MEMORANDUM

TO: Savannah River Site Work Group
FROM: SC&A, Inc.
DATE: May 1, 2018
SUBJECT: Response to NIOSH's Review of SC&A's Evaluation of SRS Subcontractor Bioassay Data Completeness

Background

SC&A was originally tasked by the Advisory Board on Radiation and Worker Health (ABRWH or the Board) to conduct a broad review of bioassay data completeness for subcontractor construction trade workers (CTWs) at the Savannah River Site (SRS), resulting in its report, *Evaluation of Savannah River Site Subcontractor Bioassay Data Completeness* (SC&A 2017). This completeness review was undertaken in parallel with a National Institute for Occupational Safety and Health (NIOSH) effort to review the completeness of bioassay data for Building 773-A for the years 1981–1986. At the time, the Board was concerned that NIOSH's review would be too narrow (in terms of facility scope and timeframe) to resolve the issue of subcontractor CTW bioassay data completeness on a sitewide basis. (ABRWH 2016a, p. 49; 2016b, pp. 150–172). There were previous attempts by NIOSH to address this question (using NIOSH/OCAS Claims Tracking System [NOCTS] data and a database maintained by the Center for Construction Research and Training [CPWR], respectively), but they proved unsuccessful in the interim since this issue first surfaced in a 2013 interview with a senior SRS internal dosimetrist.

Establishing data adequacy and completeness is a prerequisite for developing and applying any coworker model, as is currently proposed by NIOSH for CTWs, including subcontractors. As has been emphasized in various meetings and forums, SC&A finds that the rapidly changing operational circumstances at SRS in the 1990s, with emphasis given to reactor restart, decontamination and decommissioning, waste management, and environmental cleanup, contributed to a rapid influx of subcontractor CTWs to augment onsite resources, leading to questions by SC&A and the Board about their bioassay monitoring. In particular, transient subcontractors may not have been bioassayed adequately in light of their often-intermittent work on site and the lack of a comprehensive termination bioassay program. This concern was underscored by SC&A's finding that the U.S. Department of Energy (DOE) had, in fact, cited and fined Westinghouse Savannah River Company (WSRC) in 1998 for not adequately monitoring workers performing radiation work under job-specific Radiological Work Permits (RWPs) (DOE 1998a).

This commentary is in response to NIOSH's review of SC&A's SRS subcontractor bioassay data completeness report, as contained in *Response to SC&A's Evaluation of Savannah River Site Subcontractor Bioassay Data Completeness, SC&A-TR-2017-SEC009-SC&A* (NIOSH 2018).

NIOSH Statement, Executive Summary

In its Executive Summary, NIOSH states that "*SC&A judged the SRS bioassay program as 'dysfunctional' and stated that the bioassay results available for subcontractor CTWs for the period 1989 through 1998 did not satisfy NIOSH criteria for coworker datasets*" (NIOSH 2018, p. 2). SC&A respectfully disagrees with this statement and finds it to be a mischaracterization of its conclusion.

Instead, the conclusion in our report clearly states (emphasis added):

> *While there has been some discussion of what would constitute reasonable "success" criteria for sampled completeness of subcontractor CTW bioassay records, these results and compliance history indicate a dysfunctional* ***job-specific*** *bioassay program at SRS whose results are manifestly incomplete for at least the period 1989–1998 and* ***should not be relied upon*** *for coworker model development.* [SC&A 2017, p. 7]

This is not mere parsing of terms. In its review and report, SC&A made no finding regarding the overall "SRS bioassay program"; its review focused exclusively on subcontractor CTWs in terms of bioassay data completeness, which was the scope of its tasking from the Board. In this context, SC&A's caution about use of job-specific bioassay data from this period follows from the substantial evidence of wide and persistent monitoring gaps that were found by WSRC in 1997, and confirmed by DOE in its Notice of Violation in 1998 (DOE 1998a). Clearly, the number of job-specific bioassays affected is much smaller than those of CTWs, in general, and a very small fraction of the overall SRS bioassay program, as illustrated in Table 1.

Table 1. SRS Job-Specific vs. Routine Urine Samples

Urine Bioassay	1996	1997	1998 (mid-July)
Routine actinide, received	8,062	9,053	4,864
Routine tritium, received	25,691	24,210	N/A (not available)
Job-specific actinide	N/A	1,500*	564

*approximate
Source: LaBone 1997.

