



Co-exposure Model Implementation Guide: *SRS Co-exposure Model - Example*

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ABRWH Meeting

Oakland, California | December 11, 2019

Overview

- Name change to be more specific and improve communication clarity.
 - **Co-exposure Model instead of Coworker model**
- Background leading to development of co-exposure Model Criteria
- Draft Criteria for the Evaluation and Use of Coworker Datasets
- SRS co-exposure Model Example
- Summary

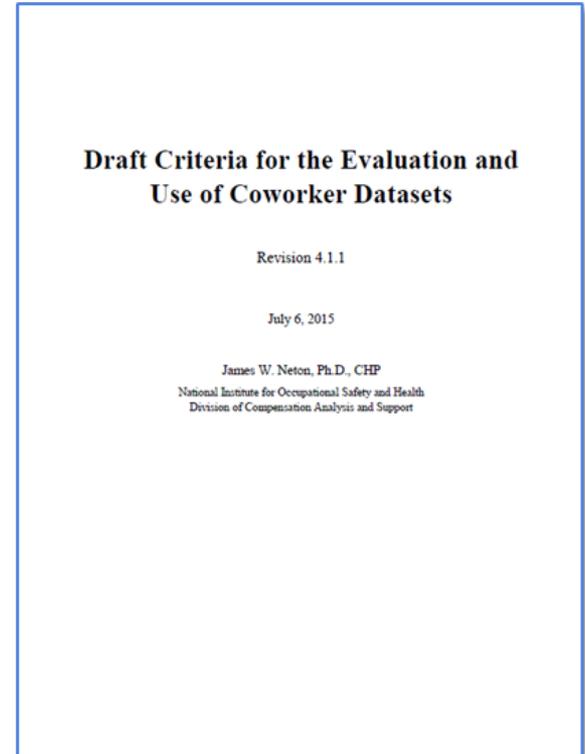
Background leading to development of co-exposure model criteria

Co-exposure Model Background

- 2010: Concern that some co-exposure models using raw bioassay were dominated by few individuals
 - ORAUT-RPRT-0053 One Person One Statistic (OPOS)
- 2014: Multiple SEC Issues Workgroup meetings discussing OPOS, stratification, statistical comparison methodology, etc
- The 2014 discussions promulgated the development of the Draft Criteria for the Evaluation and Use of Coworker Datasets

Co-exposure Model Implementation Guide

- Timeline
 - *June 2, 2014 - Rev 1*
 - *September 30, 2014 - Rev 2*
 - *October 30, 2014 – Rev 3*
 - *February 26, 2015 – Rev 4*
 - *March 12, 2015 – Rev 4.1*
 - *July 6, 2015 – Rev 4.1.1*
- SEC Issues Workgroup requested a demonstration or pilot example



Draft Criteria for the Evaluation and Use of Coworker Datasets (rev 4.1.1)

July 6, 2015 – By J. Neton

Co-exposure Model Implementation Guide - Elements

- Evaluation of Stratification
- Data Adequacy
- Data Completeness and Validation
- Applicability to Unmonitored Workers
- Analysis and Application to Unmonitored Population

Data Adequacy

- Review of sampling methods and laboratory analysis, consideration should be given to:
 - Representativeness of bioassay collection methods
 - Radiochemical recovery
 - Counting efficiency (self absorption)
 - Reliability of measurement method

Data Completeness

- Evaluate whether the data are either sufficiently representative or bounding of the exposure potential
 - Recommended minimum 30 person measurements per year
 - Assess temporal trends (gap analysis)
 - Assess data quality
 - Accuracy of the data (transcription errors)
 - Evaluation of potentially missing data
 - Compare to claimant files (NOCTS data)

Applicability to Unmonitored Workers

- Hierarchical Order
 1. Routine, representative sampling
 2. Routine measurement of highest exposure potential
 3. Collection of samples after the identification of an incident
- Representative sample of exposed population **OR** workers with the highest potential for exposure

Analysis and Application to the Unmonitored Population

- Sufficient data to construct a representative co-exposure model
 - Recommend use of 30 workers per interval, however, less data can be used if the data fit a distribution reasonably well
- Data can be reasonably represented by a statistical distribution
- Time-Weighted One Person One Statistic (TWOPOS)

When multiple bioassay samples are present during a monitoring period for a given individual, it is appropriate to average the values so that a single statistic can be computed for that individual.

Evaluation of Stratification

- Should be evaluated where:
 1. Accurate job categories or descriptions can be obtained for all workers
 2. There is reason to believe that one job category is more highly exposed
 3. There are unmonitored workers in this job category

Note: Stratification by individual job categories was never our intention from the standpoint of co-exposure models

Co-exposure Model Implementation Guide – Pilot

- ORAUT-OTIB-0081 Rev 3 – November 22, 2016
 - 3 Radionuclides
 - (Americium, Curium, Californium), Tritium, and Thorium
 - Subsequent discussion of stratification and applicability to subcontractor Construction Trades Workers (CTWs)
 - General Workgroup consensus needed the full model to evaluate all aspects
- ORAUT-OTIB-0081 Rev 4 – March 13, 2019
 - Contained models for all radionuclides

SRS Co-exposure – Stratification Decision

- NIOSH decided to *a priori* to stratify based on differences in exposure potential between routine and non-routine operations.
 - We found it difficult to make the argument that the exposure potential was similar for the two types of workers
 - 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

SRS Co-exposure Models – Stratification cont.

- In reality, the initial CTW vs. non-CTW stratification of the co-exposure model was the hard part
- We have demonstrated that we have sufficient data to stratify the workforce
- What remains unclear, based on mixed comments, is the recommendation as to how we stratify from Workgroups
 - No Stratification needed
 - CTWs and non-CTWs
 - Subcontractors vs. non-Subcontractors (all DuPont)

What SRS Co-exposure Models Are Needed?

- ORAUT-OTIB-0018 bounding approach actually takes care of a large number of the claimants who would need a co-exposure model
- Goal is to supplement ORAUT-OTIB-0018 with a best estimate co-exposure model
- Need co-exposure model for all major radionuclides at SRS

SRS Co-exposure Models – Radionuclides

4.1 Americium/Curium/Californium (Trivalent radionuclides)

4.2 Tritium

4.3 Plutonium

4.4 Uranium

4.5 Fission Products (Strontium)

4.6 Cobalt-60

4.7 Cs-137

4.8 Neptunium

4.9 Thorium

Individual Radionuclide Discussion / Format Closely Follows Co-exposure Implementation Guide Criteria

1. Data Adequacy

- Discussion of Personnel Monitoring
- Applicability to Unmonitored Workers
- Bioassay Analysis Technique

2. Data Validation

- Data Completeness and Quality
- Data Interpretation
- Data Exclusion

Individual Radionuclide Discussion / Format Closely Follows Co-exposure Implementation Guide Criteria

3. Statistical Analysis

- Development of the TWOPOS

4. Intake modeling

- Fitting TWOPOS bioassay distribution in IMBA to obtain intakes

SRS Plutonium Co-exposure Models – Data Adequacy

- Personnel Monitoring (who was monitored)
 - Bioassay Control procedures starting in 1968 (attachment C) identify types of workers and frequency of monitoring within specific areas
 - *Construction Trades Workers monitored every 3 years*
- Applicability to Unmonitored Workers
 - Number of workers monitored relatively constant over time
 - No temporal gaps in data
 - Workers with highest exposure potential monitored more frequently

SRS Pu Co-exposure Models – Monitoring Frequency

ATTACHMENT C BIOASSAY DATA TYPES AND FREQUENCIES (continued)

Table C-6. 1976 bioassay frequencies (samples per year or counts per year by analysis type) (DuPont 1976).^a

