Draft

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

National Institute for Occupational Safety and Health

FOCUSED REVIEW ON THE CONCURRENCE OF ORAUT-OTIB-0081, REVISION 03, AND THE DRAFT COWORKER IMPLEMENTATION CRITERIA

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ABBREVIATIONS AND ACRONYMS

ABRWH	Advisory Board on Radiation and Worker Health
Am	americium
Cf	californium
Cm	curium
CTW	Construction Trade Worker
dpm	disintegrations per minute
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
GSD	geometric standard deviation
HPRED	Health Physics Radiological Exposure Database
IREP	Interactive RadioEpidemiological Program
MDA	minimum detectable activity
µCi	microcurie
NIOSH	National Institute for Occupational Safety and Health
NOCTS	NIOSH OCAS Claims Tracking System
OCAS	Office of Compensation Analysis and Support
ORAUT	Oak Ridge Associated Universities Team
QA	quality assurance
SRDB	Site Research Database
SRS	Savannah River Site
Th	thorium
TWOPOS	time-weighted one person-one sample
WSRC	Westinghouse Savannah River Company

1.0 INTRODUCTION AND BACKGROUND

On November 22, 2016, Revision 03 to ORAUT-OTIB-0081, *Internal Coworker Dosimetry Data for the Savannah River Site* (NIOSH 2016a), was put into effect. The report describes the revised coworker models for trivalent actinides (americium/curium/californium [Am/Cm/Cf]), tritium, and thorium at the Savannah River Site (SRS).[1] The purpose of the coworker revisions was to implement, on a trial basis, the principles and instructions for building coworker models as detailed in the National Institute for Occupational Safety and Health (NIOSH) report, *Draft Criteria for the Evaluation and Use of Coworker Datasets Revision 04* (Neton 2015), which is also known simply as “the implementation guide.”

The implementation guide provides generic program-wide criteria that must be satisfied for a proposed coworker model to be deemed acceptable for use in assigning unmonitored doses to claimants. The Advisory Board on Radiation and Worker Health (ABRWH) accepted the criteria laid out in the implementation guide, on a trial basis, until such time that it could be tested in the context of an actual site-specific coworker model. NIOSH was then tasked with employing the criteria in Neton 2015 to select coworker models at SRS. NIOSH 2016a was produced to demonstrate the use of the implementation guide for developing coworker models for three categories of radionuclides: trivalent actinides (Am/Cm/Cf), tritium, and thorium.

The implementation guide itself can be divided into four main criteria requirements:

1. Adequacy of the Coworker Data
2. Completeness of the Coworker Data
3. Characterization of the Site- and Radionuclide-Specific Monitoring Program
4. Coworker Model Stratification

This report presents SC&A’s focused review of the three revised coworker models in the context of the application of the instructions and criteria in the implementation guide. Due to considerable overlap when examining the three separate coworker models as it relates to Neton 2015, this report is organized by the four main criterial requirements. However, specific and unique aspects of the individual coworker models are also discussed as appropriate in the individual sections. Section 6 provides additional comments that are not directly related to the coworker implementation guide.

Based on its review, SC&A has identified six findings and seven observations as follows.

Finding 1: The analysis of the completeness of trivalent logbook records provided in NIOSH 2016a ends in 1981, though the proposed coworker analysis of trivalent bioassay extends through 1989. It would be beneficial to extend the completeness analysis to all years in which trivalent urinalysis data is being proposed for coworker evaluation. This is particularly important

[1] As noted in NIOSH 2016a, coworker models for plutonium, uranium, cobalt-60, cesium-137, and neptunium were held in reserve to be added to a future revision.

because the current completeness analysis suggests that the available logbook data totals are less than those reported in monthly and annual health physics summaries beginning in 1969.

Finding 2: SC&A does not find the discrepancies between reported bioassay totals of Am/Cm/Cf and available logbook results to be credibly explained by the inclusion of fecal results beginning in 1969. Evidence suggests that fecal results were tabulated separately, as shown in a Works Technical Report from January 1972 (DuPont 1972).

Finding 3: The combination of multiple years of trivalent actinide bioassay data during the 1980s was not sufficiently justified with a corresponding discussion of site activities and/or associated exposure potential at SRS as mandated in Neton 2015. Group or cohort monitoring may justify the appropriate combination of annual data; however, this practice was not sufficiently established in NIOSH 2016a.

Finding 4: The SRS bioassay procedures for routinely monitored workers during the early periods (1954–1970 for tritium and 1964–1967 for exotic trivalent actinides) are not addressed in NIOSH 2016a. SC&A's review of the Bioassay Control Reports referenced for this period did not find any sampling schedules or bioassay procedures listed. Therefore, it would be advantageous to have additional information about the bioassay requirements for the early periods.

Finding 5: While evaluating monitoring practices related directly to thorium is not possible because SRS did not directly monitor for thorium, a discussion of the relationship between trivalent actinide monitoring practices and thorium exposure potential is warranted to establish that Am/Cm/Cf urinalysis data are an appropriate surrogate for thorium exposures. It does not appear that a verification demonstrating that a sufficient percentage of known thorium workers were included in the Am/Cm/Cf coworker dataset was performed, as was requested at the February 5, 2014, meeting of the SRS Work Group (ABRWH 2014a).

Finding 6: Derived coworker intakes were stratified into construction and non-construction workers for each of the three revised coworker models. However, NIOSH 2016a does not present the statistical basis used to determine that stratification is necessary for each radionuclide of interest and for each time period as detailed in ORAUT-RPRT-0053, Revision 02, *Analysis of Stratified Coworker Datasets* (NIOSH 2014a), as well as in the implementation guide (Neton 2015).

Observation 1: SC&A requests clarification and/or documentation of the analytical chemistry phenomenon in which chelation treatment causes heterogeneity of contaminants for aliquots of a single bioassay voiding.

Observation 2: Derived coworker doses appear to increase substantially beginning in 1958, which coincides with the change in bioassay analysis for tritium. The cause for the apparent change in exposure potential should be discussed to determine if the prior method to detect tritium intakes was insufficient or if actual exposures markedly increased during this time, which would explain the increase in coworker doses.

Observation 3: It is unclear based on NIOSH 2016a how NIOSH intends to reconstruct intakes of exotic trivalent actinides and thorium post-1989 (e.g., extension of 1989 derived coworker intake rates, use of electronic Health Physics Radiological Exposure Database [HPRED] data, or application of some fraction of the derived air concentration).

Observation 4: Discrepancies between the number of available exotic trivalent logbook entries and health physics summary reports prior to 1969 are not discussed in NIOSH 2016a. Documentation of the internal monitoring in 1967 may indicate that health physics summary reports did not include Construction Trade Workers (CTWs).

