Memorandum

To: Subcommittee for Procedure Reviews
From: Robert Anigstein, SC&A, Inc.
Date: March 27, 2023
Subject: Reply to NIOSH Response to SC&A Review Comments on Battelle-TIB-5000

At the September 29, 2022, teleconference meeting of the Subcommittee for Procedure Reviews (SPR), the National Institute for Occupational Safety and Health (NIOSH) presented its response (NIOSH, 2022) to the SC&A review (Anigstein & Gogolak, 2022) of Battelle-TIB-5000 (Battelle, 2007). According to NIOSH (2022, p. 1): "NIOSH is currently assessing the role Battelle-TIB-5000 may have on other programmatic documents that provide guidance on dose reconstructions. Once complete, NIOSH will consider cancelling this document."

SC&A presented an oral reply to the NIOSH response (ABRWH, 2022, pp. 33–38). The SPR requested SC&A to prepare a written summary of the discussion and the SPR actions (ABRWH, 2022, p. 45).

The SC&A review comprised 13 observations and no findings. To facilitate tracking the disposition of these issues, we will list each observation and the NIOSH (2022) response, followed by the SC&A reply and any SPR action and comments.

Observation 1

> Battelle-TIB-5000 makes extensive use of the computer program LOGNORM4, which is no longer publicly available.

NIOSH response to observation 1

> NIOSH concurs that LOGNORM4 is no longer being used. Currently, NIOSH employs a variety of freeware statistical programs (e.g. R-code) or commercial Excel add-ins (e.g. Vose and @Risk) for dose reconstruction tools and to perform various statistical analysis of datasets. [NIOSH, 2022, p. 1]

SC&A reply on observation 1

SC&A recommended that observation 1 be closed.

SPR action on observation 1

The SPR voted to close observation 1.

Observation 2

There are more modern methods for treating censored data.

NIOSH response to observation 2

NIOSH concurs that there are more modern methods for treating censored data. Regression on order statistics is discussed in ORAUT-RPRT-0053, *Analysis of Stratified Coworker Datasets* [ORAUT 2014]. Multiple imputation is discussed in ORAUT-RPRT-0071, *External Dose Coworker Methodology* [ORAUT 2015], and ORAUT-RPRT-0096, *Multiple Imputation Applied to Bioassay Co-Exposure Models* [ORAUT 2021]. The methods, as described in Battelle-TIB-5000, Section 2.1.3, are not currently being used. [NIOSH, 2022, p. 1]

SC&A reply on observation 2

Anigstein and Gogolak (2022, p. 10) state: "Helsel (2005 . . .) provides updated methods for treating censored data. A function, ros, that implements these methods can be found in the R package NADA." SC&A has reviewed ORAUT (2014) and noted that the report describes several additional methods for treating censored data, including those discussed by Helsel (2005) and the R package NADA (Helsel & Lee, 2010).[1] Analytical methods that are applicable to right-censored data are discussed in ORAUT (2014, attachment B). We also reviewed ORAUT (2015), which describes

> a new method, referred to as multiple imputation, to replace censored (<LOD) [limit of detection] external dosimeter readings with estimates of the dose to facilitate the calculation of annual external dose. This method replaces the previous practice of substituting <LOD readings with the LOD/2. [ORAUT, 2015, p. 13]

Consequently, we agree that NIOSH has implemented more modern methods for treating censored data. SC&A recommends that observation 2 be closed.

Observation 3

The number of observations in the highest airborne uranium concentration group in 1949 is stated to be 64 by Battelle-TIB-5000, section 2.1.4.1. This value is inconsistent with the value of 61 shown in TIB-5000, table 2.4, and with the 119 total observations in 1949 listed by TIB-5000.

NIOSH response to observation 3

"NIOSH agrees that 61 is most likely the correct number for the fourth data point, as noted in the SC&A review, this observation did not alter any conclusions in the TIB" (NIOSH, 2022, p. 2).

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[1] The present reviews of ORAUT (2014, 2015) were focused on determining if NIOSH has implemented methods for treating censored data that resolve the issues raised in observation 2. They do not constitute in-depth technical reviews of these reports, which are beyond the scope of our present task.

SC&A reply on observation 3

SC&A recommended that observation 3 be closed.

SPR action on observation 3

The SPR voted to close observation 3.

Observation 4

> The mirror image and preserved mean and variance methods are not supported by any technical background in statistical theory of which we are aware.