Much of the ensuing discussion that has been led by NIOSH has been directed at whether this larger dataset can be applied in some fashion (e.g., through use of NOCTS CTW data for pre-1989 or CTW coworker models in the WSRC era) to represent this particular job-specific cohort. While SC&A has raised concerns about the representativeness of this broader site monitoring data to bound the dose of these often transient subcontractor CTWs on RWP job-specific

bioassay, the functionality or soundness of the SRS routine or the special bioassay program itself have never been questioned.

NIOSH Issue 1

> *Bioassay data should have been separated into tritium and non-tritium and appropriate time intervals used for evaluation.* [NIOSH 2018, p. 2]

In its original sampling plan, SC&A had proposed the 30- and 90-day survey interval as the best "indicator" of RWP compliance and bioassay records completeness, given the often-intermittent nature of subcontractor CTW work at SRS. As emphasized in SC&A's report, the inconsistent nature of RWPs and SRWPs at SRS, as well as the lack of explicit target radionuclides cited, made definitive surveying of follow-up bioassays difficult, if not impossible. Therefore, applying an approach using "indices" of bioassay compliance or responsiveness, SC&A's stated approach was as follows:

> *Once the CTW compilations were available in the SRDB, SC&A commenced its bioassay review process. This involved matching the prescribed RWP job date with any corresponding urinalyses of record, either within 30 days or 90 days, respectively. The basis for this consideration is to provide* ***indices*** *of bioassay compliance or responsiveness, with 30 and 90 days used as measures of responsiveness to an RWP end-of-job bioassay requirement. For tritium urinalyses, such responsiveness would be essential for adequate dose assessments; for plutonium or uranium urinalyses, this would be considerably less so. This is not to draw a broad program judgment of SRS dose assessment or technical adequacy, but to provide an overall* ***indicator*** *of both monitoring program compliance and record completeness.* [Emphasis added.] [SC&A 2017, p. 13]

While acknowledging NIOSH's later research and assessment that bioassays for longer-lived radionuclides (i.e., non-tritium) may be undercounted under this indexing protocol, SC&A noted that, given the intermittent nature of subcontractor CTW jobs, it remained important to review any "end-of-job" bioassays for these radionuclides, as well. If such bioassays were not performed, recognizing the inadequate implementation of termination bioassays at SRS at that time, these transient workers could leave the site without any bioassays. This is emphasized in SC&A's report, as well:

> *It is also understood that the 30- and 90-day bioassay criteria are* ***"indicators"*** *of RWP compliance and bioassay records completeness, and that* ***later bioassays*** *for potential exposure to longer-lived nuclides such as plutonium and neptunium would be relevant to dose assessment* ***but problematic for subcontractor CTWs, given the intermittent nature of their work on site and common lack of compliance with termination bioassays.*** [Emphasis added.] [SC&A 2017, p. 15]

Notwithstanding these explicit qualifiers in the 2017 report, SC&A agrees with the results of NIOSH's subsequent data capture and research on how the job-specific bioassay program was

implemented at SRS. It is now clear from this more recent review that routine plutonium and uranium bioassays were collected on a biannual and annual basis, as determined by WSRC procedure, and were the means to satisfy RWP job-specific end-of-job bioassay requirements for these longer-lived radionuclides. However, with the transient nature of subcontractor CTWs during the 1990s at SRS and the inadequate implementation of a termination bioassay program, it remains unclear how many subcontractor CTWs on RWP-prescribed job-specific bioassays for plutonium or other longer lived radionuclides may have left the site without sampling because their RWP was incomplete or they missed the routine 6- or 12-month cycle of monitoring, as well as any termination monitoring.