Observation 5: It is not clear to SC&A why the date of the bioassay sample is not considered a "critical field" for the purposes of performing quality assurance (QA) tests on the transcribed dataset for trivalent actinides as well as tritium. The date of the sample is a crucial component to correctly performing the time-weighted one person-one sample (TWOPOS) calculation for Am/Cm/Cf and thorium as well as the annual dose for tritium.

Observation 6: SC&A requests clarification on what aspects of the tritium coworker model analysis were subject to the QA criteria described in Section 2.0 of Neton 2015 and proceduralized in ORAUT-RPRT-0078, *Technical Basis for Sampling Plan* (NIOSH 2016b). Based on SC&A's interpretation of the analysis in NIOSHT 2016a, it appears that only the delineation between construction and non-construction workers was tested for quality assurance.

Observation 7: The available CTW bioassay data for subcontractors has yet to be validated and verified; i.e., it has yet to be demonstrated that the majority of the subcontractor CTW bioassay data has been located and has correctly been transcribed to the databases used to create the coworker model intakes. This validation and verification activity is currently being undertaken at the direction of the SRS Work Group.

Observation 8: NIOSH 2016a appears to contradict itself on whether prime CTWs represent a similar monitoring protocol as subcontractor CTWs. Prime construction workers are described as being exposed "temporarily but frequently for short periods" but also on an annual bioassay schedule specified by the bioassay control procedures. Subcontractor workers were monitored on a case-by-case basis depending on the localized requirements of the job.

2.0 ADEQUACY OF THE COWORKER DATA

In general terms, the "adequacy" of a given dataset refers the suitability of the data to reflect the actual exposure it is intended to reconstruct. Concerns about data adequacy can vary significantly from one situation to the next. For example, if one were to use whole body count data to reconstruct the dose to a particular contaminant that was not specifically measured, one might have concerns about whether the calibration and/or energy range of the device was adequate to capture the contaminant of interest. As a corollary to the appropriateness of the data intended for use in coworker development, adjustments must often be made to the data to allow for the correct interpretation of the numerical results. In this case, the datasets in question concern the use of “modified” gross alpha[2] urinalysis to reconstruct intakes of trivalent actinides and thorium and tritium urinalysis to reconstruct tritium.

2.1 Am/Cm/Cf AND THORIUM DATA USING GROSS ALPHA TECHNIQUES

In the case of the trivalent actinides (Am/Cm/Cf), NIOSH 2016a discusses data adequacy in Sections 4.1.1.3, 4.1.1.4, 4.1.2.3, and 4.1.2.4. Section 4.1.1.3 discusses the chemical procedures and analytical limits in place for analyzing the gross alpha bioassay samples from the mid-1960s through the 1990s. It also discusses the chemicals used to limit alpha self-absorption. This is consistent with the criteria in paragraph 1, Section 2.1, of Neton 2015:

> *When urine samples are used, this should include a review of the sample collection methods, any chemical processes employed, and radiation counting equipment used.*

Section 4.1.1.4 describes how the data are interpreted, in particular, the unique situation at SRS in which a single bioassay result or “voiding” was often counted multiple times and then averaged to obtain a final result. This process has been the subject of considerable Work Group discussion (ABRWH 2014b, pages 186–198). SC&A’s February 24, 2014, memorandum, *Discussion Items and Clarifications for February 26th Work Group Meeting* (SC&A 2014a), provides examples in which aliquots of the same urinalysis sample were measuring significantly different activities even at orders of magnitude above the detection limit. This exact scenario is presented in Neton 2015:

> *If widely different results from the same aliquot are observed, the effect this might have on the usefulness of the data should be considered.* [page 5]

This potential issue of variability in the trivalent actinide data is detailed in SC&A’s 2013 white paper, *SC&A Review of Addendum 3 to the NIOSH Savannah River Site Special Exposure Cohort (SEC-00103) Evaluation Report*, and SC&A 2014a. The observation of significant variability among aliquots of the same sample, including samples well above the detection limit, is the subject of Section 4.1.1.4 and also Attachment B to NIOSH 2016a. NIOSH explains that such variability is to be expected in aliquots of the same voiding for workers who are undergoing chelation treatment. NIOSH 2016a also states that the aliquots were actually different portions of the voiding and not simply a recounting of the same portion of the sample, which is an important distinction. If the repeated disc counts had been from the same exact portion of the physical specimen, then the issue of heterogeneity among samples would be moot. However, NIOSH 2016a did not provide any reference to assert this statement that the aliquots represented *different* portions of the same specimen.

Observation 1: SC&A requests clarification and/or documentation of the analytical chemistry phenomenon in which chelation treatment causes heterogeneity of contaminants for aliquots of a single bioassay voiding.

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[2] The term “modified gross alpha” is simply intended to convey that neptunium, plutonium, and uranium have been stripped away from the sample prior to counting the exotic transuranics and thorium.

Section 4.1.1.3 of NIOSH 2016a discusses the samples that were correctly excluded from the coworker analysis. Such samples include workers who underwent chelating treatment (this issue was the subject of Finding 17 of SC&A 2013), as well as worker records associated with known significant uptake incidents. For the latter exclusion category, NIOSH identified four incidents and associated records that were associated with known intakes. This is appropriate, as bioassay samples associated with incidents are not suitable for construction of a chronic exposure coworker. Although it is probable that not all chelation and incident events were identified and removed, inadvertent inclusion of such samples is favorable to the claimant.

Finally, because the thorium coworker model uses the same modified gross alpha urinalysis that was used for the trivalent actinides, the same adequacy topics discussed for Am/Cm/Cf apply to thorium. As explained in NIOSH 2016a, thorium was modeled separately from the trivalent actinides due to the different biokinetic properties between the two radionuclide categories. However, it should be recognized that an actual uptake of Th-232 Type S that registered a positive urinalysis result would be very improbable without a known (and likely well-documented) uptake incident. Comparison of the resulting lung doses from thorium Type S are upwards of 300 times higher when compared with assigning Am-241 Type M for the same bioassay result. While this may call into question the applicability of using these data to represent thorium exposures, NIOSH has explained in the past that such large changes in the magnitude of doses are common under the auspices of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and occur in many other dose reconstruction situations (ABRWH 2014b, pages 130–138).

2.2 TRITIUM BIOASSAY ADEQUACY

For the revised tritium coworker model, NIOSH 2016a evaluates data adequacy in Section 4.2.1.3. Included in this section is a description of the changing methods for measuring tritium in urine, such as the use of liquid scintillation techniques instead of ionization chambers, which occurred in 1958. Table 5-3 of NIOSH 2016a lists the recommended annual coworker tritium doses for the period 1954–1990. This table indicates that the 50th and 95th percentile doses for both non-CTWs and CTWs increased for the period from 1958 into the 1980s when compared to the values for the prior period (1954–1957).

