



Response to SC&A’s “Focused Review of ORAUT-RPRT-0092, Revision 00, and Remaining Petition SEC-00103 Evaluation Report Period: 1991–2007”

John Cardarelli II, PhD, CHP, CIH, PE

NIOSH, Research Health Physicist

Nancy Chalmers, PhD

ORAUT, Statistician

Advisory Board on Radiation and Worker Health

Savannah River Site Work Group Meeting

March 22, 2023

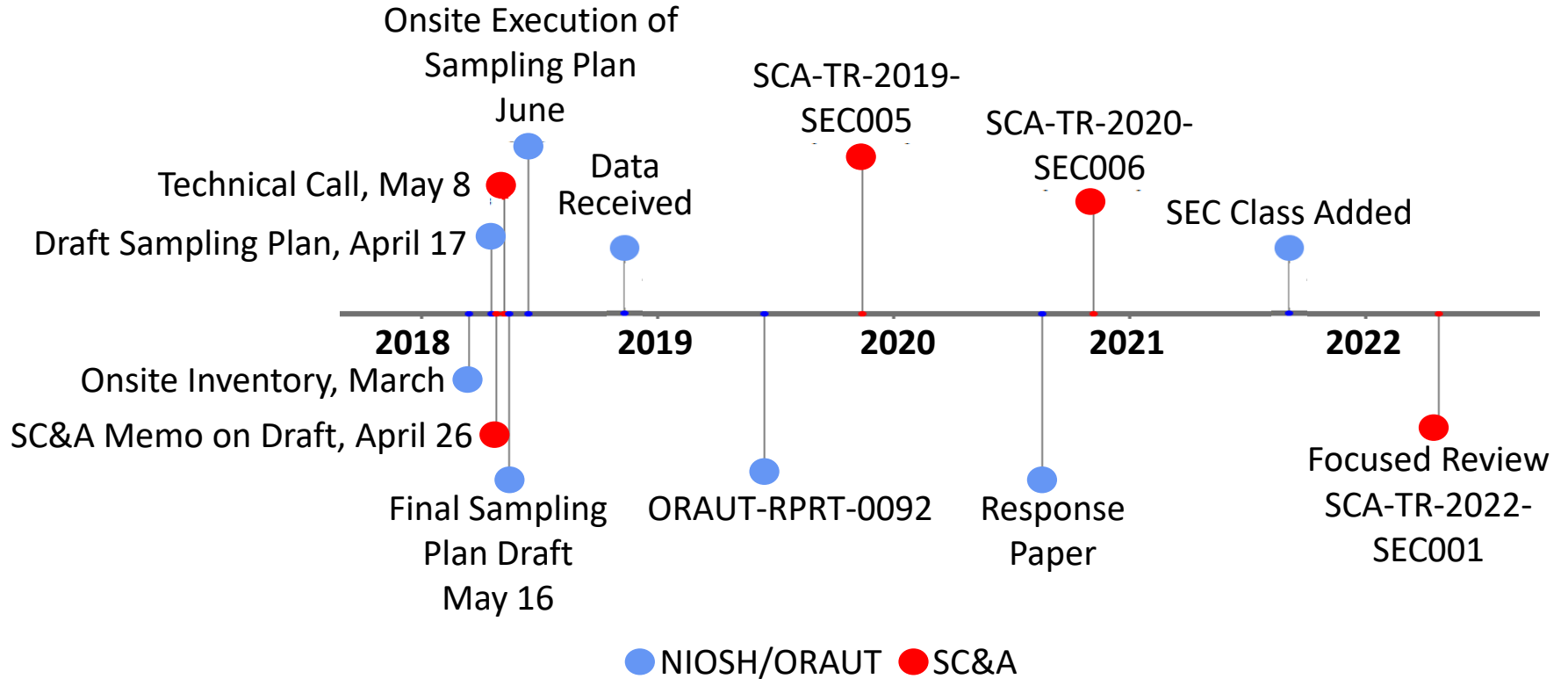
Overview

- Introduction
- NIOSH Responses to 5 SC&A Conclusions
- NIOSH Conclusion

Introduction

- ORAUT-RPRT-0092, *Evaluation of Bioassay Data for Subcontracted Construction Trade Workers at the Savannah River Site* [ORAUT 2019]
 - Original Purpose: use a Radiation Work Permit (RWP) sampling plan to determine whether subcontracted construction trade workers (subCTWs) were sufficiently monitored by bioassay such that their radiation doses could be reconstructed with sufficient accuracy