Personnel work assignment	Pu samples	EU samples	U samples	IA/FP samples	Am/Cm/Cf samples	Sr samples	H3 samples	FP samples	Days counts	Shift counts
Minimum Potential. Personnel working in tritium facilities, 200-FH facilities not mentioned below, 723-A (EED), and 305-M. Selected 100-Area and 773-A personnel.	1 ea. 3 yr	N/A	N/A	N/A	N/A	N/A	(b)	N/A	1 ea. 3 yr ^c	1 ea. 3 yr
221-FH. All operators, Separations Technology, HP, and 4th-Level personnel; E&I, Maintenance, Clerical, and Service Department personnel assigned to process areas. 241-FH, 211-FH, 723-F, A-Line, 643-G & 244-H. All assigned personnel. 772-F & 235-F. Personnel assigned to nonprocess areas. Patrol & T&T. All personnel assigned to 200-FH Areas. 773-A. Selected clerical and supervisory personnel. 100-Areas. Selected personnel.	1	(d)	(e)	N/A	(f)	(g)	N/A	N/A	1	2
221-HB Line, 221-FB Line, JB-Line. All assigned personnel. 235-F. Personnel assigned to process areas. 772-F. Personnel assigned to process areas. 773-A. Selected ACD, SED, SCD, NMD, HLC, Radiation Control, Building Services, and Maintenance personnel. 313-M. All assigned personnel.	4	(d)	N/A	N/A	(f)	N/A	N/A	(c)	1 ^h	2
322-M & 772-F (UO₃ Section). All assigned personnel. 320-M. All laboratory and selected radioactive material personnel. 773-A. Reactor Engineering and 777-M personnel.	N/A	N/A	4	N/A	N/A	N/A	N/A	N/A	N/A	N/A
322-M & 772-F (UO₃ Section). All assigned personnel. 320-M. All laboratory and selected radioactive material personnel. 773-A. Reactor Engineering and 777-M personnel.	1 ea. 3 yr	1	4	N/A	N/A	N/A	N/A	N/A	(i)	(i)
321-M. All assigned personnel except those in Casting Area.	1	4	N/A	N/A	N/A	N/A	N/A	N/A	1 ea. 3 yr	1

SRS Plutonium Monitoring – Frequency

Exposure potential	Area	Sample Frequency
Low	Tritium facilities, 100 Area, 305-M, 773-A (Select personnel, Reactor Engineering), 320-M, 777-M	1 every 3 years
Medium	221-FH, A-Line, 235-F (non-process), 772-F (non-process), 321-M	1 per year
High	221-HB Line, 221-FB Line 221-JB Line, 235-F (process area), 772-F (process area), 773A (Select personnel)	4 per year

SRS Pu Co-exposure Models – Analysis Method

- Bioassay Analysis Techniques
 - 1954 bismuth phosphate and lanthanum fluoride coprecipitation
 - 1959 nitric acid/hydrogen peroxide dissolution and ion exchange
 - 1966 tri-iso-octylamine (TIOA) liquid extraction
 - 1981 coprecipitation technique with alpha spectrometry
- Reporting / Censoring Level = 0.1 dpm/day
 - *(This is a reporting level NOT necessarily the LOD or the MDA)*

Plutonium Logbooks – Censored Data (SRDB# 51887)

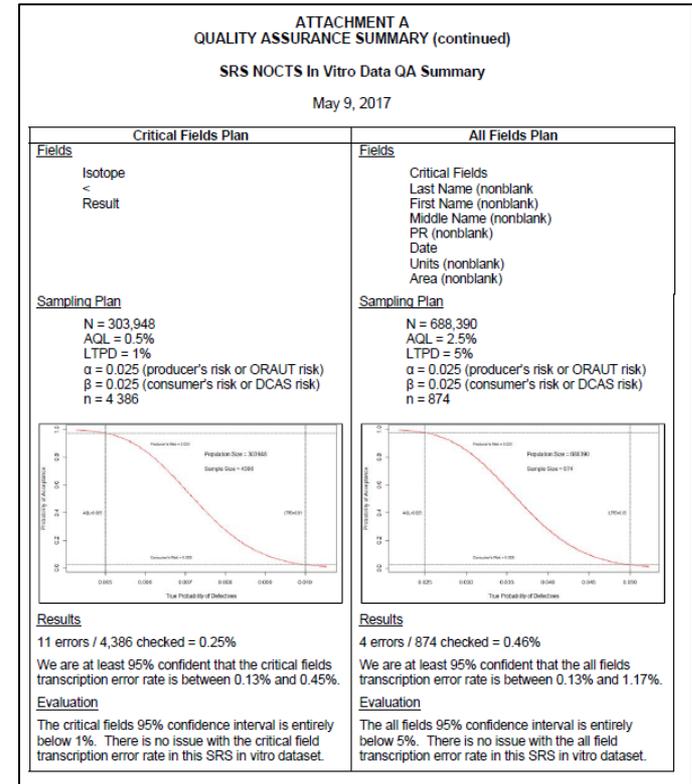
d/m 1.5l Pu			15
		Reported	Remarks
1.	.029	<0.1	
2.	0	<0.1	$\frac{175}{30.9} = 1.7$ - .046
3.	.029	<0.1	
4.	.021	<0.1	
5.	.064	<0.1	
6.	0	<0.1	$\frac{125}{500} = 2.4 = .065$
7.	0	<0.1	
8.	0	<0.1	
9.	75.00	75%	

SRS Pu Co-exposure Models – Data Interpretation

- Most measurements were gross alpha
- During the 1980s ^{238}Pu and ^{239}Pu reported separately
 - Merged into gross alpha, assumed to be 12% 10-year aged plutonium (chosen to be claimant favorable)
- Data exclusions
 - Chelation or indication of DTPA use
 - LIP (lost in process) samples
 - Insufficient identifying information
 - Samples given per unit mass (likely fecal samples)

SRS Plutonium Co-exposure Models – Data Validation

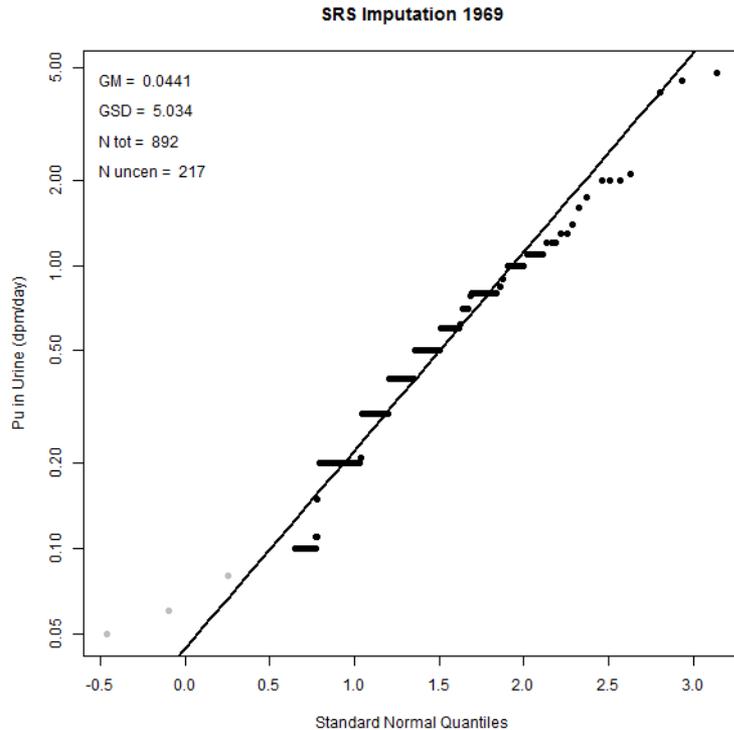
- NOCTS In Vitro Dataset
 - (which contains Pu, U, EU, FP)
- Critical Fields (1%)
 - Isotope, “<”, and Result
 - 11 errors / 4386 checked = 0.25% (0.13%-0.45%)
- All Fields (5%)
 - Last Name, First Name, Middle Name, Payroll ID, Date, Units, Area
 - 4 errors / 874 checked = 0.46% (0.13%-1.17%)