As pointed out by SC&A at both the August 2017 and December 2017 Advisory Board meetings, the WSRC completeness self-survey results of 1997 have become the dominant and overarching indicators of job-specific bioassay completeness for SRS during this timeframe. Two contemporary WSRC self-surveys in 1997 found 21% completeness in a 100% survey of all job-specific surveys and 33% completeness in a more limited sampling (for the former, a resampling found no positive intakes). Given the lack of complete RWPs for the 1989–1996 period, as well as the lack of Facility Evaluation Reports that could clarify what categories of workers were on job-specific bioassays, the 1997 self-surveys stand as the most credible measures of job-specific bioassay that exist at this point.[1] Therefore, the assessments performed by SC&A, using substantially incomplete RWP monitoring data, and by NIOSH, using data for one facility (773-A) for 1981–1986, while useful as indicators of completeness, are not sufficiently sound or representative to adequately characterize the SRS-wide exposures involved for 1972–1995, the completeness of job-specific bioassay compliance, or the actual CTW worker cohort involved with RWPs and SRWPs.

NIOSH Issue 2

> *Some SRWPs should have been excluded from analysis.* [NIOSH 2018, p. 2]

Upon further review, SC&A agrees that some standing radiation work permits (SRWPs) previously selected do contain provisions that would preclude entry of certain personnel (e.g., who are on tours or inspections) into controlled areas and therefore should have been excluded from the review. However, it is clear that this discrepancy has implications for only two of the 85 subcontractor workers surveyed who were sampled from the SRWP signup sheets at SRS for 1989–1995. It is also apparent that SRWP signup sheets were frequently not filled out correctly, using outdated forms without a bioassay designation block and not always specifying specific work locations for entry (Stafford 1998, PDF p. 75).

From additional research following the SC&A survey, further information was gleaned regarding the use of RWPs at SRS. As noted in WSRC's ESH-HPT-98-0453:

[1] NIOSH has since announced it has discovered 852 boxes of SRS RWP records at the Atlanta Federal Record Center, which it proposes to review in 2018. These records, if sufficiently complete for the years in question (1972–1996), could provide a means to adequately sample for the completeness of subcontractor CTW records.

> *An RWP is an authorization document that identifies radiological conditions, establishes requirements to perform the work identified on the permit, and contains approvals for the specified radiological work activities. Thus the RWP serves two major functions: (1) an administrative process for planning and controlling radiological work and (2) a source of information for the worker regarding the radiological conditions in which he/she will be working. There are two types of RWPs – standing and job-specific.* ***The standing RWP is used to authorize work that is of a repetitive and routine nature.*** *The job-specific RWP is written specifically for a certain task of limited duration. The RWP prescribes protective measures such as the use of protective clothing, respiratory protection, and RWP suspension limits for expected conditions to ensure a worker's radiological safety, including the prevention of intakes.* [Emphasis added.] [WSRC 1998, p. 1]

Under this definition of when to use an SRWP ("work that is of a repetitive and routine nature"), SRWPs would not have been included in the SC&A survey, in retrospect.[2] Notwithstanding the apparent routine nature of the work, the SRWPs typically employed signup sheets where workers would be assigned to specific radiological jobs in an SRS facility (e.g., K Reactor or 321-M) over an extended period of time. Of the 85 subcontractors sampled from SRWPs, all but five had follow-on bioassays within either 30 or 90 days of the SRWP job date cited. For the five that did not, three were missing any evidence of an SRS dosimetry record (external and internal). The remaining two had an SRWP (K-89S-001), for which a bioassay requirement was lacking. They had no evidence of a follow-on bioassay within 30 or 90 days of the job date listed. For the 80 subcontractors who had follow-on bioassays, most had SWRPs that explicitly required bioassays, while 23 workers under SRWP K-89S-001 did not. SC&A believes this disparity—some SRWPs having no provision provided for required bioassays, but workers showing routine bioassays for tritium, nonetheless—can be explained by inconsistent implementation of SRWPs at SRS in the 1990s, as explained below.

WSRC performed a self-assessment of the SRWP bioassay program in 1998, as part of a root cause analysis regarding WSRC's issuance Corrective Action Report 97-CAR-07-0001, "*WSRC Radiological Control Program does not adequately ensure that workers not covered by the routine bioassay program provide the required job-specific bioassay samples*" (Kornacki et al., 1998, PDF p. 14). That self-assessment surveyed SWRP bioassay sampling requirements from all applicable SRS radiological facilities. That review found the following, in part, from various SRS facilities ("Consolidated Deficiencies"):

- *Not all radiological facilities are using the most current approved version of electronic form OSR 4-639 which contains a Bioassay Requirements*

[2] In its original assessment design, SC&A "*performed sampling using SRS Radiation Work Permits (RWPs) for individual subcontractor CTWs as a means to ascertain whether corresponding job-specific bioassay results could be found in the SRS bioassay records (either hardcopy, microfiche, or electronic)*" (SC&A 2017, p. 6). While SRWPs were included at the time (due to the overall lack of RWPs), it is now understood that they constituted more "routine" and "repetitive" radiological jobs versus certain tasks of a more unique nature.

block. Additionally, not all facilities are utilizing the Bioassay Requirements block to indicate bioassay sampling requirements.

