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

Response Paper

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INTRODUCTION

In June 2019, the Oak Ridge Associated Universities (ORAU) Team issued *Evaluation of Bioassay Data for Subcontracted Construction Trade Workers at the Savannah River Site*, ORAUT-RPRT-0092 [ORAUT 2019]. The purpose of that evaluation was to 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. By November 2019, SC&A issued their first set of comments titled *Review of ORAUT-RPRT-0092, Revision 00, "Evaluation of Bioassay Data for Subcontracted Construction Trade Workers at the Savannah River Site"* [SC&A 2019]. The National Institute for Occupational Safety and Health (NIOSH) responded in a response paper titled *NIOSH Response to SC&A Comments on ORAUT-RPRT-0092* [NIOSH 2020], issued in August 2020. In November 2020, SC&A issued a follow-up response in *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* [SC&A 2020]. In April 2022, SC&A issued *Focused Review of ORAUT-RPRT-0092, Revision 00, and Remaining Petition SEC-00103 Evaluation Report Period: 1991–2007* (hereafter referred to as SC&A Focused Review) [SC&A 2022].

The timeline in Figure 1 shows the documents described above as well as other events that took place as part of the RWP sampling plan.

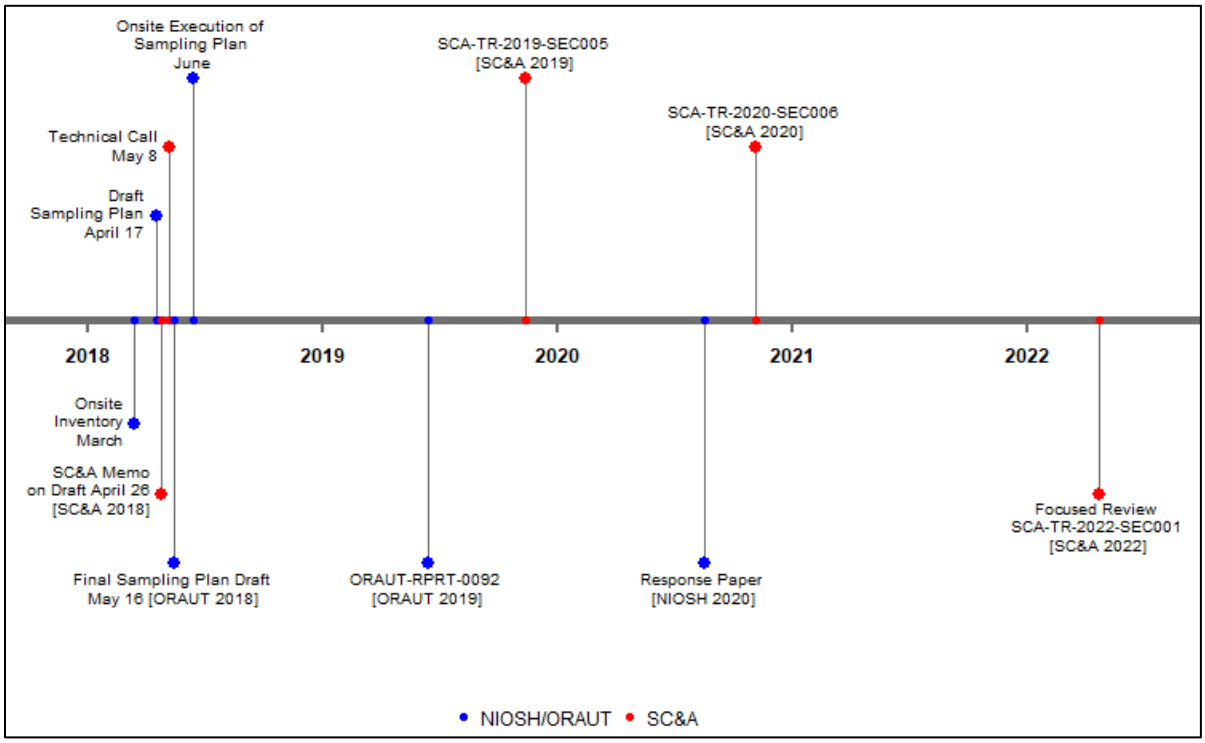

Figure 1: Timeline of pertinent events and documents regarding ORAUT-RPRT-0092 [ORAUT 2019].

In this response document, NIOSH addresses the five conclusions as outlined in Section 7 of the SC&A Focused Review [SC&A 2022]:

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.

SC&A's Conclusion 5 demonstrates that SC&A has shifted the focus of their ORAUT-RPRT-0092 review from determining whether subCTW radiation doses can be reconstructed to determining whether a co-exposure model could be constructed for the subCTWs, in which case NIOSH can reconstruct dose. NIOSH agrees with SC&A's current focus.

SC&A CONCLUSIONS WITH NIOSH RESPONSES

In the sections below, NIOSH presents SC&A's five conclusions with a detailed response following each SC&A conclusion.