Timeline of Pertinent Events



Introduction – SC&A Conclusions

- SC&A Conclusions
 1. Sampling premise is not sufficiently grounded in historical SRS practices.
 2. Results for direct and effective monitoring may be overstated.
 3. Generalized matching is not sufficient.
 4. RWP-specified, job-specific bioassay data are incomplete.
 5. Feasibility of co-exposure model needs to balance RWP implementation with completeness of coworker data.
- Focus has shifted from feasibility of dose reconstruction to feasibility of co-exposure modeling

NIOSH Response to SC&A Conclusion 1

Sampling premise is not sufficiently grounded in historical SRS practices.

Monitoring Percentages

- Based on SC&A Figure 1 and Table 2 (reproduced below)
- Percent of Pu, Sr/FPs, Am, U, and Np bioassays required by RWP & number of RWPs

| Year | % Pu | # RWPs | % Sr/FP | # RWPs | % Am | # RWPs | % U | # RWPs | % Np | # RWPs |
|------|------|--------|---------|--------|------|--------|------|--------|------|--------|
| 1991 | 0% | 16 | 0% | 13 | 0% | 4 | 25% | 4 | 0% | 1 |
| 1992 | 0% | 23 | 0% | 9 | 0% | 12 | 0% | 20 | 0% | 2 |
| 1993 | 4% | 27 | 0% | 12 | 0% | 13 | 9% | 11 | 0% | 11 |
| 1994 | 78% | 32 | 72% | 25 | 33% | 9 | 33% | 15 | NA | 0 |
| 1995 | 100% | 15 | 100% | 5 | 0% | 2 | 100% | 2 | 33% | 3 |
| 1996 | 100% | 7 | 100% | 3 | 0% | 2 | NA | 0 | 100% | 1 |
| 1997 | 100% | 9 | 100% | 8 | 0% | 1 | NA | 0 | NA | 0 |
| 1998 | 80% | 10 | 71% | 7 | 0% | 1 | NA | 0 | NA | 0 |

Radionuclides included on RWPs

- 78% for Pu in 1994
 - 78% of the 32 RWPs (or 25 RWPs) sampled from 1994 have Pu marked as required on the RWP
 - remaining 22% (or 7 RWPs) are assumed to require Pu bioassay based on the work and/or area
- “Rise” from 0% (1991) to 78% (1994) to 100% (1995)
 - Transition between procedure-driven bioassay program and RWP-driven bioassay program
 - Check boxes on RWPs
 - Early 1990s forms did not have them
 - Middle and late 1990s forms have them

Example of RWPs

OSR 4-530 (Rev 2-27-92)
Stores: 26-6548.79

Radiation Work Permit Time and Exposure Log

RWP No.
92-241-NH-246
WR No.

Job Description
TK 42 V-2 RISER Pump/Motor Installation and removal
of Slip Plates.

Location
TK 42 V-2 RISER Equipment/IDP No.

Section I - Radiological Protection Requirements

| Protective Clothing Requirements | C (cotton) | T (tyvek) | R (rubber) | P (plastic) |
|---|------------|-----------|------------|-------------|
| <input checked="" type="checkbox"/> Plastic Suit <u>6</u> mil | | | | |
| <input type="checkbox"/> Acid Suit | | | | |
| <input checked="" type="checkbox"/> Coveralls <u>2</u> pair <u>C</u> inner <u>C</u> outer | | | | |
| <input checked="" type="checkbox"/> Gloves <u>3</u> pair <u>C</u> inner <u>R</u> outer | | | | |
| <input checked="" type="checkbox"/> Boots <u>1</u> pair <u>C</u> inner <u>outer</u> | | | | |
| <input checked="" type="checkbox"/> Shoe Covers <u>3</u> pair <u>R</u> inner <u>P</u> outer | | | | |
| <input type="checkbox"/> Hood <u>1</u> pair <u>C</u> inner <u>outer</u> | | | | |
| <input type="checkbox"/> Cap | | | | |
| <input type="checkbox"/> Other | | | | |