Observation 2: Derived coworker doses appear to increase substantially beginning in 1958, which coincides with the change in bioassay analysis for tritium. The cause for the apparent change in exposure potential should be discussed to determine if the prior method to detect tritium intakes was insufficient or if actual exposures markedly increased during this time, which would explain the increase in coworker doses.

Notably, NIOSH identified that during the 1980s, results were reported that were less than the assumed reporting level of 0.5 microcuries per liter (µCi/L). NIOSH has assumed that the true minimum detectable activity (MDA), which can vary from sample to sample, was much less than the reporting level and, thus, that results that are less than the reporting level can be considered "real." While SC&A does not have cause to refute that assumption, it would be beneficial to document the relative magnitude of the true MDA to justify the use of values lower than the reporting level in coworker development.

Section 4.2.1.3 also discusses the quality control activities that included checks on a daily, weekly, monthly, and quarterly basis as outlined in the SRS *Internal Dosimetry Technical Basis Manual*, dated December 20, 1990 (WSRC 1990). While such information is useful and consistent with the criteria discussed in Section 2.1, paragraph 3, of Neton 2015, references describing the quality control process during earlier years would certainly be beneficial (if available).

In addition, Section 4.2.3 provides details on how the tritium data were specifically interpreted and calculated as tritium doses and not intakes. For a variety of reasons, tritium is correctly treated differently than other internal contaminants. Section 4.2.3 describes the use of ORAUT-OTIB-0011, *Tritium Calculated and Missed Dose Estimates,* Revision 00 (NIOSH 2004), which provides the procedure for directly calculating effective dose from tritium urine bioassay. Considerations have been made for individuals who have bioassay samples that are greater than 40 days apart, which is the biological half-life for organically bound tritium. SC&A has previously reviewed NIOSH 2004, and all issues raised during that review were discussed by the Subcommittee on Procedures Review and subsequently closed.

3.0 COMPLETENESS OF THE COWORKER DATA

The completeness of a given dataset reflects the extent to which technically acceptable monitoring data are available for coworker analysis. This consideration is related not only to the general quantity of available data but also to whether data may be missing on a temporal or location-specific basis. As Neton 2015 notes, the actual quantity of data is not directly indicative of the completeness of the records. For smaller scale operations, which may have been intermittent and involved relatively few workers, one would expect the monitoring records to reflect that. On the other hand, for larger scale operations, such as a uranium refinery that operated continuously, one would expect to see a relatively large number of samples commensurate with the exposed workforce and minimal unexplained temporal variation. Section 3.1 below presents the completeness of the exotic trivalent/thorium records, while the completeness of tritium records is discussed in Section 3.2. Section 3.3 describes the QA criteria in transcribing hard copy records into a database suitable for coworker assessment.

3.1 COMPLETENESS OF Am/Cm/Cf RECORDS FOR TRIVALENT AND THORIUM INTAKE ANALYSIS

Data completeness is discussed NIOSH 2016a in Sections 4.1.2.1, 4.1.2.2, 4.1.3, and Attachment E for trivalent actinides. As presented in Section 4.1.2.1, trivalent actinide data were transcribed from available laboratory logbooks from 1963 through 1989. Per the discussion in that section, beginning in 1991 the HPRED database provides monitoring records for trivalent actinides; however, it does not appear that these data were evaluated for assignment of intakes post-1989 despite statements in Section 4.2.3 to the contrary. Section 5.0 of NIOSH 2016a states the following concerning assignment of intakes following the last evaluated time period:

> *The intake rates or dose for the last year listed may be extended to subsequent years as a measure favorable to claimants.* [page 31]

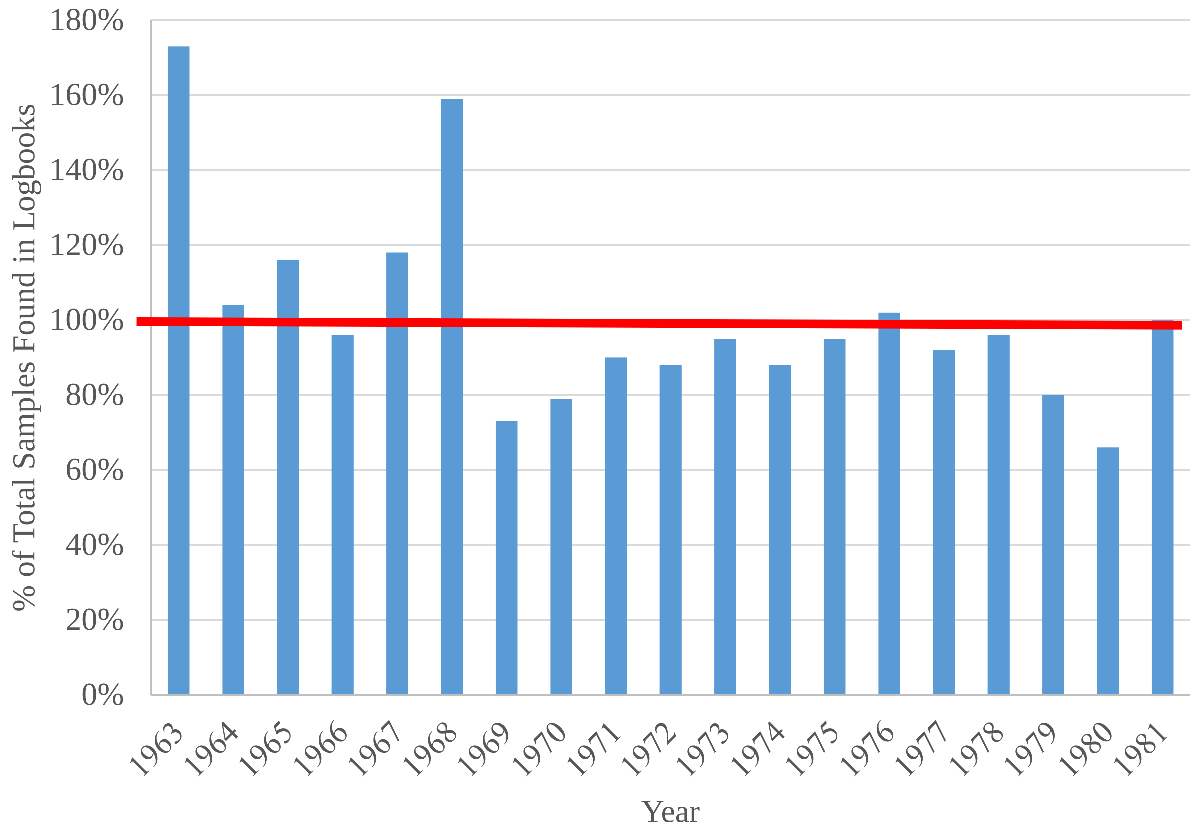
Although it is not uncommon to assume that exposures generally decreased as time went on at a given facility, the later trivalent data available in HPRED should be compared against the currently recommended methodology to assure that extension of derived intakes from 1989 into later years is an appropriate and bounding approach. Furthermore, discussions during SRS Work Group meetings had indicated that NIOSH intended to use a fraction of the derived air concentration to assign exposures to at least thorium beginning in 1990 (ABRWH 2014a, pages 242–260; ABRWH 2014b, pages 205–208).