SC&A Conclusion 1: Sampling premise is not sufficiently grounded in historical SRS practices

> *Measured against the review criteria used by SC&A's review of RPRT-0092, the sampling premise is not sufficiently grounded in actual WSRC policies, procedures, and practices within the time period 1991–1998. While RWPs were implemented by procedure in 1992 (and were being rolled out by WSRC before then), along with more specific target radionuclides listed on RWPs, SC&A finds that demonstrable implementation of these requirements was not apparent in the workplace until 1994–1995, as evidenced by figure 1 and table 2. Figure 1 shows that the percentage of required bioassays listed on the RWPs rose from very few (less than 5 percent) in 1991–1993 to over 60 percent in 1994 and over 80 percent in 1995. Correspondingly, table 2 shows that the percent of RWP-specified radionuclide bioassays compared to total bioassays listed in table C-1 of RPRT-0092 rose for plutonium from zero percent in 1991 to 78 percent and 100 percent in 1994 and 1995, respectively. While these results could also imply that prescheduled bioassays were actually performed in place of job-specific bioassays but simply not cited on the RWPs, they also indicate that RWPs may have lacked adequate documentation and completeness. (Table 2 also notes that for other radionuclides of concern—americium, uranium, and neptunium—the percent of radionuclide-specific bioassays required by RWPs ranged from zero to 25 percent for 1991–1993). While RPRT-0092 finds a relatively high level of direct and effective matches for sCTWs listed on RWPs, this may not be a valid comparison for the sake of*

bioassay data representation, given the nascent state of RWP program implementation that may bias the percentage of sCTWs bioassayed higher for the already prescheduled radionuclides of concern (e.g., plutonium, americium, and fission products). [SC&A 2022, PDF p. 42]

NIOSH Response to SC&A Conclusion 1

Conclusion 1 mentions Figure 1 and Table 2 from the SC&A Focused Review [SC&A 2022, PDF pp. 28–29] multiple times and seems to be the basis for this conclusion. Figure 1 and Table 2 are SC&A's summaries of the information presented in ORAUT-RPRT-0092, Table C-1 [ORAUT 2019, PDF p. 82–85]. Based on their Figure 1, SC&A commented on the very low percentages of listed bioassays on the RWPs from 1991–1993 and the increase in those percentages for 1994–1998. SC&A went on to describe the perceived rise in plutonium percentages from 1991 (0%) to 1994 (78%[1]) to 1995 (100%), as presented in their Table 2. It is not surprising to see the increase in percentages that SC&A identified because during the transition between prime contractors (from DuPont to Westinghouse) bioassay programs were prescribed by procedure, not RWP. The RWP forms from the early 1990s did not contain check boxes for RWP requirements, whereas the RWP forms from the middle and late 1990s did contain those check boxes. There was a proceduralized, pre-specified routine bioassay program in place in the early 1990s, so the fact that those RWPs do not specify the required bioassay is irrelevant for developing co-exposure models. As long as the workers were being monitored for the nuclides of concern, it does not matter whether the RWP specified those nuclides or the routine program did. Lack of RWP-specified bioassay requirements does not equate to an immature or inadequate bioassay program.

The preceding paragraph includes the phrase "perceived rise." The information in ORAUT-RPRT-0092, Table C-1 was from a sample of RWPs collected for a specific purpose: to be able to estimate the percentage of monitored subCTWs to within +/- 5% with 95% confidence. The summaries in Figure 1 and Table 2 of the SC&A Focused Review are not part of that specific purpose and were not characteristics captured in the March 2018 inventory (year was characterized but bioassay requirements were not), so the uncertainties in those summary statistics are unknowable. As such, all of the SC&A-provided percentages are not reliable because of their unknowable uncertainties and the point estimates should not be compared. If those uncertainties could be taken into account, the perceived "increase" and "rise" in percentages may not still be there. Therefore, the uncertainty in the point estimate of 78% (and all of the other percentages in that table) is unknowable and should cause one to question the reliability of that value because it was calculated from only 32 sampled RWPs[2] (all other

[1] For clarity, the 78% means that 78% of the 32 RWPs (or 25 RWPs) sampled from 1994 have Pu marked as required on the RWP. The remaining 22% (or 7 RWPs) are assumed to require Pu bioassay based on the work and/or area.

[2] Since bioassay requirements were not part of the March 2018 inventory, the number of RWPs in the population that require Pu is not known. For example, if there were only 32 RWPs in the population that require Pu and all were sampled, the point estimate of 78% would have no uncertainty. If there were 50 RWPs in the population that require

percentages were from fewer than 32 sampled RWPs). In general, point estimates with unknown or unknowable uncertainties (or without confidence intervals) should not be compared to other point estimates or fixed threshold values [Taylor 1997, PDF pp. 24–25].

In summary, SC&A concludes that the Savannah River Site (SRS) RWP program was not adequately implemented until 1994–1995. That conclusion is based on the change in practice from bioassay specified by procedure to bioassay specified by RWP, not an inadequate RWP program. Additionally, SC&A is basing Conclusion 1 on Figure 1 and Table 2 that have unknowable uncertainties, making all conclusions drawn from Figure 1 and Table 2 within the SC&A Focused Review suspect. It is neither necessary to have RWPs nor to analyze them to justify the feasibility of making a co-exposure model. Co-exposure models can be created without having any RWPs, so the absence of bioassay requirements on some of the RWPs is irrelevant.