NIOSH response to observation 4

> NIOSH concurs that there are more modern methods for assessing data. A more modern method to handle the sum of normal noise and lognormal signal is the normal-lognormal mixture distribution. It is described in ORAUT-RPRT-0096, *Multiple Imputation Applied to Bioassay Co-Exposure Models* [ORAUT 2021]. The methods, as described in Battelle-TIB-5000, Section 2.3.1, are not currently being used. [NIOSH, 2022, p. 2]

SC&A reply on observation 4

SC&A reviewed ORAUT (2021), which includes the following instructions for the analysis of nonpositive data using mixture imputation:

> 1. Estimate how the bioassay results in each year are distributed using a normal-lognormal mixture model. The imputation models are given by the lognormal components of the mixture and the ILs [(imputation levels)] by the normal components.
>
> 2. Replace nonpositive bioassay results below the IL in all years with random draws from the appropriate imputation models, conditioned on the value being less than the IL. [ORAUT, 2021, p. 18]

We agree that this constitutes an updated methodology for analyzing the sum of normal noise and lognormal signal.[2]

SC&A recommends that observation 4 be closed.

Observation 5

> Battelle-TIB-5000 lacks a sound basis for asserting that the NCRP assessment of the reliability of the ICRP [International Commission on Radiological Protection]

[2] The present review of ORAUT (2021) was focused on determining if NIOSH has implemented methods for analyzing the sum of normal noise and lognormal signal that resolve the issues raised in observation 4. It does not constitute an in-depth technical review of this report, which is beyond the scope of our present task.

> Publication 30 models can be applied to the currently used ICRP Publication 66 respiratory tract and biokinetic models.

NIOSH response to observation 5

"NIOSH is currently addressing this observation. We will include it in a separate report" (NIOSH, 2022, p. 2).

SC&A reply on observation 5

"[Dr.] Anigstein: . . . Observation 5: Where, obviously, it remains open. It has not been addressed yet" (ABRWH, 2022, p. 35).

Observation 6

> A GSD [geometric standard deviation] of 10, derived from redundant data across seven uranium refining plants, is excessive for a sitewide assessment of an individual worker.

NIOSH response to observation 6

> NIOSH concurs that the use of a GSD of 10 for an entire site, plant, or factory might be excessive. A GSD of 10 as described in Battelle-TIB-5000, Section 3.6, is not currently being used. As noted in the SC&A comments, NIOSH is using a GSD of 5 as the default value in DRs [dose reconstructions] when no other uncertainty data are available [NIOSH 2011]. A minimum GSD of 3 is often used for biokinetic modelling. [NIOSH, 2022, p. 2]

SC&A reply on observation 6

> Dr. Anigstein: . . . Now, observation six: We concur with NIOSH's use of GSD of 5 as the default value in DRs when no other uncertainty data are available. However, NIOSH needs to provide a basis for the assertion that a minimum GSD of 3 is often used for biokinetic modeling. As stated in our review of Battelle-TIB-5000, and I quote, Battelle cites an email correspondence from Bihl, et al., . . . (2006), with the title "Bases for GSD equals 3 for internal dose used by NIOSH. However that email according to, Tim Taulbee, . . . is not retrievable from 2006. So therefore, we note that, as [Dr.] Cardarelli stated, . . . NIOSH is developing a separate report to address the use of GSD [of] 3 for biokinetic modeling, but pending review of that resolution, we recommend that . . . observation 6 remain open.
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> Dr. Taulbee: . . . This really kind of subsumed into observation 5, because it's the same that — . . .
>
> Dr. Anigstein: The . . . two turn out to be related. [ABRWH, 2022, pp. 35–36]

Observation 7

> Dividing the operation—"removing covers from drums"—that was observed to take 24 minutes per shift, into two 12-minute periods, characterized by low and high radon concentrations, respectively, is arbitrary and not claimant favorable.

NIOSH response to observation 7

> NIOSH concurs that there are better statistical methods for consolidating data into a statistic to be used for dose reconstruction. NIOSH does not employ the results of the time-weighted average example in Battelle-TIB-5000, Section 3.8 for dose reconstructions at Lake Ontario Ordinance Works (LOOW). [NIOSH, 2022, p. 3]

SC&A reply on observation 7

SC&A performed a focused review of NIOSH (2019), which describes a proposed DR methodology for LOOW. The aim of this review was to confirm the NIOSH response to observation 7. According to this document,

> Substantial radon monitoring . . . occurred between 1948 and 1953, with a gap in monitoring between 1953 and 1974. These sample data were broken out into high, medium, and low categories based on their results, with a geometric mean established for each category. . . .
>
> For purposes of dose reconstruction, the indoor value of 108 pCi/L was used. [NIOSH, 2019, pp. 8–9]

Since NIOSH (2019) proposes a fixed radon concentration for DRs, we agree that "NIOSH does not employ the results of the time-weighted average example in Battelle-TIB-5000, Section 3.8 for dose reconstructions at . . . LOOW" (NIOSH, 2022, p. 3).[3]

SC&A recommends that observation 7 be closed.

Observation 8

> The procedure for assessing inadvertent ingestion for residual periods at AWE [Atomic Weapons Employer] sites has been updated since the issuance of TIB-5000.