….

- *There is no consistency amongst facilities when indicating bioassay sampling related information in the special precautions section of the SRWP….*

- *Some facilities require bioassay sampling only when respiratory protection is worn and others require bioassay sampling when there is no requirement for respiratory protection…. It was determined during previous document reviews of SRWP sign-ins that it is impossible to identify which workers should have left a bioassay sample and which did not have to in these cases because it is not apparent who wore a mask....*

- *Some SWRPs cover entry into different facilities with different bioassay sample requirements. It is not possible to determine by document review whether a worker has met the bioassay sampling requirement since there is no indication on the sign-in sheet as to which facility was entered….*

- *Some facilities are not performing airborne radioactivity monitoring or setting suspension limits for radionuclides identified as requiring bioassay sampling.* [Stafford 1998, PDF p. 88]

From the above findings, it would not necessarily be possible to identify whether specific workers on SWRPs entered a particular facility or area based on SRWP documentation, and whether they met the appropriate bioassay sampling requirement. SC&A emphasized the incompleteness and inconsistent implementation of RWPs and SRWPs at an early stage of review in *Evaluation of Savannah River Site Subcontractor Bioassay Data Completeness*:

> *There was a wide difference between the various permits in terms of the degree of job requirements detailed, numbers of workers assigned, and whether bioassay was required. For some RWP forms, bioassay was required upon "end of shift," while others required bioassay without specifying timing, and still others did not provide for such specification explicitly. In the last case, it has become clear from corrective actions required in the aftermath of a DOE Notice of Violation (NOV)…that RWP forms at SRS did not uniformly include a bioassay sample program checkoff despite such job-specific monitoring being required, and conducted both by procedure and practice.* [SC&A 2017, p. 11]

SC&A concludes that while two of the 85 subcontractors sampled from SWRP signup sheets were affected by the provision cited in the example SWRP, K-89S-001, this would not have influenced the final results in a significant manner. The issue is also overwhelmed by the overall inconsistent implementation of the RWP and SWRP program itself, as documented above, and

by the later results of contemporaneous self-surveys of job-specific bioassay compliance conducted by WSRC.

NIOSH Issue 3

> *The Notice of Violation applied only to RWP job-specific bioassay samples which were not required by regulation and were only one part of an overall worker protection program.* [NIOSH 2018, p. 3]

First, it is not clear why NIOSH continues to question the regulatory basis of the NOV or its implications regarding the effectiveness of the SRS bioassay program. The strength of the SRS bioassay program is neither in question nor relevant to the issue of an identified potential gap in monitoring data (job-specific bioassays for RWP/SRWP work in 1989–1996). The apparent lack of job-specific bioassays at SRS for those years is also not in question: Despite extensive data captures since the issuance of SC&A's July 2017 report, job-specific bioassays for those years have not yet been identified other than the 1997 resampling bioassays performed by WSRC following the initial NOV. In SC&A's judgment, the real and only concern is, as emphasized in its July 2017 recommendation to the Work Group, "*whether NIOSH has any available monitoring data or bounding approach that could ameliorate this fundamental data gap*" (SC&A 2017, p. 22).