| Respiratory | Dosimetry Requirements |
|--|---|
| <input type="checkbox"/> Half-Face Respirator | <input checked="" type="checkbox"/> TLD |
| <input checked="" type="checkbox"/> Full-Face Respirator | <input checked="" type="checkbox"/> Self-Reader |
| <input checked="" type="checkbox"/> Fresh-Air Hood | <input type="checkbox"/> CND |
| <input type="checkbox"/> HEPA Canister | <input type="checkbox"/> TLND |
| <input type="checkbox"/> Organic Canister | <input type="checkbox"/> Test Badge |
| <input type="checkbox"/> Combination Canister | <input type="checkbox"/> Extremities |
| <input type="checkbox"/> Other | <input type="checkbox"/> Bioassay |
| | <input type="checkbox"/> Other |

Requirements for Stand-By Personnel (if different from above)

| HP Monitoring | | Timekeeper Required? | Pre-Job Meeting Required? | HP Survey at Start of Job Required? |
|--|----------------------------------|---|--|---|
| <input checked="" type="checkbox"/> Continuous | <input type="checkbox"/> Initial | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input checked="" type="checkbox"/> Yes |
| <input type="checkbox"/> Intermittent | <input type="checkbox"/> At End | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> No |

RWP from 1992

OSR 4-639A (09-29-95)

Radiological Work Permit

Job-Specific RWP Continuation (Sheet A)

| | |
|---|-----------------------------|
| RWP Unique Identifying Number 97-FC-140 | Revision Number 0 |
|---|-----------------------------|

Section IV Special Precautions (Continuation)

TASK 3 CLOTHING AND RESPIRATORY REQUIREMENTS ARE FOR SURVEY ONLY - ONE FULL SET OF PCs OTHERWISE

Specific Radiological Conditions
A TEMPORARY CONTAMINATION AREA / AIRBORNE RADIOACTIVITY AREA MUST BE SET UP FOR DRILLING

Job Specific Bioassay Requirements: Pu Sr EU U Nb Am T (Frequency _____) X-00 (None)

Radiological Control Operations Coverage Requirements:

| | | | |
|--|---|---|---|
| <input type="checkbox"/> Continuous | <input checked="" type="checkbox"/> Initial | Timekeeper Required? | If Yes, Stay Time Shall Be Estimated For Workers Based on Individual's Cumulative Dose. |
| <input checked="" type="checkbox"/> Intermittent | <input checked="" type="checkbox"/> At Completion | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> | |

RWP from 1997

Uncertainty in Percentage Monitored

- “Rise” from 0% (1991) to 78% (1994) to 100% (1995)
- Purpose of the RWP sampling plan: Estimate the percentage of monitored subCTWs to within +/- 5% with 95% confidence
 - Uncertainty in percentage of monitored subCTWs can be calculated
 - Uncertainty in anything else can NOT be calculated, unless it was inventoried in March 2018
 - Year was inventoried.
 - Bioassay requirements were not.
- Uncertainties in SC&A Table 2 are unknowable

Summary Response to SC&A Conclusion 1

- SC&A Conclusion 1: Sampling premise is not sufficiently grounded in historical SRS practices.
 - Conclusion is based on a change from procedure-driven bioassay to RWP-driven bioassay
 - Any conclusion drawn from comparing statistics with unknowable uncertainties is suspect
 - Presence of bioassay requirements on all of the RWPs is not necessary for co-exposure modeling.
 - Having RWPs is not even necessary

NIOSH Response to SC&A Conclusion 2

Results for direct and effective monitoring may be overstated.