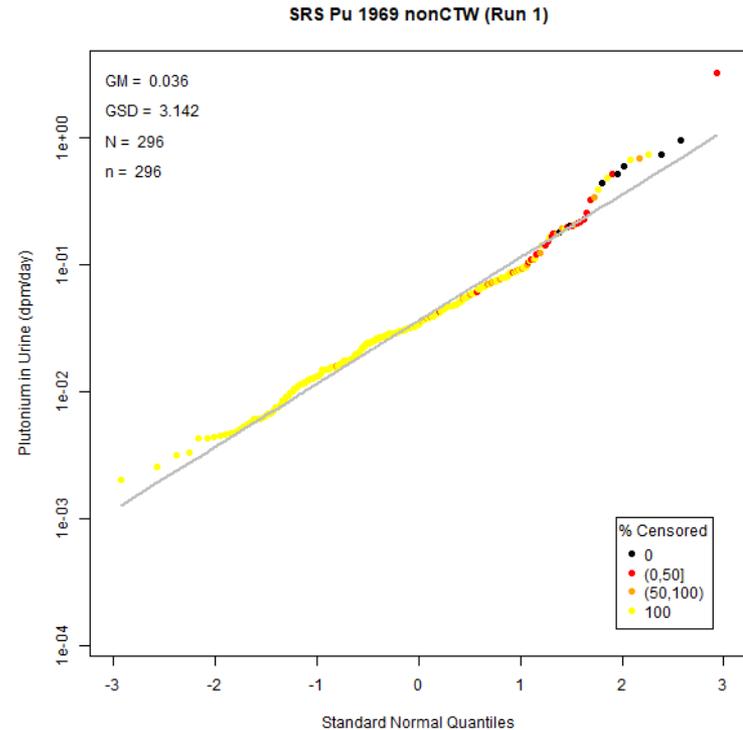
Statistical Analysis

- *Time-Weighted One Person One Statistic (TWOPOS) Methodology*
 - *ORAUT-RPRT-0053, Analysis of Stratified co-exposure Datasets*
 - TWOPOS data are fit to lognormal distributions during the statistical analysis
- **Most** of the bioassay data is censored (data reported as “less than” some value)
 - Analysis method uses multiple imputation for censored data
 - *ORAUT-RPRT-0096, Multiple Imputation Applied to Bioassay co-exposure Models*

Multiple Imputation Methodology

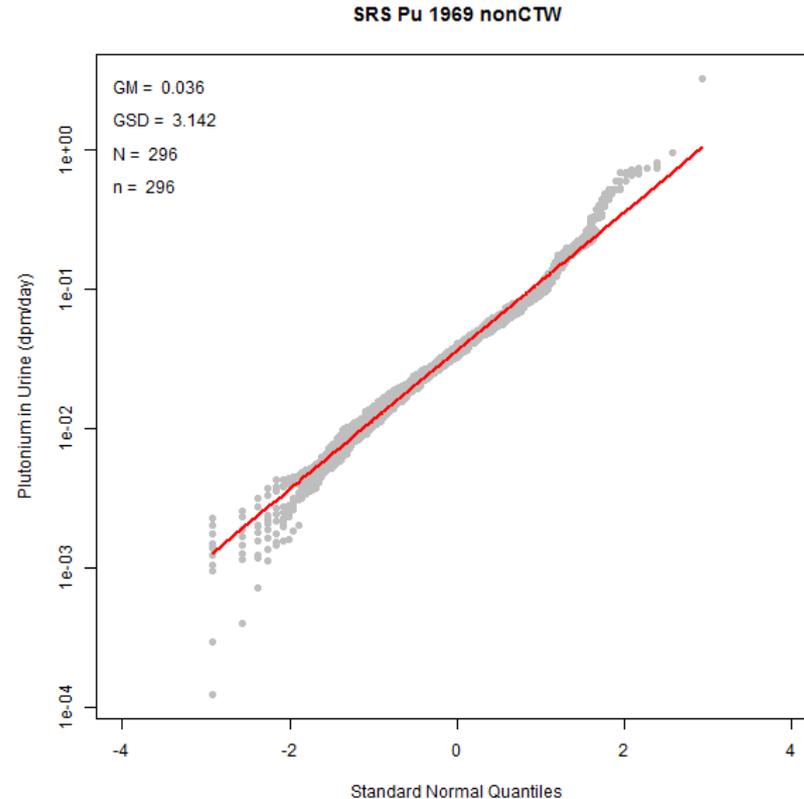


1969 Imputation Model



1969 First TWOPOS Imputation

TWOPOS Pu Plots – After Multiple Imputation



Statistical Analysis – TWOPOS Data

Example from Table 4-4. Calculated 50th- and 84th-percentile urinary excretion rates of plutonium based on a lognormal fit to the **TWOPOS** data, 1955 to 1990 (dpm/d).

Year	non-CTW 50 th percentile	non-CTW 84 th percentile	non-CTW GSD	non-CTW # of individuals	CTW 50 th percentile	CTW 84 th percentile	CTW GSD	CTW # of individuals
1967	0.00629	0.0387	6.14	358	0.00375	0.0263	7.00	152
1968	0.01186	0.0608	5.13	414	0.00957	0.0530	5.54	146
1969	0.03617	0.1136	3.14	296	0.03434	0.1188	3.46	108
1970	0.02776	0.0894	3.22	290	0.02591	0.0872	3.37	98

Steps of Co-exposure Intake Model Development

- Intake modeling for each of the nine radionuclide categories
 - 50th and 84th percentiles for each year and solubility type are used for intake modeling
 - Selection of time intervals of similar results
 - *Internal Dosimetry professional judgement*
 - Assume a chronic intake scenario for each time interval to determine intake

SRS Plutonium Intake Modeling – Time Interval #1

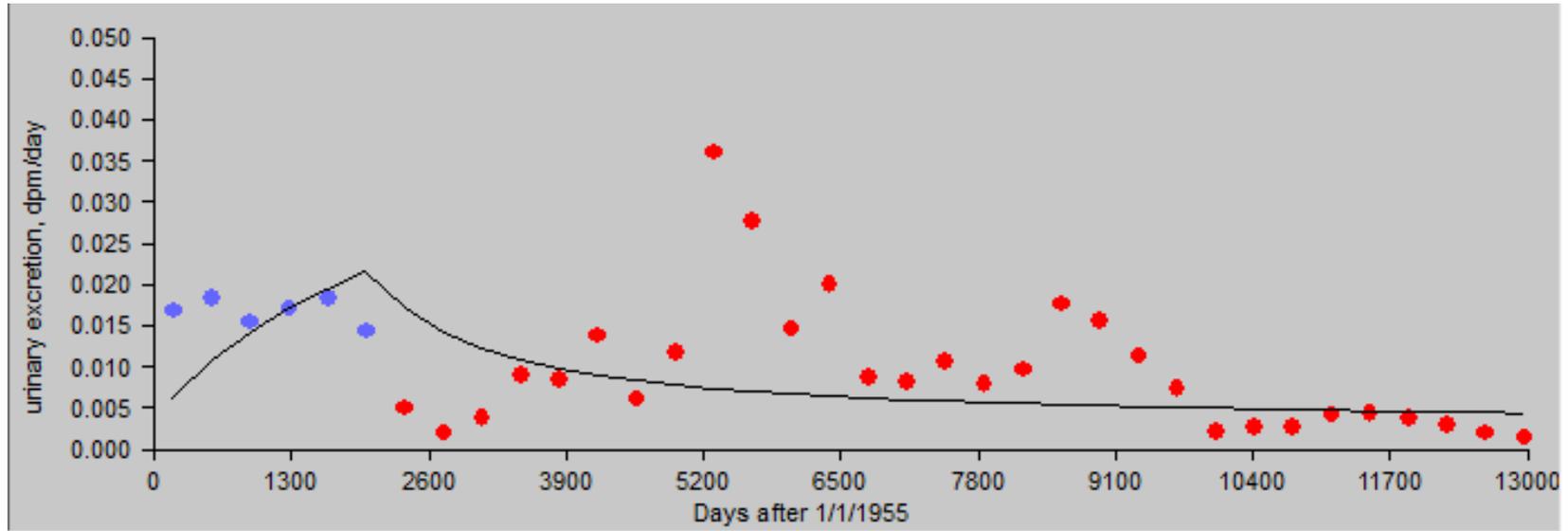


Figure F-17. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), 50th percentile, non-CTW 1955 to 1960, type M.