SC&A Conclusion 2: Results for direct and effective monitoring may be overstated

> *SC&A continues to conclude that, as with the earlier SEC period of 1972–1990, NIOSH did not address all of the radionuclides listed in the RWPs when determining data completeness for job-specific bioassay monitoring, and, therefore, the percentage of matching results for direct and effective monitoring appear to be overstated in the RPRT-0092 summary in section 6.3. This is most relevant for the 1991–1994 period, when (as noted in conclusion 1) many exposure-relevant radionuclides of concern were not yet included in RWPs and inaccurate facility source term assumptions may have been made, as noted by DOE in 1990 (DOE, 1990) and by WSRC in 1999 (WSRC, 1999a). While RPRT-0092 claims a relatively high percentage of both direct and effective matches between RWPs and listed sCTWs or their coworkers for at least one bioassay (averages of 96 and 98 percent, respectively), SC&A's review found these values to be lower (averages of 77 percent directly and 89 percent effectively monitored) when matched against all mandated radionuclides for RWPs. These results tend to be dampened in a sitewide comparison, given the much larger numbers of prescheduled bioassays (plutonium, Sr/FPs, uranium), but become more apparent at the facility level, as shown in tables 5, 6, and 7. For the period 1991–1994, there are facility-specific instances of significantly lower percentages of directly bioassayed sCTWs (e.g., 50 percent for uranium at A-773 and at F-247 in 1991, as shown in table 7). RWPs themselves would not necessarily have included complete in vitro bioassay requirements until March 1999, when WSRC expanded its bioassay specifications to include facility-specific analytic characterization information (WSRC, 1999a).* [SC&A 2022, PDF pp. 42–43]

Pu and 32 were part of the sample, the uncertainty in the 78% estimate would be fairly small. However, if there were 500 RWPs in the population that require Pu and only 32 were sampled, the uncertainty in the 78% estimate would be much larger.

NIOSH Response to SC&A Conclusion 2

Regarding SC&A's Conclusion 2 statement that "NIOSH did not address all of the radionuclides listed in the RWPs…" [SC&A 2022, PDF p. 42], ORAUT-RPRT-0092, Section 2.1 defines what it means for a subCTW to be monitored; it states "…for all radionuclides listed on the RWP other than tritium (^{3}H)" [ORAUT 2019, PDF p. 16]. This definition was also part of the final draft of the sampling plan [ORAUT 2018, PDF p. 3]. In section 4.2 of ORAUT-RPRT-0092, it is clear that the summaries for the report were created using a definition of monitoring that meant the worker needed "…at least one required bioassay…" [ORAUT 2019, PDF p. 39]. SC&A is correct that the intended definition of "monitoring" in the sampling plan is not what was tallied for the results in ORAUT-RPRT-0092.

As mentioned in the response to Conclusion 1, the sampling plan was designed to collect RWPs to be able to estimate the percentage of monitored subCTWs to within +/- 5% with 95% confidence, regardless of the definition of "monitored." Recall that direct monitoring means the subCTW was monitored, while effective monitoring means that either the worker was monitored or their coworker was monitored. The confidence interval in ORAUT-RPRT-0092 is still valid but applies to direct monitoring, where "monitored" means "at least one required nuclide." Note that while the unweighted point estimate is more easily calculated (number monitored divided by number of subCTWs), the weighted point estimate is the more appropriate summary statistic, since the sampling plan was a stratified multi-stage sample. If the sampling plan had been a simple random sample, all of the weights would be equal, and the weighted and unweighted point estimates would be the same [Biemer and Christ 2008]. Despite not being included in ORAUT-RPRT-0092, a confidence interval can also be calculated for effective monitoring where "monitored" still means "at least one required nuclide." The summary statistics for "at least one required nuclide" are in Table 1.

Table 1: Summary statistics when "monitored" is defined as "at least one required nuclide"

Monitoring type	Number of subCTWs	Number monitored	Unweighted point estimate	Weighted point estimate	95% confidence interval
Direct	662	633	95.62%	95.13%	(87.18%, 98.84%)
Effective	662	652	98.49%	97.52%[a]	(87.50%, 99.92%)[a]

[a] These summary statistics do not appear in ORAUT-RPRT-0092, but were calculated for this response using ORAUT-RPRT-0092 data.

The sampling plan was carefully designed to cover all areas and years of interest where there were RWPs inventoried. Any finer partitioning (by nuclide, craft, building, etc., or any combination thereof) of the RWP results was not part of the original design of the sampling plan, meaning those characteristics were not inventoried in March 2018. As mentioned in the response to Conclusion 1, the uncertainty in those results could be very large and cannot be calculated because the weights cannot be determined. Therefore, the remainder of this response to Conclusion 2 will deal with changing the definition of "monitored" to "all of the radionuclides

listed in the RWPs," but will only present summaries by area and year along with updated confidence intervals.

When changing the definition of "monitored" from "at least one required nuclide" to "all required nuclides," SC&A calculated monitoring percentages of 77% directly monitored and 89% effectively monitored. Note that these percentages are unweighted point estimates and their weighted counterparts would be more appropriate. Prior to the NIOSH recalculation for this response, the ORAU Team performed a very thorough Quality Assurance (QA) review of the information contained in Attachment C of ORAUT-RPRT-0092. After the QA and changing the definition of "monitored" from "at least one required nuclide" to "all required nuclides," the updated summary statistics are in Table 2.