Observation 3: It is unclear based on NIOSH 2016a how NIOSH intends to reconstruct intakes of exotic trivalent actinides and thorium post-1989 (e.g., extension of 1989 derived coworker intake rates, use of electronic HPRED data, or application of some fraction of the derived air concentration).

To evaluate the completeness of the available records, NIOSH compared their transcribed logbook data by year against summary data in the annual bioassay control reports. This constitutes a direct comparison between the number of samples collected at the site and the number available for use in coworker development. Table 4-1 of Section 4.1.2.1 of NIOSH 2016a presents this analysis, which compared records from 1963 to 1981.

Finding 1: The analysis of the completeness of trivalent logbook records provided in NIOSH 2016a ends in 1981, though the proposed coworker analysis of trivalent bioassay extends through 1989. It would be beneficial to extend the completeness analysis to all years in which trivalent urinalysis data is being proposed for coworker evaluation. This is particularly important because the current completeness analysis suggests that the available logbook data totals are less than those reported in monthly and annual health physics summaries beginning in 1969.

Figure 1. Percentage of Total Reported Bioassay Samples found in Available Logbooks (1963–1981)



As seen Figure 1 for the years 1963–1968, there were generally more samples found in the laboratory logbooks than were reported in the actual annual summaries. Beginning in 1969, there were generally fewer urinalysis samples found in the laboratory logbooks than were reported in the annual summaries. NIOSH 2016a states the following concerning discrepancies between total number of available samples and the annual summaries:

> *The ability to compare these numbers directly is limited by the fact that the logbooks record the date of sample collection while* ***the summaries indicate the number of analyzed samples and include fecal samples for 1969 and after.*** *On some occasions samples were not analyzed until months after collection. Before 1969, the number of recorded samples in the logbooks exceeds the number in the summaries. Beginning in 1969, on average, about 90% of the number of samples in the summaries are recorded in the logbooks* ***and fecal samples can be assumed to account for at least part of the difference.*** [emphasis added] [page 20]

While SC&A agrees that changes between the sampling collection and analysis date can create fluctuations when trying to compare the bioassay totals, it is logical that such fluctuations would generally center around unity, with one period having a larger number of logbook results and the subsequent period having lower numbers, and vice versa. In general, the trends shown in

Table 4-1 show consistently higher numbers of logbook samples before 1969 and consistently lower numbers of logbooks samples beginning in 1969.

NIOSH further states that starting in 1969, the bioassay control totals included fecal samples, which explains why there are fewer urinalysis samples in the laboratory logbooks than what are reported for the year. However, there is no indication given as to what portion of the apparently missing bioassay results are accounted for by the inclusion of fecal analysis totals. SC&A did not observe indications in the referenced documentation to indicate that the totals found included fecal sampling beginning in 1969, and no other references were provided to affirm that fecal sampling was included in the total.

In fact, a Works Technical Report from 1972 (DuPont 1972) appears to refute the notion that bioassay totals included fecal sampling after 1969 (see Figure 2). As can be seen in Figure 2, bioassay results are broken out by urine and feces (not pictured are also a tabulation of blood samples). The 2,016 total Am/Cm samples in 1971 exactly matches the total in Table 4-1 of NIOSH 2016a.

Figure 2. Example Works Technical Report Showing Bioassay Totals from 1971

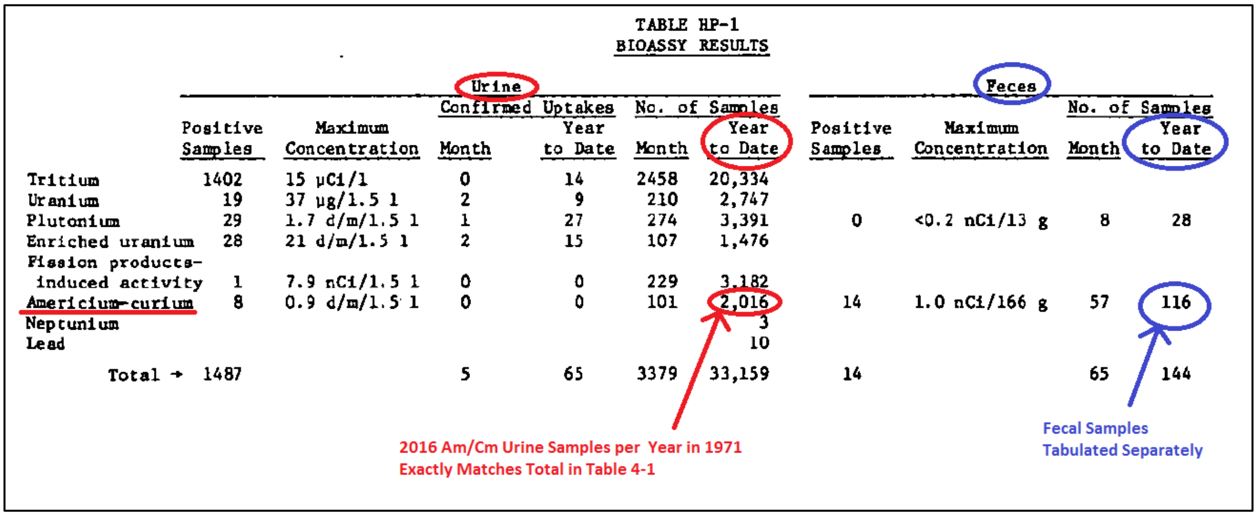


TABLE HP-1
BIOASSY RESULTS

	Urine						Feces			
			Confirmed Uptakes		No. of Samples				No. of Samples	
	Positive Samples	Maximum Concentration	Month	Year to Date	Month	Year to Date	Positive Samples	Maximum Concentration	Month	Year to Date
Tritium	1402	15 µCi/1	0	14	2458	20,334				
Uranium	19	37 µg/1.5 1	2	9	210	2,747				
Plutonium	29	1.7 d/m/1.5 1	1	27	274	3,391	0	<0.2 nCi/13 g	8	28
Enriched uranium	28	21 d/m/1.5 1	2	15	107	1,476				
Fission products-induced activity	1	7.9 nCi/1.5 1	0	0	229	3,182				
Americium-curium	8	0.9 d/m/1.5 1	0	0	101	2,016	14	1.0 nCi/166 g	57	116
Neptunium						3				
Lead						10				
Total →	1487		5	65	3379	33,159	14		65	144

Finding 2: SC&A does not find the discrepancies between reported bioassay totals of Am/Cm/Cf and available logbook results to be credibly explained by the inclusion of fecal results beginning in 1969. Evidence suggests that fecal results were tabulated separately, as shown in a Works Technical Report from January 1972.