SRS Plutonium Intake Modeling – Time Interval #2

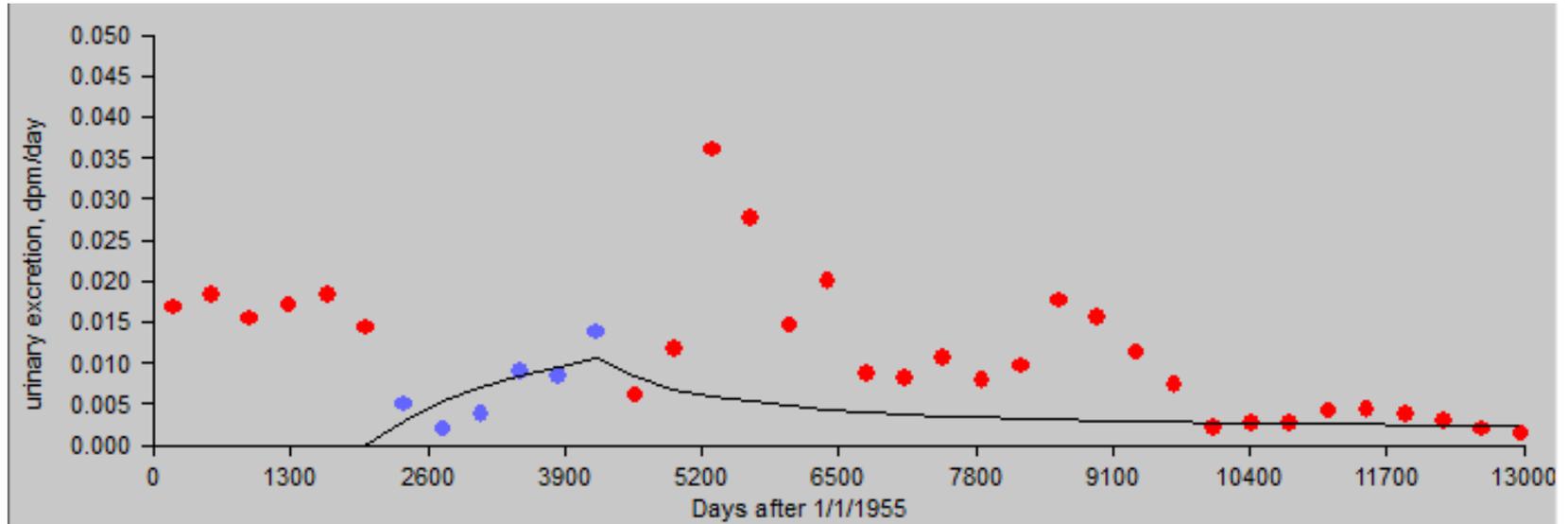


Figure F-18. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), 50th percentile, non-CTW 1961 to 1966, type M.

SRS Plutonium Intake Modeling – Time Interval #3

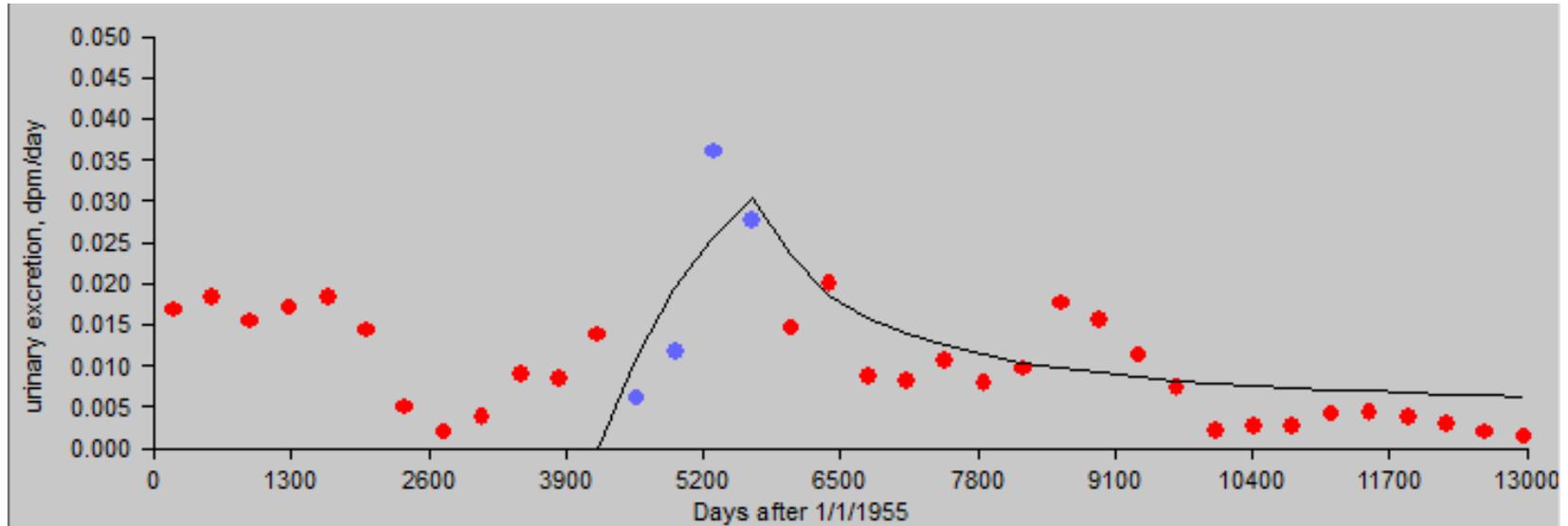


Figure F-19. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), 50th percentile, non-CTW 1967 to 1970, type M.

SRS Plutonium Intake Modeling – Time Interval #4

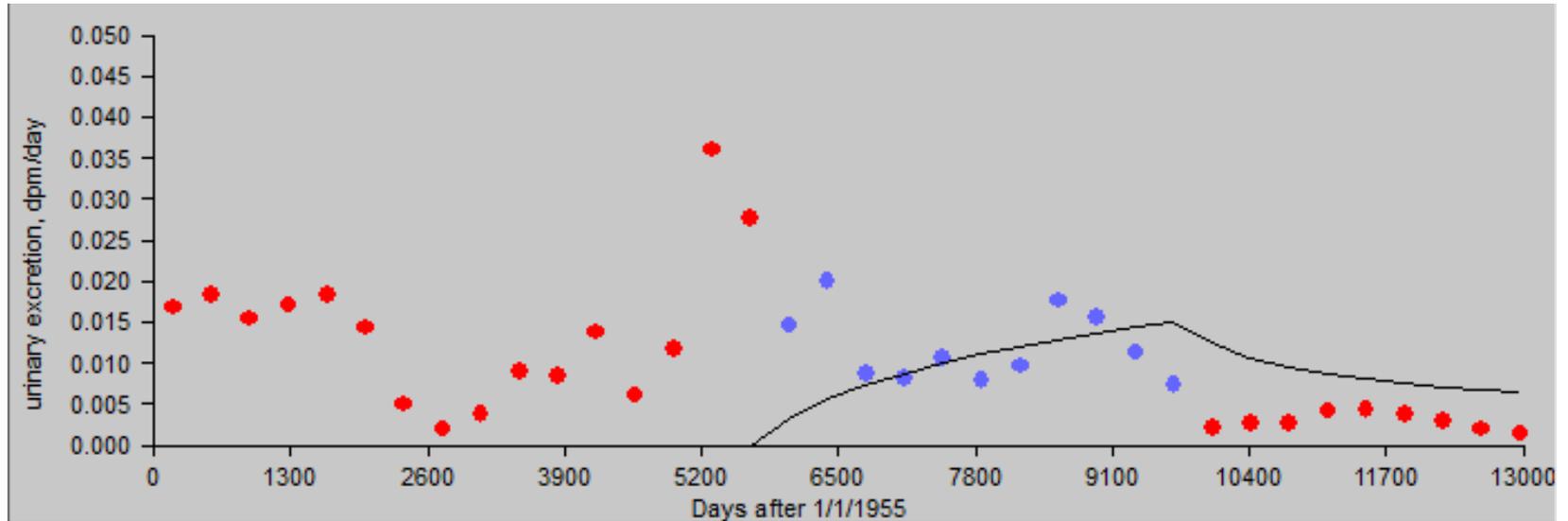


Figure F-20. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), 50th percentile, non-CTW 1971 to 1981, type M.