Apart from this overarching consideration, SC&A continues to have objections to NIOSH's characterizations of the NOV and its implications for the adequacy and completeness of the SRS job-specific bioassay program. NIOSH, in its discussion, appears to dispute that the NOV is evidence of "*a chronic history of wide noncompliance with job-specific bioassay requirements*" (SC&A 2017, p. 6).[3] The data cited by NIOSH as a basis for questioning this conclusion notes "*a participation rate for all bioassay samples of greater than 96%*" and that "*all workers who did not provide samples in 1997 were sampled in 1998 with no identified uptakes*" (NIOSH 2018, p. 3). However, whether the overall bioassay program had a high participation rate, or whether a resampling of those subcontractors who did not participate in their RWP-required bioassay programs in 1997 showed no intakes, are not relevant to the question of whether the job-specific bioassay program was compliant or complete over time at SRS. That question was settled by WSRC and DOE in 1997 and 1998, when DOE affirmed in the 1998 NOV that "[WSRC] *workers and their management routinely failed, over a period of approximately* ***two years****, to ensure that job-specific bioassay samples were submitted for analysis as required by WSRC internal procedures*" (emphasis added) (DOE 1998a, PDF p. 8). That NOV also emphasized that "*these violations are* ***not isolated instances*** *and reflect* ***multiple failures across several organizations over several years****, in addition to inadequate management attention to a*

[3] In its August 23–24, 2017, Board presentation, November 14, 2017, Work Group presentation, and December 13–14, 2017, Board presentation, NIOSH has stressed that the NOV is not relevant to the issue of an adequate coworker model for subcontractor CTWs (e.g., it was characterized by NIOSH as a "distraction" during the August 16, 2017, Work Group call). NIOSH's reasons for this position include that (1) the NOV did not cite 10 CFR Part 835 in terms of the adequacy of radiological monitoring, (2) it is based only on the assessed period of November 1995 to July 1997, and (3) it addressed just the job-specific component of radiological surveillance. NIOSH also characterized the overall SRS radiological control program as representing "defense-in-depth," with a "no intake policy" and no plutonium workers "likely" to receive an intake of 100 mrem committed effective dose equivalent or more.

continuing trend of failure *to adhere to WSRC requirements for the bioassay program as identified in the radiological work control program*" (emphasis added) (DOE 1998a, PDF p. 9). SC&A's conclusion regarding a chronic pattern of wide noncompliance (i.e., 67% and 79%) with job-specific bioassay requirements is no different from that reached by DOE in its enforcement action.

NIOSH's response likewise raises the issue of 10 CFR Part 835 versus 10 CFR Part 820 as the basis for the 1998 NOV. SC&A has not raised this as an issue nor questions the distinction between how DOE chose to exercise its regulatory basis for enforcement at SRS. However, while SC&A understands that the potential for radiation exposure in the SRS routine bioassay program may have been unlikely to exceed 100 millirem in a year, the potential exists to miss a substantial internal dose due to nonparticipation in RWP-required job-specific bioassay programs. This case was pointedly made by DOE in rejecting a WSRC argument similar to that made by NIOSH about the otherwise soundness of its routine bioassay program, particularly the low potential for intakes:

> *DOE is aware that, for all radionuclides other than* [a specific material]*, the WSRC internal dosimetry program does not knowingly permit any worker to be exposed to airborne radioactive material. Further, it is noted that WSRC has implemented a rigorous program for the comprehensive use of field indicators during work activities to signal that an unexpected radiological condition may have led to potential occupation intakes of radioactive material by a worker* [i.e., necessitating "special" bioassays]. ***Nonetheless, DOE also appreciates that the potential exists to overlook worker exposures to radioactive material due to unrecognized field conditions or other types of personnel error. For example, at*** **[a facility]** ***in 1996, one worker received an unsuspected intake of*** **[radioactive material]** ***that resulted in an organ dose in excess of*** **[a specified amount],** ***a dose that far exceeded DOE's regulatory limit of 50,000 millirem. The dose to this worker was not identified by the WSRC field indicator program but was identified through the bioassay program.*** [Emphasis added.] [DOE 1998a, PDF p. 9]

The issue is not what was required by 10 CFR Part 835, but <u>whether</u> and <u>how</u> the missing bioassay doses, whether actual (1995–1996) or postulated (1972–1995), can be characterized and bound such that a valid coworker dose can be estimated. It should be emphasized that the above DOE finding was reached following an enforcement conference between DOE and WSRC where the exact argument was made by WSRC, to no avail, that the workers on job-specific bioassays "*were not considered part of the work force likely to receive more than 100 mrem total effective dose equivalent annually*" (DOE 1998b, p. 7).