Table 2: Summary statistics after QA when "monitored" is defined as "all required nuclides"

Monitoring type	Number of subCTWs	Number monitored	Unweighted point estimate	Weighted point estimate	95% confidence interval
Direct	663	448	67.57%	75.16%	(68.15%, 81.32%)
Effective	663	525	79.19%	88.13%	(80.14%, 93.74%)

Summaries by area and year are in Tables 3 and 4, respectively. Figures 2 and 3 provide a graphical representation of the tabled information. Although it is possible to calculate uncertainties in the results by area and year, the calculation would be very complicated. The only benefit to calculating those uncertainties for Tables 3 and 4 of this document would be for comparison to the point estimates in Tables 3 and 4 of the SC&A Focused Review [SC&A 2022, PDF pp. 30–31] or Table 4-1 of ORAUT-RPRT-0092 [ORAUT 2019, PDF p. 39], but since uncertainties were not calculated in those documents, there is no need to calculate them here. Two point estimates should not be compared without their accompanying uncertainties [Taylor 1997, PDF pp. 24–25].

Table 3: Summary statistics by area when "monitored" is defined as "all required nuclides"

Area	subCTWs	Direct	Direct %	Effective	Effective %
A	112	84	75.00%	95	84.82%
E	23	16	69.57%	17	73.91%
F	199	135	67.84%	156	78.39%
H	232	149	64.22%	187	80.60%
M	18	16	88.89%	17	94.44%
Z	79	48	60.76%	53	67.09%
All	663	448	67.57%	525	79.19%

Table 4: Summary statistics by year when "monitored" is defined as "all required nuclides"

Year	subCTWs	Direct	Direct %	Effective	Effective %
1990	1	0	0.00 %	0	0.00 %
1991	81	31	38.27 %	57	70.37 %
1992	106	83	78.30 %	94	88.68 %
1993	173	122	70.52 %	136	78.61 %
1994	140	91	65.00 %	100	71.43 %
1995	57	46	80.70 %	50	87.72 %
1996	24	17	70.83 %	19	79.17 %
1997	56	41	73.21 %	49	87.50 %
1998	25	17	68.00 %	20	80.00 %
All	663	448	67.57 %	525	79.19 %

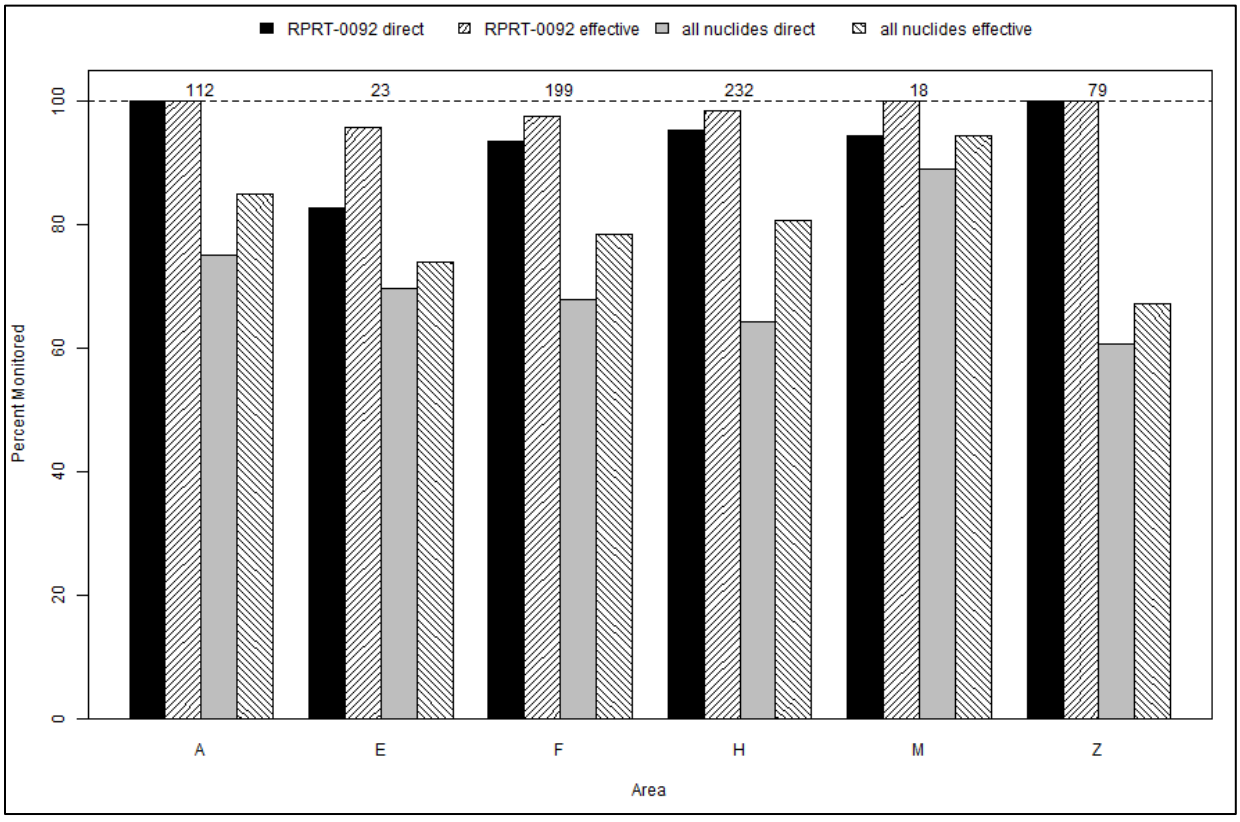

Figure 2: Percent monitored (direct and effective) by area for ORAUT-RPRT-0092 and when "monitored" is defined as "all required nuclides." The numbers above the bars are the number of subCTWs on RWPs in that area.