SRS Plutonium Intake Modeling – Time Interval #5

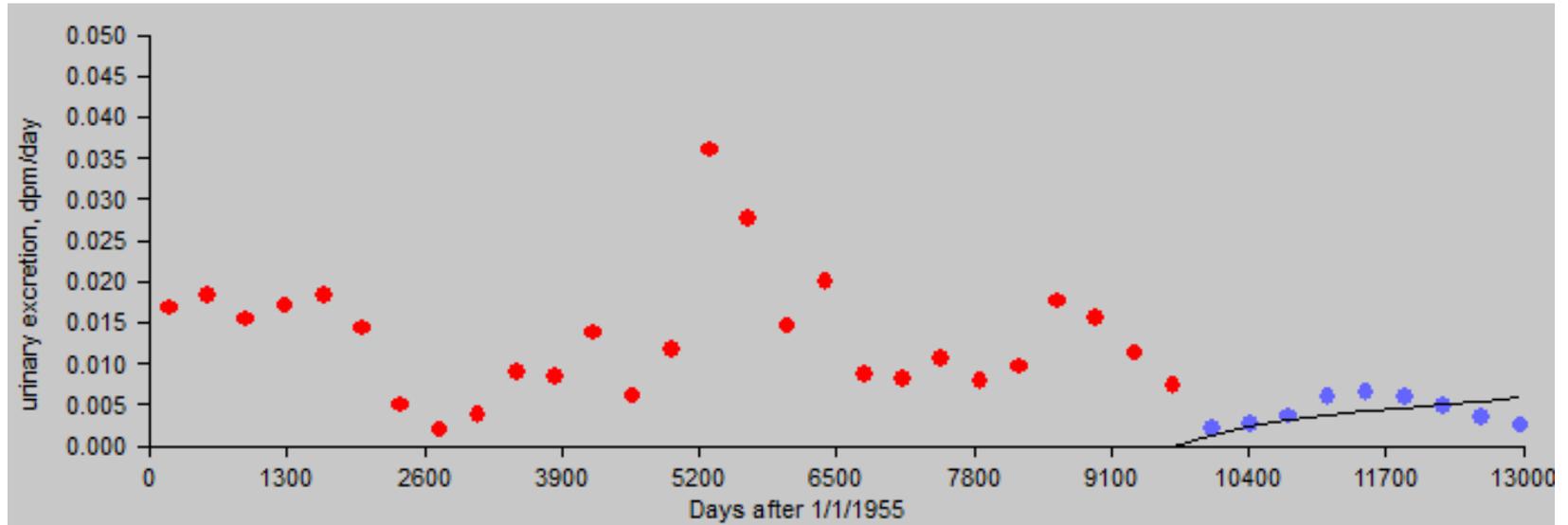


Figure F-21. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), 50th percentile, non-CTW 1982 to 1990, type M.

Complete SRS Co-exposure Plutonium Intake Model

Table F-3. Summary of plutonium non-CTW intake rates (dpm/d) and dates, type M.

Start	End	50 th percentile	84 th percentile	GSD	Adjusted GSD	95 th percentile
01/01/1955	12/31/1960	3.265	9.742	2.98	3.00	19.90
01/01/1961	12/31/1966	1.606	6.453	4.02	4.02	15.83
01/01/1967	12/31/1970	5.778	20.170	3.49	3.49	45.17
01/01/1971	12/31/1981	1.692	7.678	4.54	4.54	20.37
01/01/1982	12/31/1990	0.724	5.03	6.94	6.94	17.5

SRS Plutonium Intake Modeling – Full Interval

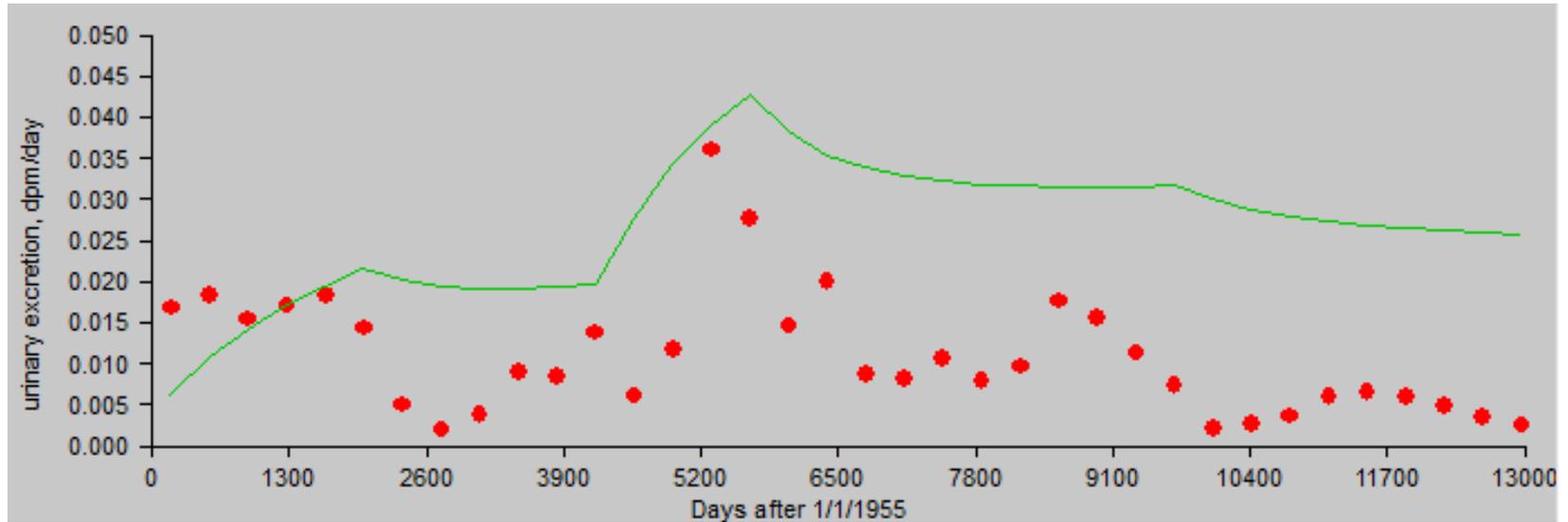


Figure F-57. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), non-CTW 50th percentile, all years, type M.

SRS Plutonium Intake Modeling – Full Interval

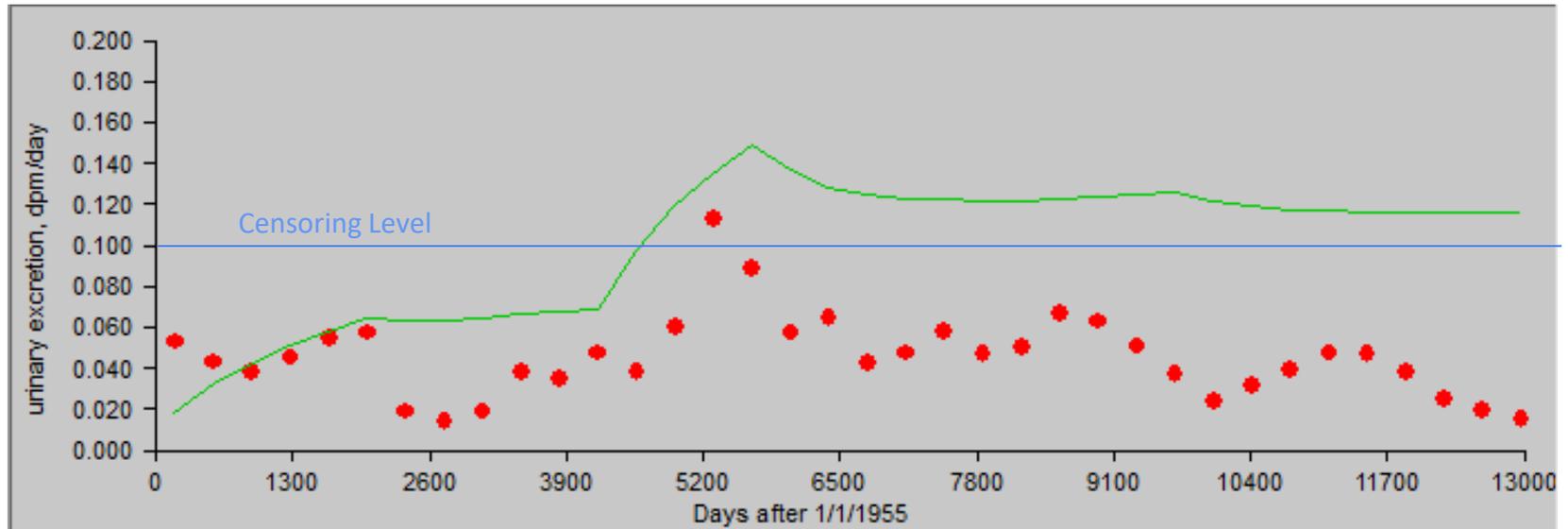


Figure F-58. Predicted plutonium bioassay results calculated using IMBA-derived plutonium intake rates (line) compared with measured bioassay results (dots), non-CTW 84th percentile, all years, type M.