Additionally, the large differences in the number of reported bioassay samples and those actually found in the laboratory logbooks prior to 1969 has not been addressed. Although it is preferable to have a higher number of samples than what was reported in the bioassay control reports, it does call into question the usefulness of the reported totals when such large discrepancies are observed.

A 1968 bioassay control report indicates that during 1967, 253 samples were taken that covered 182 employees (DuPont 1968). Inspection of Table 4-2 in NIOSH 2016a shows that NIOSH evaluated exactly 182 non-construction workers in 1967, with an additional 45 construction workers also evaluated. One possibility is that the bioassay control documents did not include CTWs in its routine monitoring totals; however, SC&A did not locate any other bioassay control reports that reported the total number of workers. Such records would have allowed for further comparison.

Observation 4: Discrepancies between the number of available exotic trivalent logbook entries and health physics summary reports prior to 1969 are not discussed in NIOSH 2016a. Documentation of the internal monitoring in 1967 may indicate that health physics summary reports did not include CTWs.

As discussed in Section 4.1.3 of NIOSH 2016a, the coworker analysis combined available coworker data for the years 1981–1982, 1983–1984, 1985–1986, and 1987–1989 due to the small amount of CTW data during those years. Neton 2015 states the following concerning combination of years:

> *If, because of data limitations, it is necessary to consider time intervals beyond one year in the coworker model, any changes in site practices or operations should be evaluated to ensure that the data can be validly combined. In general, grouped time intervals should not exceed a 3 year period, unless there is stringent justification for doing so.* [page 10]

One reasonable rationale for combining adjacent years for the purposes of coworker analysis may be the existence of cohort or "group" monitoring as described in Section 4.1.1.2 of NIOSH 2016a. However, no reference was provided to affirm if or when the practice of cohort monitoring occurred at SRS.

Finding 3: The combination of multiple years of trivalent actinide bioassay data during the 1980s was not sufficiently justified with a corresponding discussion of site activities and/or associated exposure potential at SRS as mandated in Neton 2015. Group or cohort monitoring may justify the appropriate combination of annual data; however, this practice was not sufficiently established in NIOSH 2016a.

Similar to the discussion of data adequacy, issues related to thorium data completeness are intertwined with the previous trivalent actinide discussion. Therefore, no additional discussion of thorium data completeness is warranted.

3.2 COMPLETENESS OF TRITIUM URINALYSIS RECORDS

For the tritium coworker model, data completeness is discussed in Sections 4.2.1.1 of NIOSH 2016a. In addition, Table 4-3 of NIOSH 2016a shows the total number of construction and non-construction claimants available with suitable tritium data by year. This table is recreated as Figure 3 below. The total number of claimants by year fluctuated from year to year for both construction and non-construction workers. However, as noted in NIOSH 2016a, the relative number of construction and non-construction workers generally follows the same temporal trends. This would support the notion that neither group is necessarily underrepresented on a year-by-year basis.

Because the tritium coworker model is based on claimant records, it is a "representative" and not a "complete" dataset. Because it is representative, it is difficult to establish records "completeness" for the purpose of evaluating its appropriateness in coworker model development.[3] One method would be to compare the total number of tritium workers by year found in the claimant population to the number of sitewide workers who were monitored for tritium. For example, DuPont 1968 indicates that 1,441 individuals were monitored for tritium during that year, while the NOCTS claimant population contained 253 tritium workers during this year (~18% of the total). Unfortunately, SC&A did not locate other such tabulations of the total number of workers monitored for tritium to allow for a meaningful comparison. If such information is available (or can be made available through data capture), it would help establish that the NOCTS coworker population is representative of the SRS population for the specific case of tritium coworker dose evaluation.

A corollary type analysis might be to compare the total number of samples by year at SRS with the total number of samples available in the claimant population. Unfortunately, at the time of this review, the total number of tritium samples used in the NIOSH 2016a analysis was not available to SC&A. However, a comparison of the total number of sitewide tritium samples to the number of NOCTS tritium workers can also provide some insight into the relative completeness of the coworker dataset by comparing the temporal trends (see Figure 4). As seen in Figure 4, the number of tritium workers in NOCTS roughly follows the trend of the total number of sitewide tritium samples by year (i.e., when the total number of sitewide tritium samples decreased, the total number of NOCTS workers also decreased). The exception is 1978, in which the number of sitewide tritium samples increased while the number of NOCTS claims with tritium data decreased.

[3] NIOSH 2016a cites ORAUT-OTIB-0075, Revision 01, *Use of Claimant Datasets for Coworker Modeling* (NIOSH 2016c), to establish that NIOSH OCAS Claims Tracking System (NOCTS)-based datasets are considered representative for the purpose of records completeness. It must be noted that SC&A has not reviewed NIOSH 2016c.

Figure 3. Number of Construction and Non-Construction Claimants Used in Tritium Coworker Analysis from 1954 to 1990