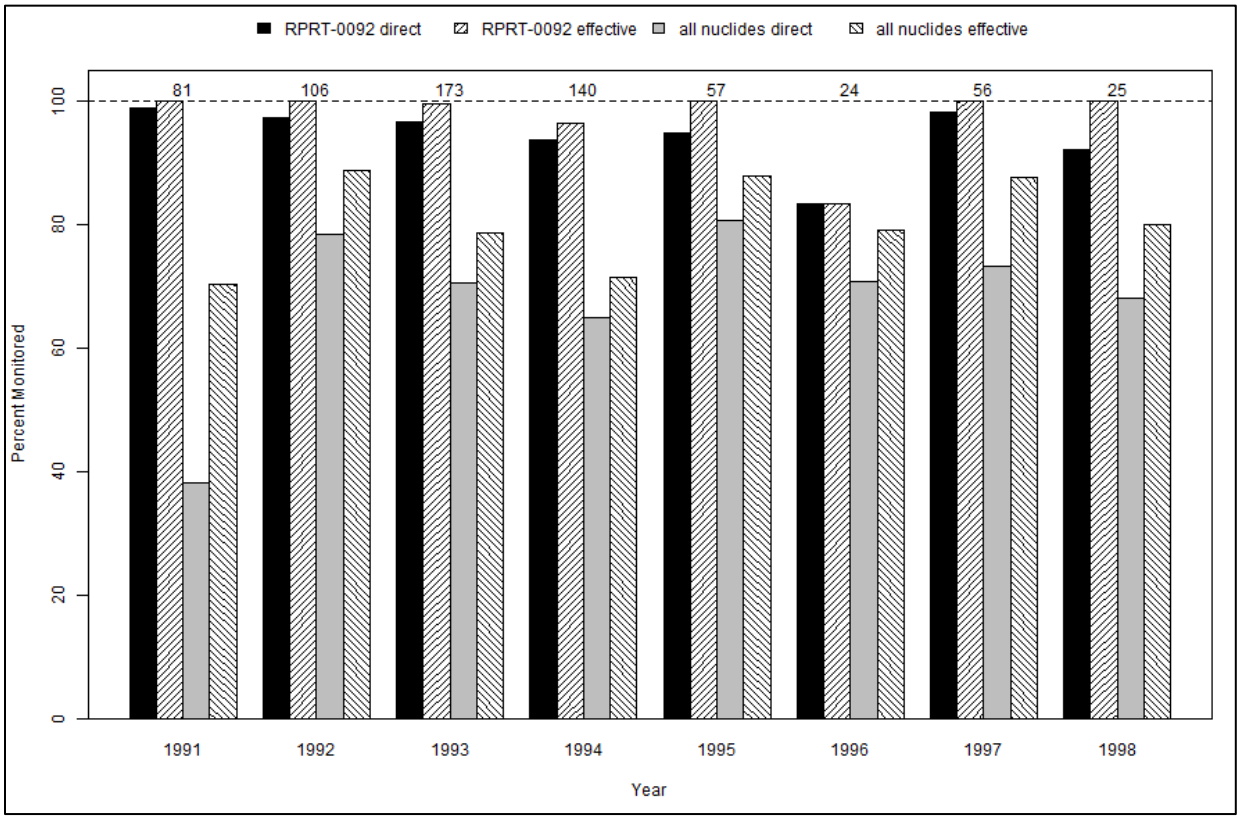

Figure 3: Percent monitored (direct and effective) by year for ORAUT-RPRT-0092 and when "monitored" is defined as "all required nuclides." The numbers above the bars are the number of subCTWs on RWPs in that year.

For convenience in comparing the effect of changing the definition of "monitored," Table 5 contains the appropriate information from Tables 1 and 2 above.

Table 5: Summary information for Conclusion 2

Monitoring type with definition	Weighted point estimate	95% confidence interval
Direct (at least one required radionuclide)	95.13%	(87.18%, 98.84%)
Direct (all required radionuclides)	75.16%	(68.15%, 81.32%)
Effective (at least one required radionuclide)	97.52%	(87.50%, 99.92%)
Effective (all required radionuclides)	88.13%	(80.14%, 93.74%)

Changing the definition of "monitored" from "at least one required nuclide" to "all required nuclides" decreases the point estimates for direct monitoring in the sample from 95.13% to 75.16% and the point estimates for effective monitoring from 97.52% to 88.13%, keeping in mind that these true monitoring percentages could plausibly be any value in their respective

confidence intervals. Because the two direct monitoring confidence intervals do not overlap (the second interval from Table 5 is completely below the first), one can conclude that the direct monitoring percentage decreases with the change in definition. Because the two effective monitoring confidence intervals overlap, the appropriate conclusion is that the change in definition does not have a significant effect on the effective monitoring percentage[3].

In Section 5.4 of the SC&A Focused Review, SC&A suggests a monitoring threshold when they state "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" [SC&A 2022, PDF p. 33]. The choice of any such monitoring percentage threshold would be completely arbitrary. Despite the arbitrary nature of the SC&A threshold, every confidence interval in Table 5 is above or contains the SC&A value of 80%, so SC&A should not consider these monitoring percentages "questionable."

Section 5.4 of the SC&A Focused Review focuses on "compliance as a function of building" and is where the arbitrary value of 80% is discussed [SC&A 2022, PDF pp. 33–37]. Their analysis is not **only** a function of building because the sampling plan results have been partitioned three ways (by building, year, and nuclide) to make those tables. As mentioned above, this triple-partitioning affects the uncertainty in all of the numbers in that section. Because building and nuclide were not a part of the design of the sampling plan, the uncertainties in those numbers cannot be calculated. It is likely that every number in that section is not significantly different from the arbitrary 80% if the uncertainty could be taken into account.