SRS Plutonium Intake Modeling – Full Interval

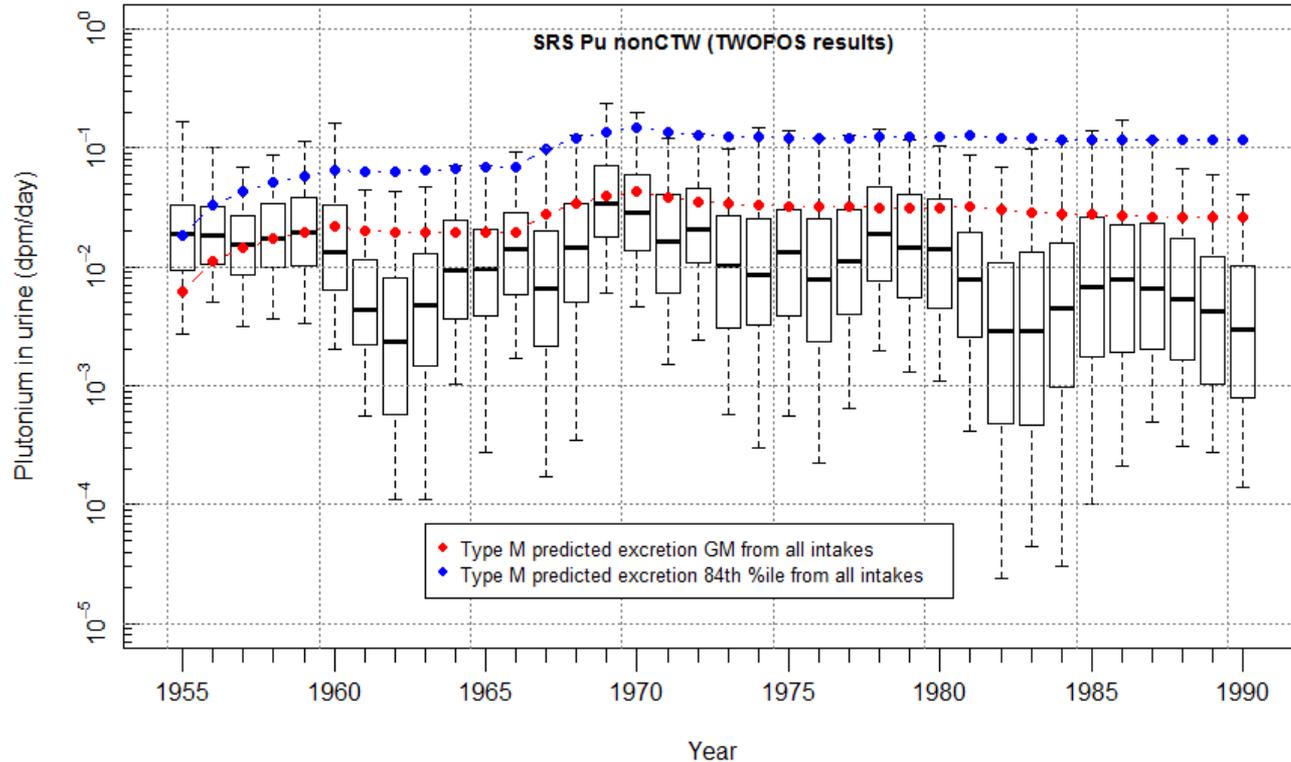
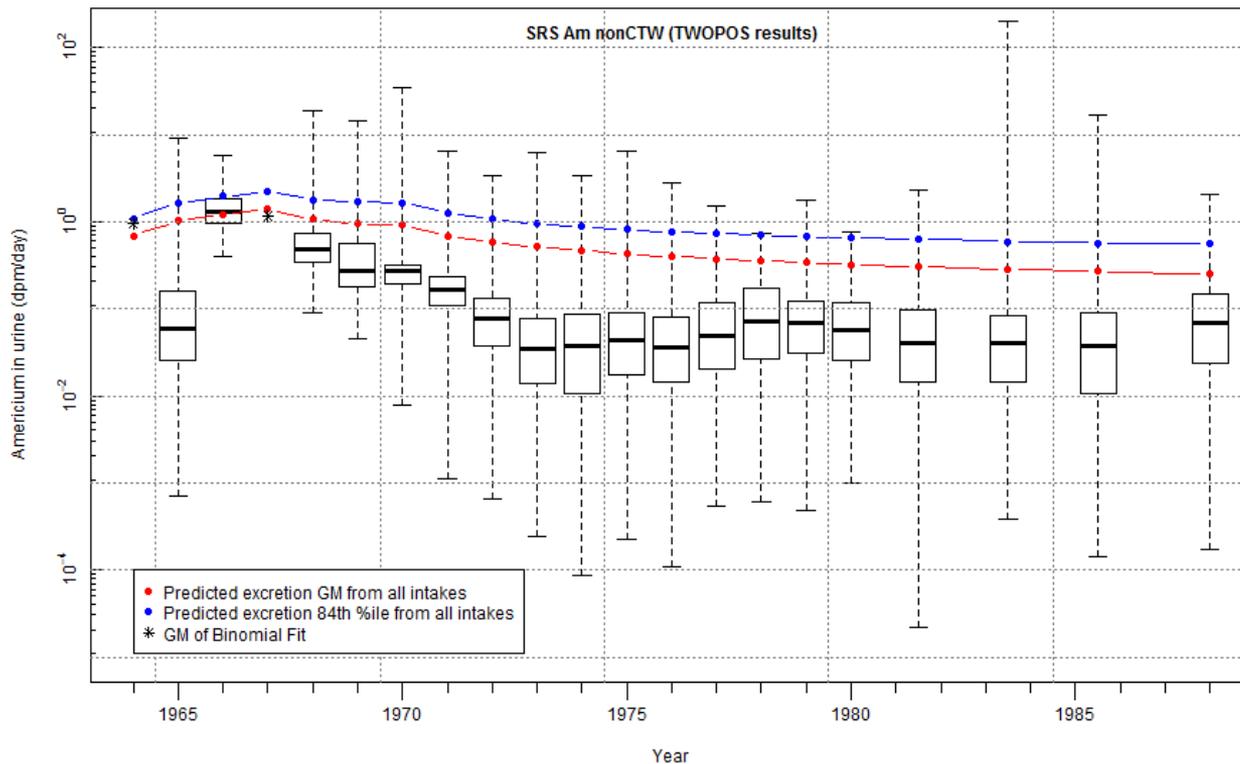
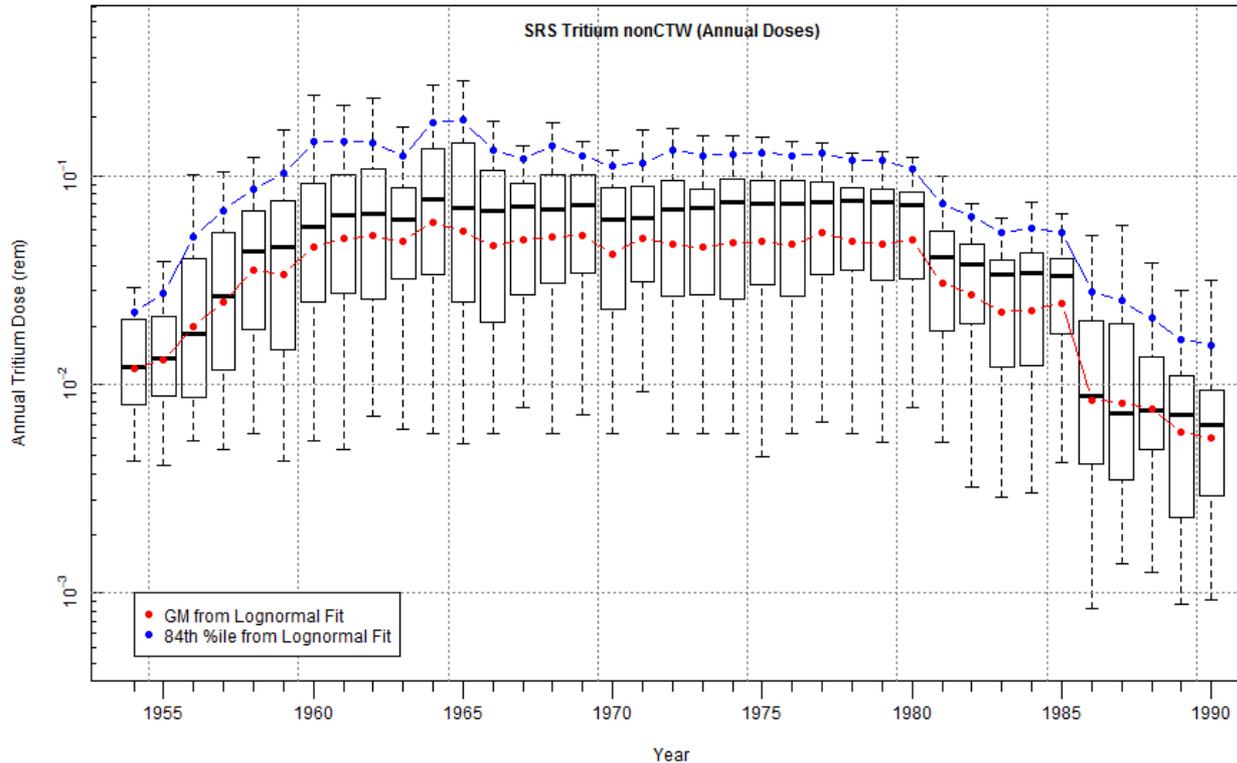


Figure 4-7. Plutonium type M non-CTW TWOPOS data box and whisker plot beginning in 1955.