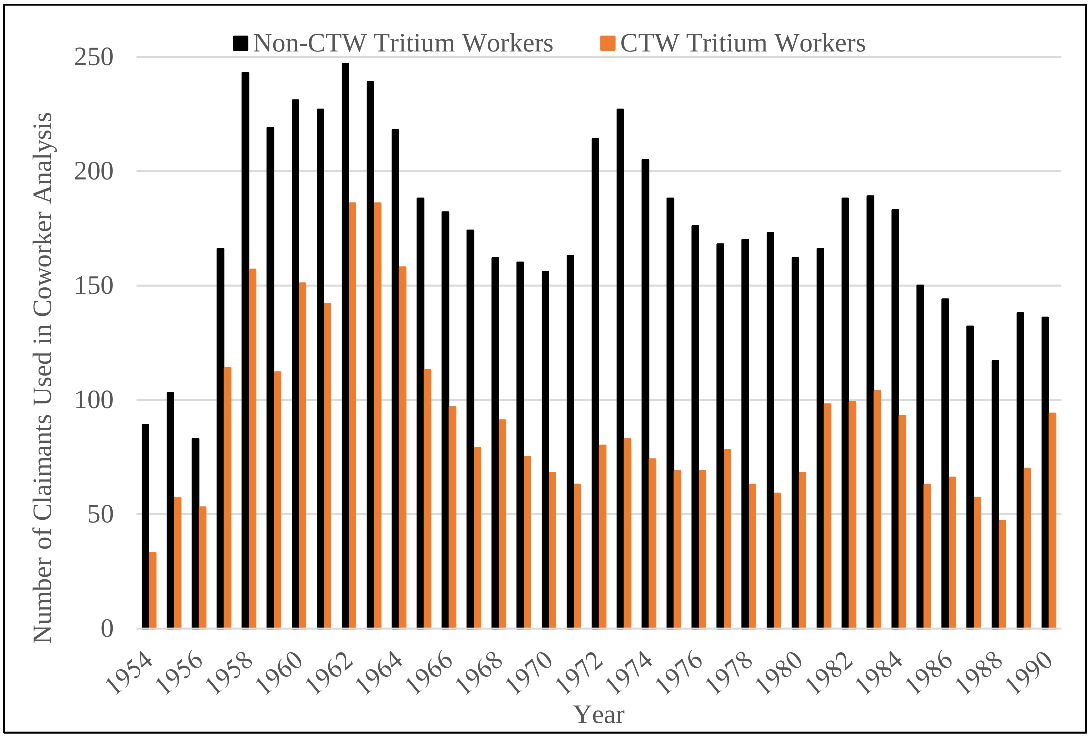
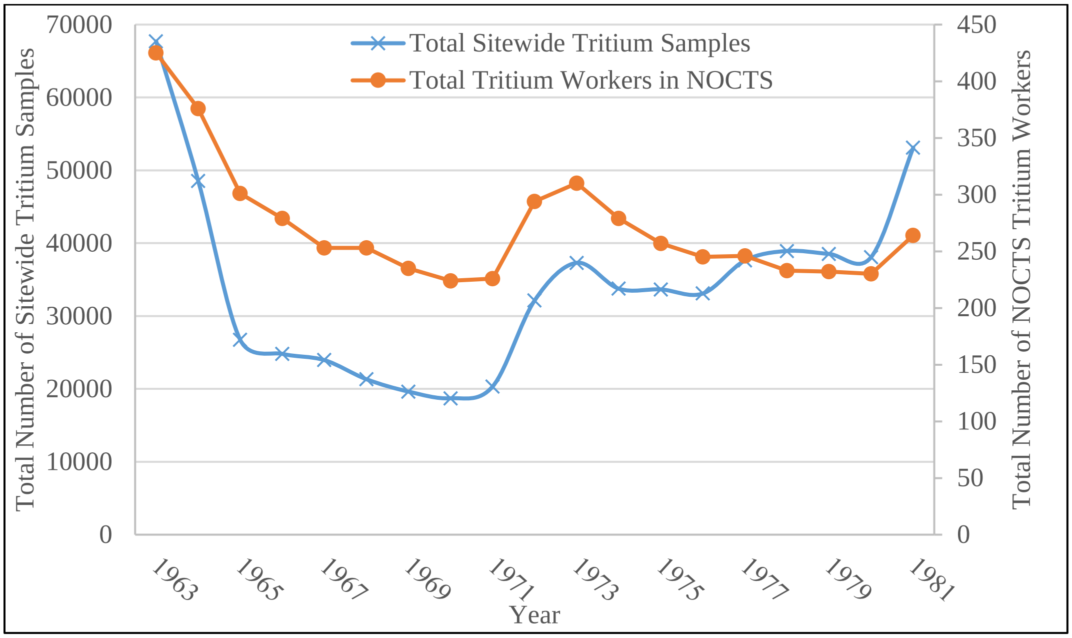


Figure 4. Comparison of the Trends in Sitewide Tritium Sampling Totals to the Total Number of Tritium Workers Available in NOCTS for Coworker Analysis



3.3 QUALITY ASSURANCE ON DATA COMPLETENESS

In addition to the general completeness concerns, data must often be transcribed from hard copy records or taken from a preexisting database. As pointed out in Section 2.0 of Neton 2015, such situations require a validation and verification of the data to assure that they have been transcribed with sufficient accuracy. Or, in the case of a preexisting database, that the electronic records appropriately reflect the primary records from which the database originates. To this end, NIOSH performed a QA check using the methods in ORAUT-RPRT-0078 (NIOSH 2016b) for the datasets used in the three coworker models in question.

Although not specifically reviewed by SC&A, NIOSH 2016b presents a method for selecting an appropriate sample size from a total data population to evaluate both the "critical data fields" and the "all fields" entries in a transcribed dataset. "Critical" data fields, in this application, are those fields that directly impact the use of transcribed data for coworker model development, while "all fields" includes both critical and non-critical data fields. NIOSH 2016a delineates the QA criteria for "critical fields" versus "all fields" as follows:

> *the fields containing the payroll ID number and the numerical sample results were evaluated with a maximum 1% allowable error rate. All other fields from the hardcopy records were evaluated with a maximum 5% allowable error rate.* [page 16]

It is not clear to SC&A why the "date" of the sample would not also be considered a "critical" field. In the case of the trivalent actinide/thorium coworker model, the date of a sample is a crucial component in performing the TWOPOS calculation. For the tritium coworker model, the date of the sample directly impacts the calculation of the individual annual tritium dose used in developing coworker model distributions.

Observation 5: It is not clear to SC&A why the date of the bioassay sample is not considered a "critical field" for the purposes of performing QA tests on the transcribed dataset for trivalent actinides as well as tritium. The date of the sample is a crucial component to correctly performing the TWOPOS calculation for Am/Cm/Cf and thorium as well as the annual dose for tritium.

The details of the QA analysis are provided in Attachment E to NIOSH 2016a and also described in Sections 4.1.2.2 and 4.2.2 for Am/Cm/Cf/Th and tritium, respectively. The results of the QA tests for the trivalent actinides are shown in Table 1. As seen in Table 1, the critical fields include the payroll ID, bioassay result, and reported result (often censored at a standard detection level). In both the "critical field" and "all field" case, the dataset passed the QA criteria.