Inconsistency of the term “monitored”

- SC&A states, “*NIOSH did not address all of the radionuclides listed in the RWPs...*” [SC&A 2022]
 - Final draft sampling plan – “*for all radionuclides listed on the RWP other than tritium*” [ORAUT 2018]
 - ORAUT-RPRT-0092 [ORAUT 2019]
 - Section 2.1 – “*for all radionuclides listed on the RWP other than tritium*”
 - Section 4.2 – “*at least one required bioassay*”
- SC&A is correct that the definition of “monitored” in ORAUT-RPRT-0092 is not consistent.
 - “All required nuclides” vs. “at least one required nuclide”

Re-evaluated monitoring percentages by type

- Monitoring Types
 - Direct monitoring
 - subCTW was monitored
 - Effective monitoring
 - Either the worker was monitored or their coworker was monitored
- NIOSH recalculated direct and effective monitoring percentages where “monitored” means “all required nuclides”

Purpose of Sampling Plan

- Purpose of the RWP sampling plan: Estimate the percentage of monitored subCTWs to within +/- 5% with 95% confidence
 - Uncertainty in percentage of monitored subCTWs can be calculated
 - Uncertainty in anything else can NOT be calculated, unless it was inventoried in March 2018
 - Year and area were inventoried.

Results showed no significant difference

| Monitoring Type and Definition | Weighted Point Estimate | 95% Confidence Interval |
|---|-------------------------|-------------------------|
| Direct (at least one required nuclide) | 95.13% | (87.18%, 98.84%) |
| Direct (all required nuclides) | 75.16% | (68.15%, 81.32%) |
| Effective (at least one required nuclide) | 97.52% | (87.50%, 99.92%) |
| Effective (all required nuclides) | 88.13% | (80.14%, 93.74%) |

- Direct intervals do not overlap, so direct percentage decreases with change in definition.
- Effective intervals overlap, so change in definition does not have a significant effect.

Arbitrary monitoring threshold

- SC&A section 5.4 [SC&A 2022] suggests a monitoring threshold
 - *“SC&A’s selection of the compliance value less of [sic] than 80 percent was arbitrary, but it was a reasonable value below which the rate of compliance certainly would be questionable”*
- Any suggested monitoring threshold would be completely arbitrary.
- Every interval on the previous slide is above or contains the arbitrary SC&A value of 80%.

Alternatives to monitoring threshold

- RWP sampling plan focused on subCTWs.
- Must Account for Exposure Potential of Unmonitored Workers
 - If unmonitored subCTWs represent a small fraction of the highest exposed group, then a CX model can be developed.
 - If 90% of subCTWs were unmonitored, but a large fraction of highly-exposed workers within the entire population were monitored, then a bounding CX model can be developed.

Summary Response to SC&A Conclusion 2

- SC&A Conclusion 2: Results for direct and effective monitoring may be overstated.
 - NIOSH agrees that we did not address all radionuclides when tallying results for ORAUT-RPRT-0092.
 - Updated tallies are presented here.
 - NIOSH conclusion has not changed: a co-exposure model can still be constructed.

NIOSH Response to SC&A Conclusion 3

Generalized matching is not sufficient.

What constitutes a coworker?

- For effective monitoring, what constitutes a coworker?
- Final draft sampling plan [ORAUT 2018]
 - “co-worker on the same RWP”
 - subCTW is implied since that was the sole focus
- ORAUT-RPRT-0092 [ORAUT 2019]
 - subCTW on same RWP, same date, same time (within no more than 15 minutes), any job title but “laborer” could be used for another craft
- SC&A suggestion [SC&A 2022]
 - subCTW on same RWP, same date, same time, same craft

Coworker matching criteria too restrictive

- NIOSH believes the criteria for coworker matching (in ORAUT-RPRT-0092 and SC&A suggestion) are more restrictive than necessary for developing co-exposure models.
- “Coworker” vs. “Co-Exposure” Misconception
 - Discussed during 12/5/19 SRS and SEC Issues WG meeting [NIOSH 2019a]
 - Discussed during 12/11/19 Advisory Board meeting [NIOSH 2019b]
 - Co-exposure models are based on workers with similar exposure potentials, not necessarily coworkers that worked right alongside them.