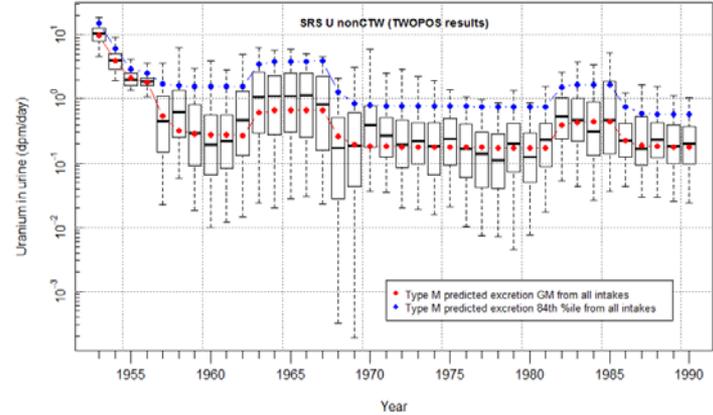
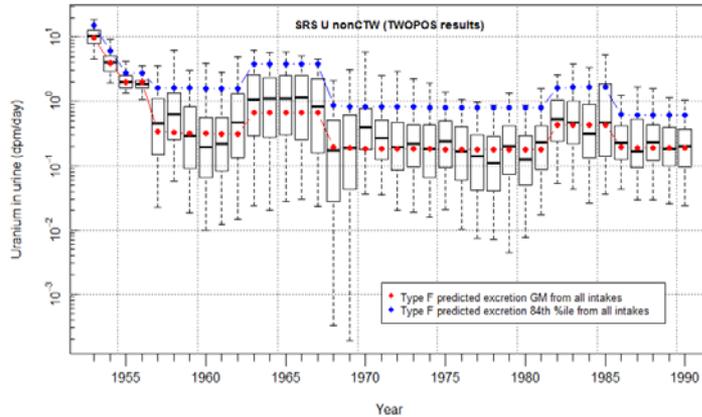
Americium Intake Results