As mentioned above, any suggestion of a quantitative monitoring threshold based solely on subCTWs would be an arbitrary choice. If there is agreement between SC&A and NIOSH that monitoring for prime construction trade workers (CTWs) and/or nonCTWs was adequate enough to construct co-exposure models, then those monitoring percentages could be used as thresholds for the subCTWs. Given the monitoring percentages (and their uncertainties) for subCTWs, prime CTWs, and nonCTWs, statements could be made about how the monitoring percentages for these groups of workers compare to each other (i.e., Is the monitoring percentage for subCTWs significantly different from the percentage for nonCTWs?).

While there is an expected drop in the monitoring percentages with the change in definition, the monitoring percentages, by either definition, must be combined with what is known about the exposure potential for the unmonitored workers. Consider a few scenarios:

- The smallest weighted point estimate from Table 5 is approximately 75%. If the 25% of subCTWs from the sampling plan sample who were unmonitored constitute an insignificant fraction of the most highly-exposed workers in the entire population, a co-exposure model could still be constructed.

[3] Strictly speaking, overlapping confidence intervals do not always mean that there is not a significant difference, but with this much overlap, this is an appropriate conclusion.

- To take the scenario above a step further, if only 10% of the subCTWs in the sampling plan sample were monitored, but a significant fraction of the most highly-exposed workers from the entire population are monitored, a bounding co-exposure model could be made.
- At the extreme, if only the single most highly-exposed worker in the population was monitored (and his/her dose is known), this would result in a monitoring percentage estimate from the sample of at most 1/663. Even with a percentage that low, a bounding co-exposure model could be made by assigning the known dose to all the other workers.

In summary, as expected, changing the definition of monitored from "at least one required nuclide" to "all required nuclides" causes the monitoring percentage point estimates in Table 5 to decrease (confidence intervals show a decrease for direct but no difference for effective). Comparing monitoring percentage estimates to any subCTW threshold is inappropriate; a comparison (including uncertainties) with another group of workers would be more appropriate. While the definition of "monitored" affects the resulting summary statistics, those summary statistics from the sampling plan sample should be balanced with the consideration of the exposure potential of the population of unmonitored workers when considering whether it is feasible to create a co-exposure model.

SC&A concludes that NIOSH did not address all of the radionuclides listed (or assumed) on the RWPs when summarizing results. NIOSH agrees that they did not address all radionuclides but has updated those tallies in this response. NIOSH contends that their conclusion has not changed: a co-exposure model can still be constructed.

SC&A Conclusion 3: Generalized matching is not sufficient

> *Concerning co-exposure model datasets, SC&A found in a focused review of RPRT-0092 plutonium coworker matches during the 1991– 1998 WSRC period that, while nearly 96 percent of identified coworker matches involved the same RWP, inclusion of additional criteria (e.g., the same date, time, and craft) decreases this percentage significantly (down to 45 percent) (SC&A, 2019a, p. 66). Given the often nonroutine and intermittent nature of sCTW jobs under RWPs, sometimes involving unique radiological source terms, SC&A believes such matching needs to be more closely aligned with what is listed on the actual RWP. While the co-exposure implementation guide (NIOSH, 2020b) does not specify an objective measure for data completeness to support the representativeness of a co-exposure model, it does require a determination be made that "there are sufficient measurements to ensure that the data are either bounding or representative of the exposure potential for each job/exposure category at the facility" (NIOSH, 2015, p. 5). SC&A does not consider a generalized match of workers to RWP-specified, job-specific bioassays to satisfy the need to demonstrate that this data set is either bounding or representative of subcontractor exposure potential that should have been monitored by job-specific bioassay.* [SC&A 2022, PDF p. 43]

NIOSH Response to SC&A Conclusion 3

SC&A concludes that the coworker matching criteria should be more restrictive than was used in ORAUT-RPRT-0092. For example, the SC&A Focused Review states for plutonium, "while nearly 96 percent of identified coworker matches involved the same RWP, inclusion of additional criteria (e.g., the same date, time, and craft) decreased the percentage significantly (down to 45 percent[4])." In the final draft of the SRS Work Permit Sampling Plan, the matching criterion was only "co-worker on the same RWP" [ORAUT 2018, PDF p. 16]. At that point, there was no documented objection to the matching criterion [SC&A 2018]. While not documented in ORAUT-RPRT-0092, the criteria used for a coworker match was a subCTW on the same RWP, same date, and same time (within no more than 15 minutes). Additionally, a laborer could not be used as a coworker for another craft, even if all the other matching criteria were met [ORAUT 2019]. There are only two differences between what SC&A is suggesting (same RWP, date, time, and craft) and what was done in ORAUT-RPRT-0092 (same RWP, date, time within 15 minutes, and laborer exception): (1) 15 minutes of time and (2) the exact craft versus the laborer exception.