Matching criteria for co-exposure models

- No requirement that the monitored person works closely with unmonitored person
- Model is representative or bounding for unmonitored worker if those monitored had the same or higher exposure potential
- Sampling plan focused on subCTWs, but if any monitored worker (another subCTW, prime CTW, or nonCTW) with the same or higher exposure potential was monitored, the model would be representative or bounding

Summary response to SC&A Conclusion 3

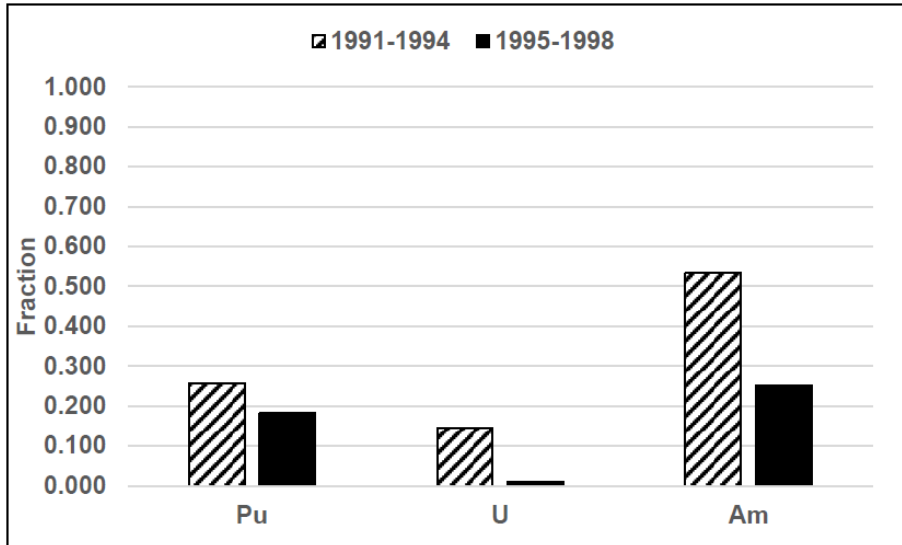
- SC&A Conclusion 3: Generalized matching is not sufficient.
 - For co-exposure modeling, coworkers used for effective monitoring matches need only have the same or higher exposure potential.
 - SC&A's criteria of same RWP, same date, same time, same craft are far too restrictive

NIOSH Response to SC&A Conclusion 4

RWP-specified, job-specific bioassay data are incomplete.

Fraction of noncompliant monitoring

- Nearly half of conclusion 4 focuses on SC&A Figures 4 and 5
 - The fraction on the y-axis is a noncompliance fraction.



Nuclides in left (right) plot had a perceived decrease (increase) in noncompliance between the time periods.

Noncompliance uncertainties are unknown

- Uncertainties in noncompliance fractions are unknowable
 - Year was inventoried. Nuclide was not.
- Comparison of point estimates without their uncertainties is inappropriate.
- SC&A use of these phrases is inappropriate:
 - “significantly higher”
 - “statistically significant”
 - “essentially the same”
- With uncertainty considered, the sets of bars on the previous slide may not show any differences.

Noncompliance does not prevent development of co-exposure models

- Other half of conclusion 4 deals with job-specific sampling, audits, a 1990 Tiger Team finding, and the 1997-1998 Westinghouse Savannah River Company actions.
- ORAUT-RPRT-0102 states “compliance with the regulations in place at the time the radiological work was performed is not required in order to perform a dose reconstruction or develop a co-exposure model” [ORAUT 2021]
- Dr. Paul Ziemer made a very similar statement during 4/15/21 Advisory Board meeting [NIOSH 2021]
- Audits, Tiger Team findings, and Company actions do not necessarily prevent co-exposure modeling for SRS.