Table 1. Summary of Quality Assurance Tests on Am/Cm/Cf Dataset Using NIOSH 2016b Methodology

Field Category	Error Rate Resulting in Rejection of the Sample	Field Description	Field Point Estimate Error Rate	Critical Field 95% Confidence Interval Error Rate	QA Determination
Critical Fields	1%	Payroll ID#, Am dpm/1.5 L (nonblank), Am Report (nonblank)	0.59%	0.39–0.86%	Pass
All Fields	5%	Critical Fields, Last Name, First Initial, Middle Initial, Volume, Area, Occupation Title, Bottle Date, Remarks (nonblank)	0.69%	0.25–1.49%	Pass

Quality assurance tests performed on the dataset for tritium are less clear. It appears as though the QA test was performed to determine if workers were correctly classified as CTWs or non-CTWs. However, it is not apparent that any QA was performed on the transcription of the actual tritium bioassay data from the claimant files that were used in developing the coworker model (this would include the bottle date and result). Section 4.2.2 of NIOSH 2016a states:

> *all fields were evaluated with a maximum 5% allowable error rate.* [page 26]

This would indicate that no fields in the tritium dataset were determined to be critical fields (which are evaluated to a 1% allowable error rate). Furthermore, Attachment E describes the tritium QA process as follows:

> *QA of tritium data CTW determination. The CTW determinations based on the Master Occupation Table and the CTW Designation Instructions were checked against the worker history cards (or claimant interviews or personnel dosimetry quarterly reports).* [NIOSH 2016a, page 82]

Observation 6: SC&A requests clarification on what aspects of the tritium coworker model analysis were subject to the QA criteria described in Section 2.0 of Neton 2015 and proceduralized in NIOSH 2016b. Based on SC&A's interpretation of the analysis NIOSH 2016a, it appears that only the delineation between construction and non-construction workers was tested for quality assurance.

4.0 SITE-SPECIFIC MONITORING PRACTICES

The previous two general criteria dealt with the technical aspects of a proposed coworker dataset and the general availability and quality assurance of utilized records. The criteria discussed here relates to the actual monitoring policies of the specific site; specifically, characterization of the types and categories of worker, time periods, and applicable site locations where the monitoring activities of interest took place. Ideally, the monitoring practices at a given site would monitor all workers who could have been exposed to the contaminant of interest for all relevant periods and locations.

However, when monitoring coverage does not cover all applicable situations (such as cases that warrant coworker development), it is important to establish that a representative and/or bounding cohort of workers were monitored. If that criterion can be established, then it can logically be inferred that the use of available monitoring records will be appropriate for unmonitored workers. On the other hand, if it is established that the group of monitored workers is not representative of the cohort of workers with the greatest potential for exposure, use of such records in coworker model development is likely inappropriate.

The listing of the sitewide monitoring policies at SRS is found in Attachment A to NIOSH 2016a. This attachment includes tables that list the specific area of SRS and the mandated bioassay schedule for specific contaminants based on procedures from 1968, 1970, 1971, 1976, 1985, and 1989.

SC&A compared the NIOSH 2016a characterization of the monitoring procedures to those recommended in Neton 2015 for coworker applications. Section 3.1 of Neton 2015 states that before applying the monitoring data to a coworker model, the type of monitoring program at the site should be determined. Specifically, does the monitoring protocol represent:

1. Routine representative monitoring
2. Routine monitoring of workers with the highest exposure potential
3. Incident-driven monitoring

If routine monitoring was used, it must be demonstrated that the monitored workers represented the exposed population, or that the workers with the highest potential for exposure were monitored.

NIOSH 2016a provides a sampling of the Health Physics monitoring procedures for routinely exposed workers in Table A-2 through A-8 for various years from 1968 through 1989. The lists in these tables outline in some detail the monitoring requirements for different categories of workers at the various SRS facilities. This would indicate that monitoring requirements were in place at the SRS during the middle and latter period that the coworker model was developed for.

Finding 4: The SRS bioassay procedures for routinely monitored workers during the early periods (1954–1970 for tritium and 1964–1967 for exotic trivalent actinides) are not addressed in NIOSH 2016a. SC&A's review of the Bioassay Control Reports referenced for this period did not find any sampling schedules or bioassay procedures listed. Therefore, it would be advantageous to have additional information concerning the bioassay requirements for the early periods.

For workers who were not routinely exposed (e.g., CTWs), bioassay protocols were administered on a localized level. That is, bioassay monitoring requirements were determined on a case-by-case basis depending on the job and at the discretion of Health Physics oversight. NIOSH 2016a states the following for both the exotic trivalent actinides/thorium and tritium (see NIOSH 2016a, Sections 4.1.1.2 and 4.2.1.2):

> *For workers intermittently present in an area (i.e., some CTWs, the monitoring was based on the job plan). For the duration of the job plan and the duration of exposure potential, the required monitoring was specified.*

Therefore the monitoring protocol for non-routine workers is difficult to evaluate in terms of applicability to unmonitored workers. It is clear from the job plan forms provided in NIOSH 2016a that bioassay requirements were part of the pre-planning process before “off-normal” activities that would involve CTWs. However, it should be noted that the validation of construction worker bioassay, in particular subcontractor bioassay, is currently still under evaluation by the SRS Work Group.

Observation 7: The available CTW bioassay data for subcontractors has yet to be validated and verified; i.e., it has yet to be demonstrated that the majority of the subcontractor CTW bioassay data has been located and has correctly been transcribed to the databases used to create the coworker model intakes. This validation and verification activity is currently being undertaken at the direction the SRS Work Group.

NIOSH 2016a does not contain a specific discussion about thorium monitoring practices; however, this is expected because SRS did not specifically monitor workers for thorium.[4] However, because the thorium coworker intakes are derived based on the trivalent actinide urinalysis data, a discussion of the relationship between monitoring practices for Am/Cm/Cf and thorium exposure potential is warranted.

Based on discussions during the February 5, 2014, Work Group meeting, the proposed path forward had been to evaluate a cohort of uniquely identified thorium workers and review how their individual dosimetry records compared with derived coworker excretion rates. Or, alternately, simply confirm that a sufficient percentage of known thorium workers were included in the overall dataset (ABRWH 2014a pages 331–346).

Finding 5: While evaluating monitoring practices related directly to thorium is not possible because SRS did not directly monitor for thorium, a discussion of the relationship between trivalent actinide monitoring practices and thorium exposure potential is warranted to establish that Am/Cm/Cf urinalysis data are an appropriate surrogate for thorium exposures. It does not appear that a verification demonstrating that a sufficient percentage of known thorium workers were included in the Am/Cm/Cf coworker dataset was performed as was requested at the February 5, 2014, meeting of the SRS Work Group (ABRWH 2014a).

5.0 STRATIFICATION

In general terms, stratification refers to the practice of developing multiple coworker distributions to account for different levels of exposure potential among specific worker categories. Specifically, Section 4.0 of Neton 2015 states that stratification of a given coworker dataset is appropriate for situations where:

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[4] SC&A recognizes that the process used to monitor workers for exotic trivalent actinides also captured thorium, as stated in DuPont 1964.

> *1) accurate job categories and/or descriptions can be obtained for all workers making up the general coworker dataset; 2) there is reason to believe that one of the job categories is more highly exposed; and, 3) there were unmonitored workers in this job category…* [page 10]

Once these criteria have been established and the dataset has been appropriately stratified, a statistical analysis should be performed to determine if there is actually a statistical difference in the datasets. If the two stratified datasets are determined to be statistically different, then a test of practical significance is used to determine what periods warrant stratification. The statistical process of determining whether stratification is warranted is detailed in ORAUT-RPRT-0053, Revision 02 (NIOSH 2014a).

