

 **Memorandum**

To: SEC Issues Work Group, Savannah River Site Work Group
From: SC&A, Inc.
Date: July 29, 2021
Subject: Application of NOCTS Data 2021

1.0 Introduction and Purpose

Some members of the Savannah River Site (SRS) and Special Exposure Cohort (SEC) Issues work groups have recently expressed interest in the representativeness of data from the National Institute for Occupational Safety and Health (NIOSH) DCAS Claims Tracking System (NOCTS) for use in co-exposure models. This concern was most recently broached during discussions by these work groups about ORAUT-RPRT-0094, “Bioassay for Subcontractor Construction Trade Workers at the Savannah River Site from 1972 to 1997” (NIOSH, 2019b), and the recent “bootstrap” pilot analysis for SRS (NIOSH, 2021a, 2021b) that exemplify NIOSH’s continued interest in making more use of its NOCTS dataset. With the lengthy history of this issue, it is best to provide a brief chronology and summary of what SC&A believes are the key considerations; this memorandum is that summary, tasked in May 2021.

2.0 SC&A Summary of Reports and Past Advisory Board Discussions of NOCTS Dataset Applications

SC&A believes that three main NIOSH documents are most germane to this discussion: ORAUT-OTIB-0075 (OTIB-0075), ORAUT-OTIB-0081 (OTIB-0081), and ORAUT-RPRT-0094 (RPRT-0094), discussed in sections 2.1, 2.2, and 2.3 of this memorandum, respectively. Section 2.4 describes key discussion points raised during work group deliberations concerning the use of NOCTS as a substitute for obtaining and evaluating the full worker population.

2.1 ORAUT-OTIB-0075, “Use of Claimant Datasets for Coworker Modeling”

In SC&A’s opinion, the first substantive treatment of the subject was NIOSH’s report, ORAUT-OTIB-0075, “Use of Claimant Datasets for Coworker Modeling.” NIOSH issued revision 00 on May 25, 2009 (NIOSH, 2009), and revision 01 on June 17, 2016 (NIOSH, 2016). It presented “the results of a study of Y-12 Plant worker and claimant data to determine the feasibility of using claimant data in place of complete coworker data for reconstruction of doses at sites that do not have complete coworker data [in an electronic database]” (NIOSH, 2009, p. 2). This report also included Mound and SRS datasets as a supportive basis for using NOCTS monitoring records in sitewide co-exposure development.

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SC&A reviewed revision 00 of OTIB-0075 and provided comments in a January 13, 2010, white paper (SC&A, 2010). SC&A's overall conclusions were divided into two issues:

1. whether the hypothesis that NOCTS data are representative of all worker data can be proven
2. whether the claimant database as compiled from NOCTS provides a satisfactory basis for a co-exposure model for construction trade workers (CTWs) at SRS such that it would meet the requirements of dose reconstruction with sufficient accuracy

For OTIB-0075 issue 1, it is important to note that "representative" in the context of OTIB-0075 simply refers to whether the derived distribution and parameter estimates for the two groups (NOCTS and all worker) are statistically similar. "Representative" in the OTIB-0075 context does *not* refer to the extent to which diverse worker types, monitoring protocols, and associated exposure potential (i.e., strata) are appropriately captured in the NOCTS dataset.

On the first issue, SC&A found the following:

1. The uranium dataset for the Y-12 National Security Complex (Y-12) conforms to the OTIB-0075 hypothesis of claimant data representativeness.
2. The data for Mound indicate significant differences between claimant and all-worker plutonium bioassay data.¹
3. The SRS tritium data cover a very narrow period from 1990 to 2001. These data show no significant differences at the annual level of aggregation, but the sample size is very small, and the regression results were dominated by a single year with high exposure, 1991.

In summary, SC&A (2010) found in its review of OTIB-0075 that it appears NOCTS can be considered statistically similar at the aggregate level to the full worker population in these specific instances, but only for uranium urinalysis at Y-12 (1950–1988), plutonium urinalysis at Mound, and tritium dose at SRS (1991–2000).