“Job-specific” sample definition is confusing

- SRS 5Q1.1-506 (emphasis added):
 - “Caution: It is EXTREMELY IMPORTANT to note that the effectiveness of the bioassay program in general depends on combining both the routine program and the non-routine, job-specific program. Any time unusual events occur, or jobs are performed that may expose personnel to unusual hazards, a job-specific program should be considered per Section 5.1.2.1.” [WSRC 1992, PDF p. 60]
 - “Any time jobs are undertaken with the potential for unknown radiological conditions to occur or unusual radionuclides to be present, a non-routine, job-specific bioassay program should be considered. In such cases, an in-vitro sample and/or in-vivo count may be required prior to commencing work and again at the conclusion of work. Such a sampling program is at the discretion of HPO supervision and is noted on the Radiological Work Permit for the task. Additional guidance on job-specific sampling programs is available from the Dosimetry Evaluation Group at x5-2931.” [WSRC 1992, PDF p. 57]

“Job-specific” samples are not “special” samples

- Portions of 5Q1.1-506 seem to imply that job-specific samples are non-routine (or special) samples.
- This contradicts a 2017 interview with former site internal dosimetrist at SRS [ORAUT 2017]
 - “Job-specific bioassay is a program prescribed in response to a specific event (the job) but is not a special bioassay”

DOE changed Notice of Violation

- Follow-up interview in August 2022 [ORAUT 2022a]
 - Job-specific samples were part of the routine program and were not special samples according to site practices, despite what the procedures say.
 - 1997 NOV was changed from Health and Safety violation to Procedures violation, because DOE agreed that job-specific samples were not special samples.
 - Special bioassay samples
 - Prescribed by RadCon prior to 1991
 - Prescribed by internal dosimetrist starting in 1991 [ORAUT 2022b]

Co-exposure models should include “special” samples

- A bounding co-exposure model can be constructed if a significant portion of the most highly-exposed workers are part of the dataset.
- If samples collected when there were suspected intakes of radioactive material are part of the dataset, a bounding co-exposure model could be constructed, regardless of job-specific sampling and RWP work.
 - Follow-up question in October 2022 [ORAUT 2022c]
 - Requests for special samples triggered by events were tracked by the internal dosimetrist in a computer program called *TRACK* starting in 1991.

Summary response to SC&A Conclusion 4

- Conclusion 4: RWP-specified, job-specific bioassay data are incomplete.
 - If the samples prescribed by the site internal dosimetrist when a suspected intake occurred (samples in the *TRACK* database) are part of NIOSH's co-exposure database, this is evidence that a bounding co-exposure model could be constructed, despite SC&A Conclusion 4.

NIOSH Response to SC&A Conclusion 5

Feasibility of co-exposure model needs to balance RWP implementation with completeness of coworker data.

Conclusion 5 Summary

- Email exchange [NIOSH/SC&A 2022]
 - NIOSH
 - *“It appears this conclusion is a general statement that if conclusions 1–4 are addressed, then SC&A ‘would consider NIOSH’s conclusion valid...to support development of a co-exposure model...’ ”*
 - SC&A
 - the NIOSH interpretation is correct
- No detailed response necessary

NIOSH Conclusions

Conclusions

- NIOSH addressed the five conclusions in the SC&A Focused Review and concludes:
 1. Absence of bioassay requirements on RWPs in the early 1990s is irrelevant because bioassay programs were prescribed by procedure.
 2. Changing the definition of “monitored” has the expected effect, but the new summary statistics do not prevent creating a co-exposure model.
 3. SC&A’s coworker matching criteria are far too restrictive because for co-exposure, the only necessary criterion is that the monitored worker has the same or higher exposure potential than the unmonitored worker.
 4. Regardless of the issues SC&A pointed out, if the samples from the most highly-exposed workers (in the *TRACK* database) are part of the co-exposure database, this is evidence that a co-exposure model could be constructed.
 5. NIOSH has addressed the SC&A issues from the Focused Review and maintains that co-exposure models can be developed.