Tritium Dose Results

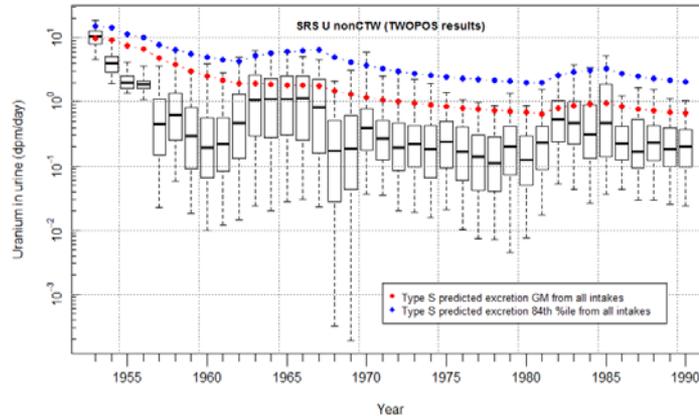


Uranium Intake Results



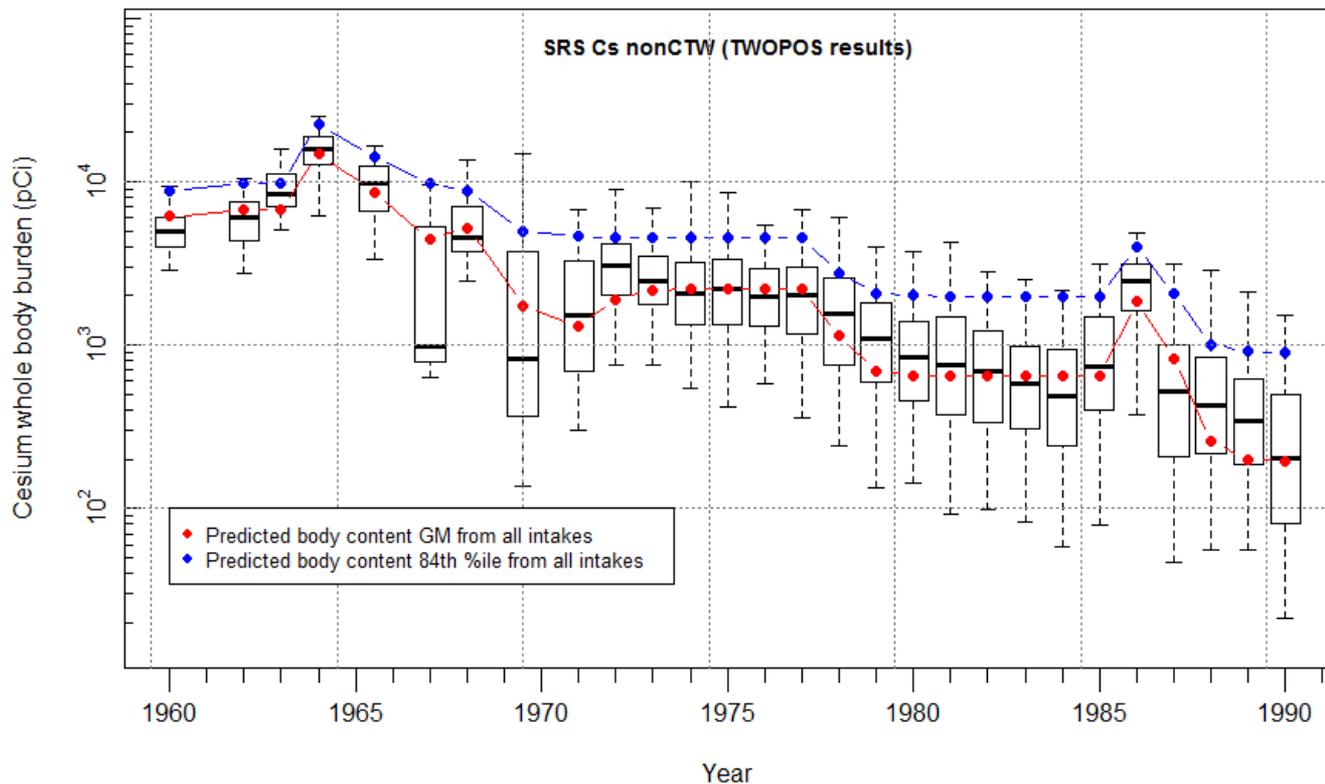
Type F

Type M

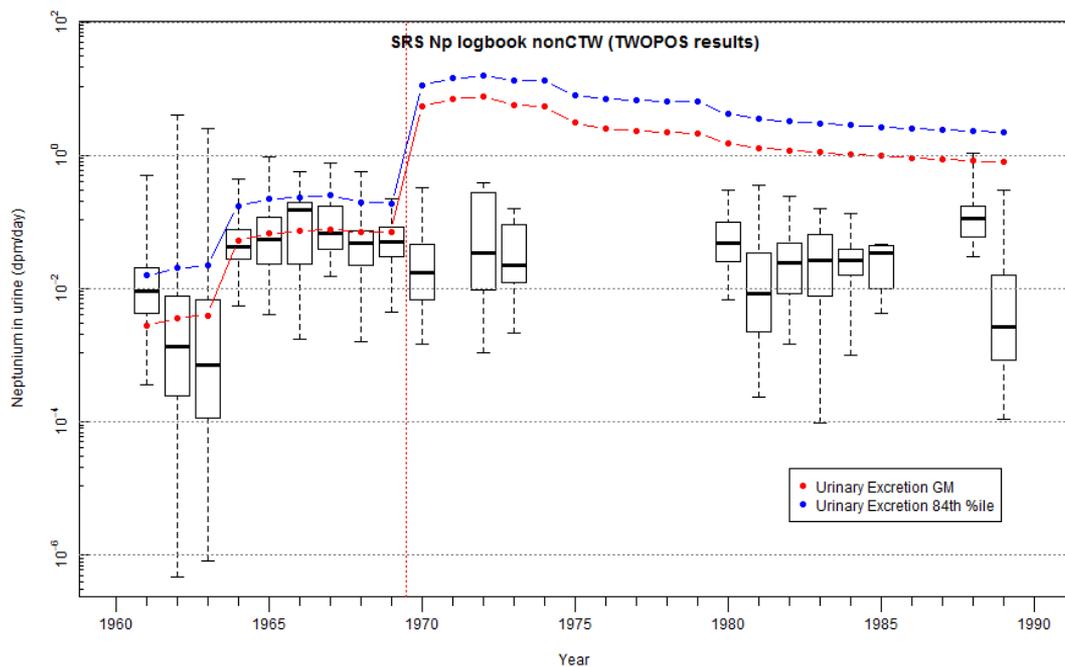


Type S

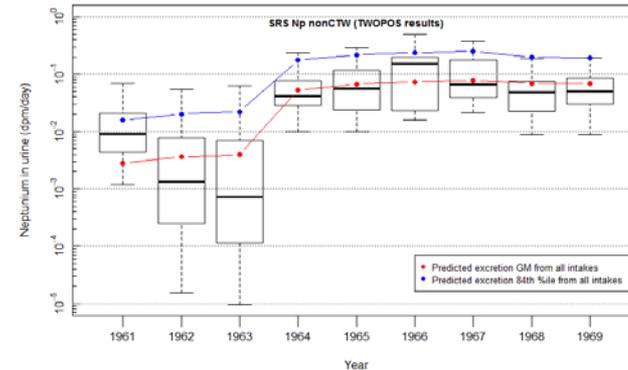
Cesium Intake Results



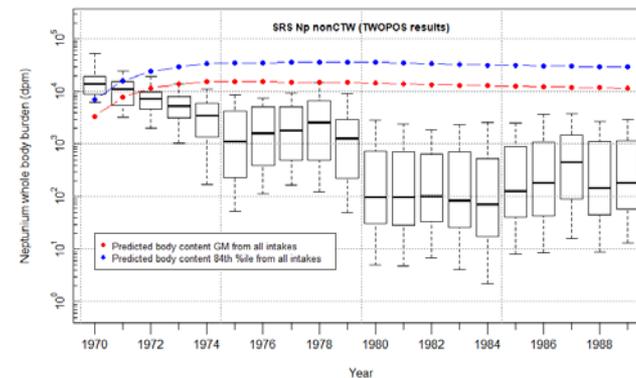
Neptunium Intake Results



urinalysis



Whole Body Count



Application of Co-exposure Models to Unmonitored Workers

- Normally, the 50th percentile with full lognormal distribution will be assigned to workers who may have been exposed to greater than environmental levels but less than a typical operations worker
- Workers considered to have a high potential for exposure may be assigned the 95th percentile of the co-exposure distribution on a case by case basis as determined by the Dose Reconstructors (*Professional Judgement*)

Co-exposure Model Summary

- This example co-exposure model demonstrates how the Draft Criteria for the Evaluation and Use of co-exposure Datasets will be implemented
 - NIOSH believes the intent of the Draft Criteria for the Evaluation and Use of co-exposure Datasets has been met
 - NIOSH believes the co-exposure models presented are claimant friendly, reasonable (*best estimate*), and adequately bound the potential doses for compensation purposes

Co-exposure Model – Next Steps

- Now that the workgroup has approved the methodology
- Change the name and update to our standard implementation guide format and post on our website
- Start implementing the method across all of the sites where co-exposure models are needed
 - **The implementation of this methodology is going to take some significant time (*years*) to complete**

SC&A Review of Co-exposure Model - Pilot
(ORAUT-OTIB-0081) SRS Model

*Bob Barton, Ron Buchanan, Harry Chmelynski, Rose Gogliotti,
and Joyce Lipzstein, SCA, Inc.*

SC&A Finding #1 – Bioassay Variability

- 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 high variability observed in trivalent actinide bioassay results 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 – Open, **SC&A Action:**
 - Review bioassay methods and provide feedback to workgroup on issue of data adequacy

SC&A Finding #2 – Multiple Imputation

- Finding 2: Use of imputed values 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.”
 - Per that guidance, bioassay values that are censored are assumed to be equal to one-half of the MDA rather than the use of an alternate imputed value. In order to further address this issue, SC&A performed scoping calculations using imputed values, numerical values reported less than MDA, and missed dose approaches.
 - Scoping calculations are illustrative and not all encompassing.
- Status – Open, **SC&A Action:**
 - Review ORAUT-RPRT-0096 Multiple Imputation Method

SC&A 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 – Open, **SC&A Action:**
 - Review ORAUT-RPRT-0096 Multiple Imputation Method

SC&A Finding 3 – Multiple Imputation

- Finding 3: The sample comparison of coworker intakes to a missed dose method for uranium showed that the coworker 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 – Open, **SC&A Action:**
 - Review ORAUT-RPRT-0096 Multiple Imputation Method

SC&A Finding 4 – Data Completeness (Additional Data)

- 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 – **Closed**
 - Workgroup decided not to pursue inclusion of additional data

SC&A Observation 3 – Data Completeness (Trivalent Logbooks)

- 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 – Open, **NIOSH Action**
 - NIOSH to provide reference indicating a backlog of bioassay analyses during these years explain the noted differences.

SC&A Observation 4 – Stratification Evaluation

- Observation 4: 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 – Statistical comparison not necessary at SRS, workers are stratified a priori. No Action Required.

SC&A Observation 5 – Stratification Evaluation

- Observation 5: SC&A believes a quantitative assessment of available job plans, rather than a qualitative basis, is appropriate to determine that prime contractor and subcontractor CTWs are part of the same exposure strata. Such an assessment has been performed by NIOSH, and a report of their findings has recently been issued.
- Status – **To be determined**
 - Issue is discussed via alternate white paper, no action required at this time

SC&A Finding 5 – Strata Misclassification

- 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 – **Closed**
- 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

SC&A Finding 6 – Misclassification Sensitivity Analysis

- 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**
- Workgroup discussed this issue and decided not to pursue the sensitivity analysis since the misclassification rate is less than 5%

SC&A Observation 6 – Scoping Analysis

- Observation 6: 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 – **Closed**
- Workgroup discussed this issue and decided not to pursue the sensitivity analysis since the misclassification rate is less than 5%

SC&A Observation 7 – Quality Assurance Assessment

- 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.
- Status – **Closed**
- NIOSH explained the payroll ID issue with the workgroup and the workgroup concurred that this should not impact the QA assessment

Status of ORAUT-RPRT-0092: Evaluation of Subcontractor monitoring at the SRS

ORAUT-RPRT-0092: Update Subcontractor Monitoring

- Discussions are ongoing:
 - June 2019, ORAUT-RPRT-0092 *Evaluation of Bioassay Data for Subcontracted Construction Trade Workers at the Savannah River Site* was submitted to Workgroup
 - November 2019, SC&A provided comments on the report
 - December 2019, Both NIOSH and SC&A presented their respective views to the SRS and SEC Issues Workgroups.
 - **Status:** NIOSH to provide responses to SC&A's comments

Major topics needing further discussion to resolve

- Stratification (non-CTW, Dupont CTW, subCTW)
 - June 2019, NIOSH submitted a white paper entitled Savannah River Site Plutonium Construction Trade Worker Stratification Refinement
 - November 2019, SC&A provided comments on the white paper
 - **Status:** NIOSH to provide response to SC&A comments in 2020
- Americium Monitoring at the Savannah River Site (SRS)
 - June 2019: ORAUT-RPRT-0091 Rev 00, *Evaluation of Savannah River Site Americium-241 Source Terms Between 1971 and 1999 Using Bioassay Frequency Tables*
 - **Status:** SC&A to provide comments on this report in 2020