Specific to SRS, SC&A's (2010) review of OTIB-0075, revision 00, found that a conclusion that the SRS claimant data from the 1990s for tritium are representative of the overall claimant population can, at best, be applied to that radionuclide and that period, but that conclusion cannot be back-extrapolated to other periods. Even within the period in question, there are differences between construction workers disaggregated by craft and non-construction workers. SC&A also found that there are considerable differences in exposures between job types and areas, and the data indicate that construction workers in some areas and periods had greater exposure potential than all non-construction workers.

¹ This issue was addressed in a subsequent revision of OTIB-0075 with the evaluation of additional claimant data coded by NIOSH, as discussed later in this section.

In 2017, SC&A performed a focused review of revision 01 of OTIB-0075 to address the extent to which the revision addressed these concerns (SC&A, 2017). However, the primary revisions to OTIB-0075 were the incorporation of the time-weighted, one-person one-sample method for evaluating bioassay data and an updated lists of claimants and claimant data that expanded the available dataset for statistical analysis. Notably, the expansion of the Mound plutonium data in revision 01 addressed SC&A's concerns about observed differences between the claimant and all-worker populations for plutonium (SC&A, 2017). However, SC&A found that revision 01 of OTIB-0075 did little to address SC&A's main concerns about adequate and complete representation of exposures among the claimant population when compared to the full worker population.

2.2 ORAUT-OTIB-0081, "Internal Dosimetry Co-exposure Data for the Savannah River Site"

On February 8, 2013, NIOSH issued ORAUT-OTIB-0081, revision 00, which has since been revised a number of times up to revision 05, issued on September 1, 2020 (NIOSH, 2020a). Bioassay data in the NOCTS dataset for SRS employees were used to develop what was intended to be a representative database of co-exposure bioassay data using the guidance of OTIB-0075, revision 01 (NIOSH, 2016), supplemented by original data from laboratory logbooks (i.e., non-claimant data) for the trivalent actinides, thorium, and neptunium. The additional laboratory logbook data were compiled due to inadequate data for those radionuclides in the claimant population. For the period before availability of the Health Protection Radiation Exposure Database data (before 1991) at SRS, NOCTS data were used in lieu of capturing and coding the full site dataset for a number of the remaining pertinent radionuclides (e.g., plutonium, uranium, fission products, tritium). While the NOCTS compilation is not a complete set of SRS worker data, OTIB-0081 (i.e., the SRS co-exposure model) notes that NOCTS was "the best available compilation of data in a usable form (i.e., electronic spreadsheet or database)" (NIOSH, 2020a, p. 28).

From its analysis for the three evaluated cases in OTIB-0075, NIOSH concluded that claimant datasets can be considered to be random samples of the complete site dataset and that this justifies applying this assumption to other sites and datasets. Thus, NIOSH assumed the NOCTS data to be close enough to a random sampling that they can be considered representative of co-exposure bioassay data for the full SRS site based on the example analyses in OTIB-0075. In its review of OTIB-0081, revision 04, SC&A (2019) describes several open findings related to OTIB-0075 in the focused context of the co-exposure model. Specifically, SC&A (2019, p. 75) notes:

Issues associated with the representativeness of claimant datasets to the sitewide worker population is beyond the scope of this report and thus should be addressed separately.

2.3 ORAUT-RPRT-0094, "Bioassay for Subcontractor Trade Workers at the Savannah River Site"

ORAUT-RPRT-0094, revision 00, was issued on September 13, 2019 (NIOSH, 2019b). This report provides estimates of the numbers and fractions of subcontractor construction trade workers (subCTWs) identified in NOCTS who were monitored by SRS for external and internal exposure during 1972 through 1997. These estimates were established from the number of claims

in the NOCTS database in which one or more position descriptions met the definition of a CTW and then through a manual review of SRS dosimetry documents in which those claimants had records of external monitoring, whole-body counts, and urine bioassay results within each year.