References (1 of 3)

- NIOSH [2019a]. Centers for Disease Control National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health Savannah River Site (SRS) and SEC Issues work groups joint meeting Thursday, December 5, 2019. Transcript. Washington, DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Advisory Board on Radiation and Worker Health. [SRDB Ref ID: 182846]
- NIOSH [2019b]. Centers for Disease Control National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health 132nd meeting Wednesday, December 11, 2019. Transcript. Washington, DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Advisory Board on Radiation and Worker Health. [SRDB Ref ID: 184395]
- NIOSH [2020]. NIOSH/ORAU: NIOSH response to SC&A comments on ORAUT-RPRT-0092. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. August 18. [SRDB Ref ID: 182968]
- NIOSH [2021]. U.S. Department of Health and Human Services Centers for Disease Control National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health 139th Meeting Thursday, April 15, 2021. Transcript. Washington, DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Advisory Board on Radiation and Worker Health. [SRDB Ref ID: 187719]
- NIOSH [2022]. U.S. Department of Health and Human Services Centers for Disease Control National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health 145th Meeting Thursday, April 28, 2022. Transcript. Washington, DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Advisory Board on Radiation and Worker Health. [SRDB Ref ID: 193031]

References (2 of 3)

- NIOSH/SC&A [2022]. Seeking clarification on conclusion 5 from the SC&A focused review of ORAUT-0092 2022. E-mail chain including NIOSH and SC&A. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. Arlington, VA: S. Cohen and Associates, Inc. May, June, October. [SRDB Ref ID: 194363]
- ORAUT [2017]. Documented communication with Tom LaBone on Savannah River Site. Oak Ridge, TN: Oak Ridge Associated Universities Team. October 6. [SRDB Ref ID: 168231]
- ORAUT [2018]. SRS work permit sampling plan. Oak Ridge, TN: Oak Ridge Associated Universities Team. May 16. [SRDB Ref ID: 194480]
- ORAUT [2019]. Evaluation of bioassay data for subcontracted construction trade workers at SRS. Oak Ridge, TN: Oak Ridge Associated Universities Team. ORAUT-RPRT-0092 Rev. 00, June 14. [SRDB Ref ID: 176739]
- ORAUT [2021]. Assessment of Los Alamos National Laboratory plutonium bioassay programs 1996 to 2001. Oak Ridge, TN: Oak Ridge Associated Universities Team. ORAUT-RPRT-0102 Rev. 00, December 2. [SRDB Ref ID: 187245]
- ORAUT [2022a]. Documented communication – interview with Tom LaBone – follow-up question about SRS. Oak Ridge, TN: Oak Ridge Associated Universities Team. August 19. SRDB Ref ID: 193551
- ORAUT [2022b]. Documented communication with Dennis Hadlock on SRS procedure regarding who made the decision to put workers on special bioassay program. Oak Ridge, TN: Oak Ridge Associated Universities Team. August 15–16. [SRDB Ref ID: 193470]
- ORAUT [2022c]. Documented communication – follow-up interview question with Tom LaBone about SRS 2022. Oak Ridge, TN: Oak Ridge Associated Universities Team. October 18. [SRDB Ref ID: 194367]

References (3 of 3)

- SC&A [2018]. SC&A comments on NIOSH draft permit sampling plan. Memo to Savannah River Site Work Group. Arlington, VA: SC&A, Inc. April 26. [SRDB Ref ID: 176648]
- SC&A [2019]. Review of ORAUT-RPRT-0092, revision 00, “evaluation of bioassay data for subcontracted construction trade workers at the Savannah River Site” draft. Arlington, VA: SC&A, Inc. SCA-TR-2019-SEC005 Rev. 0, November 12. [SRDB Ref ID: 179239]
- SC&A [2020]. Review of NIOSH response to SC&A on ORAUT-RPRT-0092, revision 00, on bioassay data for subcontracted construction trade workers at the Savannah River Site draft. Arlington, VA: SC&A, Inc. SCA-TR-2020-SEC006 Rev. 0, November 5. [SRDB Ref ID: 184019]
- SC&A [2022]. Focused review of ORAUT-RPRT-0092, revision 00, and remaining petition SEC-00103 evaluation report period: 1991–2007 – draft. Arlington, VA: SC&A, Inc. SCA-TR-2022-SEC001 Rev. 0, April 22. [SRDB Ref ID: 192680]
- WSRC [1992]. Routine in vivo and in vitro bioassay scheduling and administration. Savannah River Site, Aiken, SC: Westinghouse Savannah River Company. WSRC-5Q1.1-506 Rev 3. [SRDB Ref ID: 152159]

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