NIOSH believes that the criteria for coworker matching in ORAUT-RPRT-0092 were more restrictive than necessary and that the additional criteria suggested by SC&A are far too restrictive. SC&A is suggesting that a monitored coworker needed to be working right alongside the unmonitored worker for the match to count. This same misconception spawned a discussion during the December 5, 2019, SRS and SEC Issues Work Group Joint Meeting where it was suggested that coworker modeling be referred to as co-exposure modeling to clarify that these models are based on workers with similar exposure potential to the unmonitored worker, not necessarily their coworker who worked right alongside them [NIOSH 2019a, pp. 104–105]. This suggested change from coworker to co-exposure modeling was also discussed at the December 11, 2019, Advisory Board meeting [NIOSH 2019b, pp. 136–138]. While there was no formal adoption of the term, NIOSH, SC&A, and the Advisory Board have all consistently used the term co-exposure when referring to these models since December 2019.

As such, if a worker was unmonitored, the co-exposure model would be representative or bounding for that worker if the workers who were monitored had the same or higher exposure potential. There is no requirement that the monitored person work right alongside the unmonitored worker, or that the two workers be on the same RWP, same date, same time, and same craft (SC&A's suggestion). In fact, the sampling plan for ORAUT-RPRT-0092 focused only on subCTWs. If there was any worker monitored (subCTW, prime CTW, or nonCTW) with the same or higher exposure potential, the co-exposure model would be representative or bounding for that unmonitored worker.

In summary, coworkers used for effective monitoring matching need only have the same or higher exposure potential than the unmonitored worker. SC&A's criteria of same RWP, same

[4] Note that the SC&A Focused Review references (SC&A 2019a, p. 66) for the value of 45%. That value is actually found on page 60.

date, same time, and same craft are far too restrictive and do not need to be considered when creating a co-exposure model.

SC&A Conclusion 4: RWP-specified, job-specific bioassay data are incomplete

> *RWP-required, job-specific bioassay data should be assumed to be substantially incomplete for purposes of demonstrating monitoring data completeness and representativeness for use in a co-exposure model until the end of 1996 (a 100-percent resampling of all workers on job-specific bioassays was performed for 1997; enhanced accountability and tracking of job-specific bioassays were implemented in 1998). This is based on independent program audits that found that lapses in bioassay submission existed during the 1991–1996 timeframe, spanning from the initial 1990 Tiger Team findings about bioassay program noncompliance to the 1997–1998 WSRC actions in response to DOE field audits, internal FEB findings, and DOE headquarters enforcement action. This is consistent with SC&A's analysis in figures 4 and 5, where SC&A compared the noncompliance fraction (missed bioassay results) of directly bioassayed radionuclides (plutonium, uranium, americium, Sr/FPs neptunium), in terms of being greater or lower for the period 1991– 1994, as compared with 1995–1998, respectively. These comparisons are most evocative for uranium and americium, with bioassay noncompliance being significantly higher for the earlier period. The opposite is true for neptunium and Sr/FPs, but by only a small margin over fewer data points. As expected, plutonium is essentially the same for both periods, likely due to its outsized prevalence in SRS operations and by its prescribed, prescheduled monitoring*[.] [SC&A 2022, PDF p. 43]

NIOSH Response to SC&A Conclusion 4

SC&A concludes that regulatory issues related to job-specific sampling and noncompliance fractions indicate that RWP-specified job-specific data are incomplete. Nearly half of the summary of Conclusion 4 is a discussion of Figures 4 and 5 of the SC&A Focused Review. SC&A compares what they call a "noncompliance fraction" for 1991–1994 to the fraction for 1995–1998. As mentioned in the NIOSH responses to Conclusions 1 and 2, making any comparison for which the sampling plan was not designed should be done with great caution, if it is done at all. Uncertainties for what SC&A refers to as "noncompliance fraction" cannot be calculated. Nuclides were not considered in the sampling plan or its preceding inventory. Therefore, to use statements such as "significantly higher," "statistically significant," and "essentially the same" without confidence intervals or uncertainties is inappropriate. If the bars in Figures 4 and 5 of the SC&A Focused Review could have error bars, the "noncompliance fractions" in those sets of years may be indistinguishable. SC&A also mentions that there are "fewer data points" for neptunium and Sr/FPs. While that may be true, it would be helpful to include that information on the plots because the number of results by nuclide for the two time periods does not seem to be readily available in the SC&A Focused Review. When considering

percentages, proportions, or fractions, it is always good practice to also consider the total number of results from which those values come.

The other half of the summary 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 is an assessment of plutonium bioassay at Los Alamos National Laboratory, but it also contains generic co-exposure concepts in Sections 2 and 4 [ORAUT 2021, PDF pp. 11–14]. Section 4 of ORAUT-RPRT-0102 discusses regulatory compliance and co-exposure modeling. The conclusion from that section is that "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, PDF p. 14], which was echoed by Dr. Paul Ziemer at the April 15, 2021, meeting of the Advisory Board on Radiation and Worker Health [NIOSH 2021, PDF p. 91]. Therefore, the 1990 Tiger Team finding and the 1997–1998 Westinghouse Savannah River Company actions do not necessarily prevent co-exposure modeling for SRS. Section 2 of ORAUT-RPRT-0102 discusses the components of co-exposure models and concludes that "…a representative or bounding co-exposure model can be constructed unless a significant portion of the most highly exposed workers were not monitored or do not appear in the study sample" [ORAUT 2021, PDF p. 13]. This means that if a significant portion of the most highly-exposed workers appear in the SRS datasets, co-exposure models could be constructed.