The three revised coworker models presented in NIOSH 2016a stratified the derived intakes into CTWs and non-CTWs. However, NIOSH 2016a does not specifically present the statistical basis for stratifying the derived coworker intakes into construction and non-construction workers as instructed in NIOSH 2014a and Neton 2015.

ORAUT-RPRT-0055, *A Comparison of Exotic Trivalent Radionuclide Coworker Models at the Savannah River Site*, Revision 00 (NIOSH 2012), provides a previous analysis comparing construction and non-construction worker strata. However, it is not clear that the newly developed protocol for identifying construction and non-construction workers, as described in Section 3 of NIOSH 2016a, applies to the revised coworker evaluation. Regardless, NIOSH 2012 would not have incorporated the more recent TWOPOS methodology, which could have a significant impact on coworker distributions. This would be particularly important for subcontractor construction workers who were on an intermittent job-based bioassay program as opposed to a regular routine monitoring schedule.

The annual 50th and 95th percentile intake values listed in Table 5-2 of NIOSH 2016a for exotic trivalent actinides appear to be similar for non-construction workers and construction workers. Therefore, these data should be analyzed per ORAUT-RPRT-0053 (NIOSH 2014a) to determine if the data should be stratified, or if there is statistically only one group of exposed workers instead of two.

Finding 6: Derived coworker intakes were stratified into construction and non-construction workers for each of the three revised coworker models. However, NIOSH 2016a does not present the statistical basis used to determine that stratification is necessary for each radionuclide of interest and for each time period as detailed in ORAUT-RPRT-0053 (NIOSH 2014a), as well as in the implementation guide (Neton 2015).

In addition, SC&A found that the determination of CTW was not always straightforward on examination of the available records. Some early hard copy bioassay sheets in the 1980s and 1990s contain a roll number (1, 2, 4, 5, or 7), but the electronic databases (Pro-Rad and EDWS) do not have these roll numbers. Some records, such as whole body counts, list the company/subcontractor and may indicate a CTW, but many have only the energy employee's work location at SRS. Therefore, it is difficult to determine a non-CTW from a CTW in some cases.

With regard to characterizing construction and non-construction workers, NIOSH 2016a states the following in the last paragraph on page 10:

> *At SRS, CTWs were deployed temporarily but frequently for short periods to perform specific tasks usually pertaining to facility construction and modification, system maintenance, and decontamination. These types of jobs were performed by workers in both categories* [prime CTWs and subcontracted CTWs as per the previous paragraph]. *Workers from both categories worked around the site, while production and operation staff normally worked at fixed locations.*

However, the last paragraphs on pages 17 and 25 state:

> *Both of these types of monitoring programs can be considered to be variations on routine, representative sampling. For workers normally present in an area (i.e., nonCTWs and Roll 2 CTWs), the monitoring was specified on an annual basis in the bioassay control procedures. For workers intermittently present in an area (i.e., some CTWs), the monitoring was based on the job plan.*

Based on these two excerpts, there is an apparent contradiction in that the non-CTWs and the Roll 2 CTWs were governed by routine bioassay control procedures, while subcontractor construction workers were on a job-specific monitoring basis (NIOSH 2016a, pages 17 and 25). However, based on the discussion in Section 3.2 of NIOSH 2016a, Roll 2 CTWs were grouped together with subcontract CTWs for the purposes of stratification (NIOSH 2016a, page 10).

Observation 8: NIOSH 2016a appears to contradict itself on whether prime CTWs represent a similar monitoring protocol as subcontractor CTWs. Prime construction workers are described as being exposed "temporarily but frequently for short periods" but also on an annual bioassay schedule specified by the bioassay control procedures. Subcontractor workers were monitored on a case-by-case basis depending on the localized requirements of the job.

6.0 ADDITIONAL COMMENTS

Section 5 of NIOSH 2016a provides implementation instructions to dose reconstructors concerning the application of coworker intakes. Table 5-1 provides dosimetry codes that can be used to identify a specific work area for a given worker and lists the appropriate contaminant intakes to assign. The use of area codes to assign coworker intakes was discussed thoroughly at the February 26, 2014 meeting of the SRS Work Group (ABRWH 2014b, pages 87–122). As a result, SC&A performed a detailed evaluation of the Table 5-1 methodology, which is presented in SC&A 2014b.

In addition to SC&A 2014b, a complementary analysis of the issue of dosimetry codes for coworker placement is forthcoming in SC&A's review of ORAUT-RPRT-0077, Revision 00, *Evaluation of Health Physics Area and Health Physics Department Codes to Identify Neptunium Workers at the Savannah River Site* (NIOSH 2016d).[5] While NIOSH 2016d is specific to neptunium operations, the use of dosimetry codes to identify a worker's area is universal to SRS

[5] SC&A's review of NIOSH 2016d is planned for release in March 2017.

coworker model implementation. SC&A acknowledges that NIOSH 2016a has modified its implementation language to address more transient worker types (such as CTWs); however, concerns remain over the use of dosimetry area codes to assign coworker intakes.

Finally, Section 3.2 of Neton 2015 recommends that the 95th percentile values be used to assign intake (or dose) to workers with elevated exposure potential, and that the 50th percentile value be used to assign intake (or dose) to the less likely exposure workers. NIOSH 2016a provides 50th and 95th percentile values in Tables 5-2 through 5-5 and contains a similar recommendation on assignment of the 50th and 95th percentile intake/dose.

This implementation concept is common in current EEOICPA methodologies, and SC&A agrees that the method is appropriate. However, specific instructions are not necessarily provided as to what circumstances would require assignment of the 95th percentile versus the 50th percentile. Specifically, NIOSH 2016a states:

> *the 50th percentile of the calculated intake rates should be assigned as a lognormal distribution with the associated GSDs…to the majority of workers for whom coworker intakes are assigned as the default assumption. For cases in which there is justification that the individual could have had intakes larger than the 50th percentile, dose reconstructors should use the 95th-percentile intake rates input into IREP as a constant.* [page 31]

Based on the previous statement, it appears that application of higher intake rates is at the behest of the dose reconstructor and not necessarily proceduralized. SC&A notes that for some EEOICPA sites, the delineation has been made between claimants who are considered “radiation workers” and those workers who only rarely entered radiation areas, such as administrative personnel (see NIOSH 2014b). To assure consistency and claimant favorability, NIOSH might consider similar instructions for the assignment of coworker intakes at SRS. Regardless, these additional comments do not directly relate to the adherence of NIOSH 2016a to the coworker model development criteria presented in Neton 2015 and so do not warrant further discussion in this report.

7.0 REFERENCES

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