NIOSH response to observation 8

> NIOSH concurs that the use of OCAS-TIB-009, *Estimation of Ingestion Intakes* [NIOSH 2004], to assess inadvertent ingestion during an AWE site's residual period is not appropriate. During an AWE site's residual period, NIOSH is currently standardizing our approach to be consistent with NUREG/CR-6755

[3] The present review of NIOSH (2019) was focused on determining if NIOSH has proposed DR methods for estimating radon exposures that resolve the issues raised in observation 7. It does not constitute an in-depth technical review of this methodology, which is beyond the scope of our present task.

> [NUREG/CR-6755 2002] which is based upon NUREG/CR-5512 (1992) Volume 1. Section 6.3.2 for guidance on inadvertent ingestion [NUREG/CR-5512 1992]. [NIOSH, 2022, p. 3]

SC&A reply on observation 8

NIOSH needs to clearly specify the hourly ingestion rate, based on hand-to-mouth transfer from a contaminated surface, as was discussed during the SPR teleconference meeting:

> [Dr. Anigstein:] This is a technical issue that we're raising with the procedure for inadvertent ingestion [that] no longer uses OCAS-009. It relies on a set of NUREG reports, which . . . [include] NUREG CR 6755 [Biwer et al., 2002], which is based on in principle, NUREG CR 5512, Volume 1 [Kennedy & Strenge, 1992]. However, we noticed that if you take together . . . NUREG CR 6755, NUREG[/CR-]5512, Volume 3 [Beyeler et al., 1999], which is a later revision of Volume 1, it came . . . 7 years later. And there are three different values for the ingestion rate. They're not very different, but . . . [NUREG/CR-]6755 recommended the mean . . . ingestion rate from contaminated surface of 1.12 [×] 10[$^{-4}$ m^2/h] . . . And [NUREG/CR-]5512, Volume 3 has a value of 1.1 [×] 10[$^{-4}$] . . . so it's about 2 percent less, but it's still more favorable than the rate of simply 1 [×] 10[$^{-4}$] . . . This is in NUREG . . . [/CR-]5512, Volume 1.
>
> And I could just add parenthetically that Volume 3 is an update of Volume 1. It was . . . a different set of authors, came seven years later. So we would recommend that NIOSH first of all, specifies which of these three, because a dose reconstructor could have, based on what we've seen -- not have guidance as to which of these three values to use, and 1.1 . . . [$\times 10^{-4}$] seems to be the more robust value because it's a mean of [an] uncertainty distribution, whereas the Volume 1 [value], it's just a qualitative assertion. So anyway, until this has been a resolved, [we] recommend observation 8 remain open. [ABRWH, 2022, pp. 36–37]

SPR action on observation 8

"[Chair Beach:] NIOSH needs to come back with observation 8, which volume they're using, clarifying that after Bob writes his . . . notes on that" (ABRWH, 2022, pp. 42–43).

Observation 9

> The revised guidance on dose reconstruction from occupational medical x-ray procedures (ORAUT-OTIB-0006, revision 05) should be used for the assessments of external doses from such procedures.

NIOSH response to observation 9

"NIOSH concurs and is using the current version of ORAUT-OTIB-0006 when performing current . . . dose reconstructions [ORAUT 2018]" (NIOSH, 2022, p. 3).

SC&A reply on observation 9

SC&A recommended that observation 9 be closed.

SPR action on observation 9

The SPR voted to close observation 9.

Observation 10

> Missed doses should be assigned according to the current procedures: OCAS-IG-001, revision 3, and ORAUT-OTIB-0020, revision 03. Assigning a triangular distribution with minimum = 0, mode = 0.5 × LOD, and maximum = LOD is not consistent with current guidance.

NIOSH response to observation 10

> NIOSH agrees that external missed dose should not be assigned using a triangular distribution. Guidance associated with assignment of external missed dose is covered in OCAS-IG-001, *External Dose Reconstruction Implementation Guideline* [NIOSH 2007] and ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Dose Assignment* [ORAUT 2011]. The method described in Battelle-TIB-5000, Section 3.14, is not currently being used. [NIOSH, 2022, p. 3]

SC&A reply on observation 10

> [Dr. Anigstein:] Missed doses . . . are now based on OCAS-IG-001 and ORAUT-OTIB-20. . . . SC&A has at various times reviewed these documents. We found them to be acceptable, and therefore . . . [we recommend that] observation 10 should be closed. [ABRWH, 2022, p. 37]

SPR action on observation 10

The SPR voted to close observation 10.

Observation 11

> Ingestion should be added to the pathways of environmental doses.