The SRS 5Q1.1-506 manual seems to indicate that workers exposed to unknown conditions should be considered for job-specific sampling. This could lead one to incorrectly conclude that the most highly-exposed workers were monitored with job-specific sampling. SC&A quotes SRS 5Q1.1-506:

> ***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]

Section 5.1.2.1 of 5Q1.1-506 states:

> *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]

These two statements from 5Q1.1-506 seemingly imply that job-specific samples are non-routine (or special) samples. This implication contradicts a 2017 interview response given by Dr. Tom LaBone, a former site internal dosimetrist at SRS, stating that "Job-specific bioassay is a program prescribed in response to a specific event (the job) but is not a special bioassay" [ORAUT 2017, PDF pp. 10–11]. NIOSH conducted a follow-up interview in August 2022 to ask Dr. LaBone about this apparent contradiction [ORAUT 2022a]. In the August 2022 interview, Dr. LaBone acknowledges the confusion that may arise from the 5Q1.1-506 quotes above, but he maintains that job-specific samples were part of the routine program and were not special samples according to site practices, despite what the procedures say. In fact, regarding the 1997 Notice of Violation (NOV), he says:

> *Examining the correspondence associated with the 1997 NOV, it is clear that DOE initially considered job-specific samples to be special samples required by 10CFR835 – a reasonable conclusion based on written site procedures as we have already discussed. At the enforcement meeting we had an opportunity to present our case for job-specific samples not being special samples and hence not being required by 10CFR835. DOE agreed with our position as evidenced by the change of the violation from 10CFR835 (Health and Safety) to 10CFR820 (Procedures). In other words, in the final analysis DOE agreed that job-specific samples were not special samples.* [ORAUT 2022a, PDF p. 6]

Dr. LaBone also describes the program for special samples, samples that were collected when there were suspected intakes of radioactive material. At some point in 1991, field procedures were changed to require RadCon to call the internal dosimetrist for a suspected intake. This change in field procedures was corroborated by Dennis Hadlock, a current Radiation Protection Department Regulatory and Technical Advisor and former field health physicist [ORAUT 2022b]. According to Section 2 of ORAUT-RPRT-0102, a bounding co-exposure model could be constructed if a significant portion of the most highly-exposed workers are part of the dataset [ORAUT 2021, PDF p. 13]. Therefore, 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.

In April 2022, during an Advisory Board discussion on Sandia National Lab [NIOSH 2022, PDF pp. 67–70], SC&A presented an analysis where they looked at the DAC-hr logs and WebDose databases that "should contain all the most highly exposed workers" and compared those results to the data NIOSH had captured. Nearly 100 percent of the results from the most highly-exposed workers (in DAC-hr logs and WebDose) were in the NIOSH dataset, so the SC&A (and NIOSH) conclusion was that a bounding value could be justified, despite not having all of the monitoring data in the NIOSH dataset. Although this analysis and discussion pertains to an SEC evaluation where NIOSH was only trying to come up with a bounding value, this same concept can be applied when developing co-exposure models.

Because Dr. LaBone didn't provide more details of his prescription of special programs at SRS, a follow-up question was asked to give him an opportunity to explain more about those programs. That October 2022 follow-up response [ORAUT 2022c] states that the requests for special samples triggered by events at SRS were tracked in a computer program called Track, until that information began to be entered into ProRad. There is also a procedure that governed the incident response.

In summary, 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 the SC&A conclusion that "RWP-specified, job-specific bioassay data are incomplete."

SC&A Conclusion 5: Feasibility of co-exposure model needs to balance RWP implementation with completeness of coworker data

> *Given conclusion 4, it is also clear that sCTWs who were on RWPs and may not have been monitored likely worked alongside coworkers who were monitored according to the RWP requirements. If RWPs can be considered complete and adequate (because the concerns identified in conclusions 1 and 2 have been addressed) and implemented in an accountable manner with the requisite bioassays substantially performed (per conclusion 4), SC&A would consider NIOSH's conclusion valid that the RPRT-0092 sampling review demonstrates sufficient matches (direct and effective) in the 1991–1998 period to support development of a co-exposure model for sCTWs on job-specific bioassays who lacked internal monitoring data. While job-specific bioassays and source terms may be incomplete, given the programmatic shortfalls, this is mitigated by two considerations: (1) job-specific bioassays made up only 5 percent of total bioassays by 1997 and (2) a full resampling of job-specific bioassay results for the second quarter of 1997 found no evidence of intakes. Accordingly, a conclusion about the feasibility of a co-exposure model for workers lacking bioassay results for nonroutine work may be reached by balancing the programmatic limitations of the RWPs and job- specific bioassays with the availability of suitable coworker bioassay data (as given in RPRT-0092).* [SC&A 2022, PDF pp. 43–44]

NIOSH Response to SC&A Conclusion 5

NIOSH asked for clarification of SC&A Conclusion 5 in an e-mail exchange [NIOSH/SC&A 2022]. The NIOSH e-mail states "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...' " [PDF p. 3]. The SC&A e-mail response says that the NIOSH interpretation is correct, so a detailed response to SC&A's overall conclusion is not necessary.

CONCLUSION

NIOSH has addressed the five conclusions as outlined in Section 7 of the SC&A Focused Review and concludes:

1. The absence of bioassay requirements on RWPs in the early 1990s is irrelevant because bioassay programs were prescribed by procedure during that time.
2. Changing the definition of "monitored" has the expected effect, but the new summary statistics do not inhibit 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 NIOSH's co-exposure database, this is evidence that a co-exposure model could be constructed.
5. NIOSH has addressed the SC&A issues from the SC&A Focused Review and maintains that co-exposure models can be developed.

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