Finally, SC&A respectfully disputes NIOSH's statement that SC&A has concluded that "*this NOV would prohibit dose reconstruction of subcontractor construction trades workers*" (NIOSH 2018, p. 23). As noted repeatedly in presentations before the Board and to NIOSH, SC&A never made that statement. What SC&A has concluded and recommended, is as follows:

> *SC&A concludes that the bioassay dataset for CTW subcontractors, specifically, and CTWs, generally, is demonstrably incomplete for 1989–1998 (and likely before that time period) and does not satisfy the criteria set forth in NIOSH's* Draft Criteria for the Evaluation and Use of Coworker Datasets *(NIOSH 2015).* ***SC&A recommends that the Work Group discuss the implications of these findings with NIOSH and determine whether NIOSH has any available monitoring data or bounding approach that could ameliorate this fundamental data gap.*** [Emphasis added.] [SC&A 2017, p. 22]

Neither this conclusion and recommendation nor our statements before the Board assert that dose reconstruction would somehow be "prohibited" by the monitoring gaps cited in the NOV. However, as with any monitoring and record gaps identified under the Energy Employees Occupational Illness Compensation Program Act, there is a need to conduct additional research to augment available data, review the validity of existing coworker models, and to investigate options for bridging the identified data gaps (e.g., determining bounding dose values based on exposure potential for representative work activities). All of this has been underway and is advancing to a new phase of reviewing the 852 newly found boxes of RWP records at the Atlanta Federal Records Center.

NIOSH Conclusion

> *NIOSH agrees with SC&A that some workers did not provide job-specific bioassay samples but does not agree with their conclusion that the existing bioassay data do not meet the NIOSH requirements for coworker analysis.* [NOISH 2018, p. 3]

While NIOSH and SC&A apparently agree that a gap exists in job-specific bioassays, it should be clarified that "some" should not be taken as a "few" workers. Workers on RWP- and SRWP-required job-specific bioassays in the 1989–1998 timeframe represent a cohort numbering at least in the hundreds, if not thousands of total workers during that time period.

As noted in SC&A's 2017 report:

> *With almost 80% of bioassays not submitted by the operating contractor's own assessment, it is not feasible to know what exposure potential existed and internal dose resulted for CTWs performing specific radiological jobs at SRS before effective corrective actions were compelled in 1998 by enforcement action. As these were job-specific and RWP-prescribed, these jobs would have involved a potential for potential intake of tritium, plutonium, uranium, neptunium, mixed FPs, and other significant SRS source terms. While an argument can be made that the longer-lived radionuclides would have been detected in later* in vivo *or* in vitro *bioassays, this does not consider that, for CTWs, their intermittent work at the site may have precluded such later assessments.* [SC&A 2017, p. 22]

While the 256 CTWs lacking job-specific bioassays in 1997 were resampled and found to have no positive intakes, no earlier CTWs in the same circumstances were resampled for prior years

despite evidence of persistent nonparticipation as far back as 1995 (and likely before). Therefore, more than "some" CTWs are implicated before 1997 in terms of potentially lacking job-specific bioassays. Essentially, a whole cohort of workers numbering, at least, in the hundreds per year (i.e., those performing work prescribed by RWPs or SWPs, necessitating job-specific bioassays) have not been adequately characterized in terms of worker identity, nature of work, exposure potential, and bioassay completeness.

To satisfy NIOSH's requirements for coworker analysis, it would seem imperative to demonstrate that sufficient information exists to address these factors and to demonstrate that available monitoring data (e.g., for CTWs, overall) can be used to bound the internal doses for this particular cohort. One option that has been proposed by NIOSH since the SC&A report was issued would use NOCTS data for subcontractor CTWs prior to 1989. The issue for that option is whether the NOCTS dose distribution for CTWs is representative of subcontractor CTWs, many of whom are transient workers under RWP job-specific bioassays. While this and other proposals have been made, sufficient questions remain about representativeness and stratification of coworker CTWs to seemingly preclude a conclusion about feasibility of a coworker model at this point.

NIOSH most recently has discovered 852 boxes of RWPs for SRS that encompass the years of interest (1972–1996). Given the paucity of RWPs identified for SRS to date, these records offer a means to conduct sampling for bioassay completeness and to characterize the subcontractor CTW cohort for the years in question. The context for all these inquiries is to address a clear monitoring data gap for those workers (particularly transient subcontractor CTWs) on job-specific bioassays. Once data adequacy and completeness are demonstrated, coworker model development can proceed on a sound basis consistent with established guidelines.

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