NIOSH response to observation 11

> NIOSH agrees that ingestion is a possible pathway of environmental intakes and should be considered when developing an environmental exposure approach. ORAUT-PROC- 0031, *Site Profile and Technical Basis Document Development* [ORAUT 2012 . . .], Section 6.7.3, call for the ingestion pathway to be evaluated if it is applicable to the site. [NIOSH, 2022, p. 4]

SC&A reply on observation 11

"[Dr. Anigstein:] We confirmed that soil and water ingestion are cited as environmental pathways in . . . ORAUT-PROC-0031 [ORAUT 2012]. We recommend that observation [11] be closed" (ABRWH, 2022, p. 37).

SPR action on observation 11

The SPR voted to close observation 11.

Observation 12

> Using a lognormal distribution with a mean value of 0.02 to represent an equilibrium factor for thoron is questionable. A bounding, site-specific equilibrium factor should be derived as needed, based on available data.

NIOSH response to observation 12

"The equilibrium factor, as described in Battelle-TIB-5000, Section 3.17.3, is not currently being used. Guidance associated with the thoron equilibrium factor is provided in DCAS-TIB-011, *Dose Conversion Factors for Radon WLM* [NIOSH 2018]" (NIOSH, 2022, p. 4).

SC&A reply on observation 12

We have reviewed NIOSH (2018) and observe that this document does not employ the equilibrium factor cited in Battelle-TIB-5000, section 3.17.3, which could be used to calculate a worker's exposure to thoron in working level months (WLM). Furthermore, according to NIOSH (2018), such a calculation is not used in a DR:

> The Interactive RadioEpidemiological Program (IREP) is used to determine the Probability of Causation (POC) that a cancer was caused by occupationally related radiation exposure. Annual radiation dose is the normal IREP input but in the case of Rn-222, a direct exposure model is also included for lung cancers. The exposure model was based on studies performed at uranium mines and thus applies to Rn-222 and its associated decay products. Rn-220 (also known as thoron) . . . decay products have characteristics that are sufficiently different from Rn-222 so that the exposure model is not applicable to Rn-220. [NIOSH, 2018, p. 4]

SC&A finds that NIOSH (2018) does present guidance for calculating an individual's exposure to thoron and the subsequent organ doses.[4] SC&A recommends that observation 12 be closed.

Observation 13

> Even if the true underlying distribution of concentrations were lognormal, there is no real reason to assume that the distribution of the uncertainty of the representativeness parameter is also lognormal.

NIOSH response to observation 13

"NIOSH concurs that there are more modern methods for dealing with uncertainty distribution. This method, as described in Battelle-TIB-5000, Section 3.20, is not currently being used" (NIOSH, 2022, p. 4).

[4] The present review of NIOSH (2018) was focused on determining if NIOSH has replaced the thoron equilibrium factor cited in TIB-5000 and thus resolved the issues raised in observation 12. It does not constitute an in-depth technical review of NIOSH (2018), which is beyond the scope of our present task.

SC&A reply on observation 13

> [Dr. Anigstein:] NIOSH said there are more modern methods of dealing with the uncertain[ty] distribution. However, they don't specify what are these more modern methods so we can . . . evaluate NIOSH's solution to observation 13 . . . pending this clarification, we recommend observation 13 remain open. [ABRWH, 2022, p. 38]

SPR action on observation 13

"[Chair Beach:] I think NIOSH needs to answer that question on 13, what methods are being used" (ABRWH, 2022, p. 41).

Summary

SC&A has reviewed the NIOSH (2022) responses to our original review (Anigstein & Gogolak, 2022) of Battelle-TIB-5000. Our review resulted in 13 observations. Based on the NIOSH responses, SC&A recommended closing observations 1, 3, and 9–11. At its September 29, 2022, teleconference meeting, the SPR voted to close these five observations. The SPR further tasked SC&A with reviewing several documents cited by NIOSH as resolving some of the issues raised in several remaining observations. Following such reviews, as discussed in the present memo, SC&A recommends closing observations 2, 4, 7, and 12. The SPR left observations 5 and 6 open, pending a report from NIOSH addressing the issues raised by these observations.

The SPR left observation 8 open, pending clarification from NIOSH as to which rate of inadvertent ingestion is to be applied during the residual period at AWE sites. To recapitulate the SC&A oral presentation at the SPR teleconference (ABRWH, 2022, pp. 36–37), three ingestion rates have been presented. The earliest one was in NUREG/CR-5512, vol. 1 (Kennedy & Strenge, 1992), which lists a value of 1×10^{-4} square meters per hour (m^2/h). The next publication, NUREG/CR-5512, vol. 3 (Beyeler et al., 1999), reports an uncertainty analysis with a geometric mean of 1.1×10^{-4} m^2/h. The third value, 1.12×10^{-4} m^2/h, is from Biwer et al. (2002), who cite Kennedy and Strenge (1992) as their source. SC&A is of the opinion that Beyeler et al. provide the most robust value.

The SPR left observation 13 open, pending clarification from NIOSH of its methods for dealing with uncertainty distributions.

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