SC&A's March 8, 2021, review of RPRT-0094 (SC&A, 2021) found that while a considerable amount of NOCTS data cover the timeframe and facilities in question, the RPRT-0094 analysis suffers from two basic flaws:

1. It homogenizes all forms of SRS internal monitoring data into a single metric for application, which precludes a definitive treatment of data completeness for specific radionuclide source terms.
2. More fundamentally, it does not substantiate the actual representativeness of the claimant data sample collected as compared to that of the overall site worker population.

At the subsequent March 23, 2021, meeting of the joint SRS and SEC Issues work groups, NIOSH presented a subset of the NOCTS internal monitoring dataset that focused specifically on plutonium bioassay data. NIOSH found for plutonium that for 1990–1998, a high percentage of subCTWs (>75 percent) in NOCTS were monitored and would be sufficiently represented in a co-exposure model. For 1980–1989, a moderate percentage (>50 percent) of subCTWs in NOCTS were monitored. For 1972–1979, initially a moderate percentage of subCTWs were monitored for internal exposures, with a marked decrease into the late 1970s followed by a surge of monitoring starting in 1980 (NIOSH, 2021c). NIOSH's overall conclusion was that the trend observed in these data is that the subCTWs who were monitored were represented as well as other SRS workers and that the completeness of the data is more than adequate for dose reconstruction and for the basis of the SRS co-exposure model (NIOSH, 2021c).

SC&A's view is that data representativeness in this context is different from whether subcontractors are "represented" as well as other worker categories. In SC&A's view, data representativeness is more aligned with how "representativeness" is defined in the co-exposure guideline, DCAS-IG-006, revision 00, "Criteria for the Evaluation and Use of Co-Exposure Datasets" (NIOSH, 2020c; IG-006). Specifically, IG-006 states that a given co-exposure model should "be established from monitored workers with comparable activities and relationships to the radiation environment. . . . [and] ensure that it is either **representative of the distribution of exposures for the intended population** or that it provides a plausible upper bound for those workers" (emphasis added) (NIOSH, 2020c, pp. 4–5).

2.4 Summary of prior work group discussion points

SRS and SEC work group discussions about application of the NOCTS dataset focused primarily on the three previously discussed NIOSH reports. The following list summarizes pertinent comments by NIOSH, SC&A, and the work group members:

- SC&A commented that notwithstanding the high percentage of monitored subcontractors reported for NOCTS, the key question is "monitored for what?" Were they monitored for the correct radionuclide based on the job-specific work to which they were assigned? SC&A pointed out that the original intent of ORAUT-RPRT-0092 (NIOSH, 2019a) was to determine if subcontractors were monitored similar to other SRS workers and not

simply whether they had any bioassay (ABRWH, 2020, p. 98). NIOSH acknowledged that coworker comparisons in relation to the work environment are not feasible with the NOCTS dataset and “therefore the data completeness really must be inferred” (ABRWH, 2019, p. 216).

- Work group members questioned the representativeness of the NOCTS dataset, as compared with the general site worker population, given that it consists of claimants who have some compensable form of cancer under the Energy Employees Occupational Illness Compensation Program Act. NIOSH responded that “these are the people with cancer and so they are the ones who might have been harmed from that standpoint, therefore did they have any exposure and do they have monitoring data?” (ABRWH, 2019, p. 219). However, work group members noted that they were unaware of any literature that linked people who had contracted cancer as being representative of larger populations and that “the criteria” (i.e., IG-006) prescribes representation from the workforce rather than a subsegment of the workforce (ABRWH, 2019, pp. 219–220). Similar brief discussions of the joint SRS and SEC Issues work groups concerning the assumed exposure potential of the claimant population versus the full site population occurred during the March 2021 teleconference (ABRWH, 2021a, pp. 29, 91–93) and continued during the full Advisory Board on Radiation and Worker Health (ABRWH, Board) meeting in April 2021 (ABRWH, 2021b, pp. 57, 65, 86–89). However, the issue was not resolved during those discussions.
- For NOCTS as a measure of completeness, NIOSH cites the high percentage of subcontractors with internal monitoring data for SRS in NOCTS (e.g., 89 percent with any form of internal monitoring in 1990 (NIOSH, 2020b, p. 44)) but, at the same time, acknowledges that:

There is a potential detriment. We can't directly compare coworkers, therefore the data completeness really must be inferred . . . We can look at subcontractors, but we can't look at this subcontractor, were they paired with another subcontractor on the RWP. We can't do that. [ABRWH, 2019, p. 216]

SC&A commented that while a NOCTS-based approach does offer some advantages in its simplicity, timeliness, and resource efficiency, SC&A continues to conclude that it does not meet the intent of IG-006 that data completeness be determined from sufficient measurements “established from monitored workers with comparable activities and relationships to the radiation environment” (NIOSH, 2020c, p. 4).

- SC&A notes that the co-exposure guideline (IG-006) provides for use of claimant information as a “useful starting point . . . to look at the distribution of samples among the various categories of workers represented in the claimant population at the site,” with the illustrative example in that guidance being workers monitored for plutonium-239 at the Nevada Test Site (NIOSH, 2020c, p. 6). However, SC&A believes the actual intent of this example is to have NOCTS as a backup means to validate or check whether the “right people [worker categories] were monitored” (ABRWH, 2014, p. 26), not as

guidance for wholesale substitution of NOCTS data for pertinent site-specific information and datasets to support co-exposure models.

- SC&A further notes that although IG-006 does discuss the use of claimant data as a potential source to verify the completeness of electronic datasets intended to reflect the full monitored site population, it does not indicate these comparative analyses would provide adequate basis for substitution of the claimant data in lieu of obtaining and using the monitoring records for the full site population. The specific language used in IG-006 is as follows: “if electronic records or summary databases are used to develop the co-exposure model, these should be reviewed against a representative sampling of original data where possible to verify that they contain a complete and unbiased listing of all the data collected at the site” (NIOSH, 2020c, p. 8). As such, IG-006 recommends using NOCTS to validate available site-specific data, not to replace site-specific data.

The issue of applying NOCTS bioassay data came up in other work group discussions, but the preceding list represents key points relevant to the question of broader application of NOCTS bioassay datasets to support co-exposure models where readily available site-specific electronic dosimetry records are unavailable or incomplete (i.e., the electronic records do not contain all of the available monitoring results).

3.0 Overall Status and Conclusions

From the assessments and proceedings discussed in the previous three sections, SC&A concludes that NOCTS does have utility as supplementary evidence of who was monitored, as well as a means to validate site-specific electronic databases intended to represent the full monitored population. However, SC&A did not find sufficient past evidence that NOCTS has been approved by the Board to be applied as a wholesale substitution of the full monitored worker population at a site without evidence of its representativeness in relation to those workers. If a particular site can be shown to have sufficiently complete electronic datasets, the NOCTS dataset for that site can be compared with site data to validate its representativeness, therefore permitting its sitewide use for the time periods and facilities covered (as was done for uranium at Y-12 in OTIB-0075).

Conversely, if site monitoring practices or recordkeeping can be shown to have potential gaps, the corresponding completeness and/or representativeness of the available data in any form (whether hardcopy, NOCTS, or electronic datasets) would be questionable. The ultimate question is whether one can balance the available weight of evidence of a site’s monitoring adequacy and data completeness with the availability and representativeness of NOCTS data to arrive at a judgment supporting its application under IG-006 guidelines. Fundamentally, such an assessment cannot be performed in isolation of the historical monitoring program conducted at the site; it is not enough to infer data completeness by a review of NOCTS alone.

SC&A recommends that further evaluation of NOCTS and its merits as a basis for broader site application in developing co-exposure models is not warranted until the Board resolves the fundamental policy question of whether a universal programmatic assumption concerning representativeness of the claimant population can ever be sufficiently validated across all sites of intended application.

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