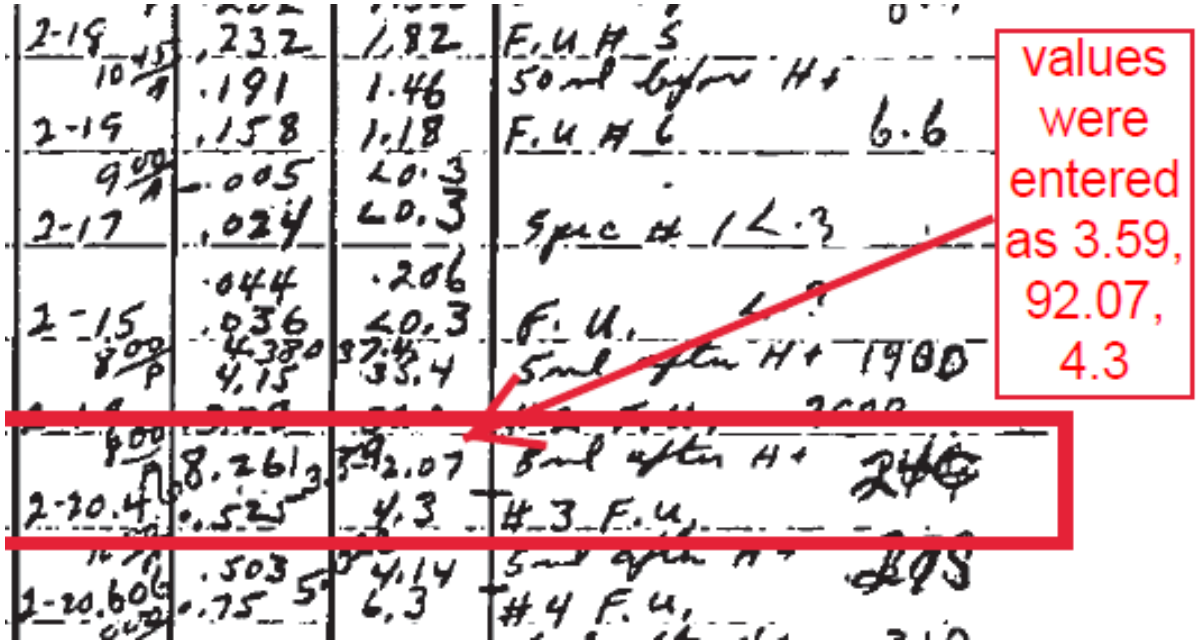
d/m disc	d/m 1.5ℓ	Report	Remarks
.043 1.	.325	<0.3	
.013 2.	0	<0.3	
.374 3.	3.534	7 % ←	7.278
.006 4.	0	<0.3	
.0036 5.	0	<0.3	
.004 6.	0	<0.3	
.543 7.	8.336	17 % ←	16.915
.006 8.	0	<0.3	
.012 9.	0	<0.3	
.011 10.	0	<0.3	
1.019 11.	10.835	21 % ←	21.230
(.081) .026 .075 12.	.629 .569	0.5	.505
.023 13	.232	<0.3	

Rerun

#'s 8-11 results confirmed in batch 12-11-79

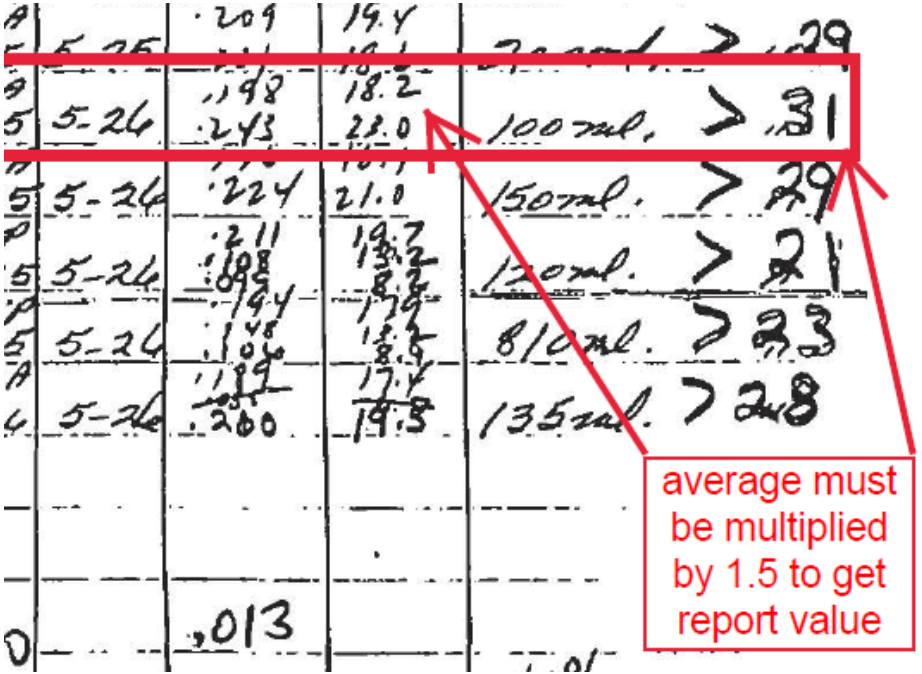
(9-17-79) mgp #3, 7, 11, were spiked w/ Pu spike 1.25 & later spiked w/Am 4.96
#18 - spike with Pu 1.25
#19 - Blank

Extreme Typo Example (SRDB, 52006, PDF pg 84)



Example of misinterpretation data (SRDB 52006, PDF p. 3)

- Occasionally (not always) when aliquot size was non-standard, additional multiplication was needed to obtain the reported value in dpm/1.5L
- In this case the coded results under report the true value



Path Forward (1 of 2)

- Issue was discovered in August 2020
  - the extent and bias evaluated (bias both directions)
  - no clear impact on result (co-exposure model)
- Recoding all of the Am-241 data was initiated in late August with an additional Health Physicist Quality Assurance (QA) step to each to ensure appropriate interpretation of the data
  - A data coder enters the data and a Health Physicist checks each result

Path Forward (2 of 2)

- As of 11/2/2020, 12 of the 13 Logbooks have been coded
- Expected completion is November 2020
- Health Physicist QA expected completion is early December 2020
- We will rerun the Am-241 analysis and update the co-exposure models in ORAUT-OTIB-0081
- Coefficient of Variation (CV) can be re-evaluated

Questions?