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SC&A RESPONSE TO NIOSH WHITE PAPER ON FMPC MOBILE IN VIVO RADIATION MONITORING LABORATORY CALIBRATION AND DATA INTERPRETATION AND ASSOCIATED REFERENCES

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ABBREVIATIONS AND ACRONYMS

ABRWH or Board	Advisory Board on Radiation and Worker Health
AEC	Atomic Energy Commission
FEMP	Fernald Environmental Management Project
FMPC	Feed Material Production Center
keV	kilo electron volt
LOD	limit of detection
MDA	minimum detectable activity
mg	milligrams
MIVRML	Mobile In-Vivo Radiation Monitoring Laboratory
nCi	nanocuries
NIOSH	National Institute for Environmental Safety and Health
NLO	National Lead of Ohio
ORAUT	Oak Ridge Associated Universities Team
REMAB	Radiation Equivalent Manikin Absorption
ROI	Region of Interest
SC&A	S. Cohen and Associates
SEC	Special Exposure Cohort
SRDB	Site Research Database
µCi	microcurie

1.0 INTRODUCTION

1.1 Historical Milestones Leading up to This Report

The issue of the use of chest count data to reconstruct intakes of Th-232 for workers at Fernald[1] has been the subject of several Work Group discussions and numerous white paper exchanges. A summary of these interactions is provided herein to orient the reader as to how this complex issue has evolved.

During the Fernald Work Group meeting held on January 29, 2010, SC&A identified six issues that were discussed by the Fernald Work Group. Issue 6 is concerned with the National Institute for Occupational Safety and Health's (NIOSH's) approach for reconstructing the doses to workers exposed to Th-232. This issue has two parts. The first part deals with pre-1968 breathing zone samples and the degree to which that data can be used to reconstruct worker internal exposures to Th-232. The second part of this issue is the use of chest count data to reconstruct Th-232 internal exposures post-1968 and is the subject of this technical response.

Prior to the January 29, 2010, meeting, NIOSH had provided a white paper describing their approach to using chest count data to reconstruct worker doses to Th-232, and to build a coworker model using these data. The title of the Oak Ridge Associated Universities Team (ORAUT) white paper is *Thorium In Vivo Coworker Study for FEMP – A Proposed Attachment for ORAUT-TKBS-0017-5, Rev. 1* (NIOSH 2008). The paper describes the use of in-vivo thorium chest monitoring results to build a coworker model and assign thorium intakes to unmonitored workers during the period 1968–1989.

In June 2010, SC&A transmitted its review of the proposed NIOSH thorium coworker model for the period of 1968–1989: *Review of Thorium In-Vivo Coworker Study for FEMP – A Proposed Attachment for ORAUT-TKBS-0017-5, Rev. 1* (SC&A 2010). SC&A (2010) performed two different kinds of analyses on the thorium in-vivo data. The first, associated with the quality of the data, is the subject of this report. The second involved investigating data completeness. SC&A (2010) identified eight findings related to data quality, which are summarized in the next section.

On February 3, 2011, NIOSH posted responses to the findings in SC&A (2010), which were discussed at the end of the February 8, 2011, Work Group meeting. In March 2011, SC&A provided a memo demonstrating the high degree of variability and uncertainty in Th-232 measurements reported in milligrams (mg), as tasked by the Board at the February 8 meeting (SC&A 2011). That memo was discussed in detail at the Fernald Work Group meeting held on April 19, 2011. NIOSH stated at that meeting that new documents related to the calibration of the Y-12 Mobile In-Vivo Radiation Monitoring Laboratory (MIVRML) and totaling over 300 pages had been located. NIOSH was tasked by the Board to post those documents to the common drive (referred to herein as the "O-Drive," access to which is restricted) and SC&A was tasked to review them for relevance to the data adequacy issue.

[1] The Fernald Site is also referred to as the Feed Materials Production Center (FMPC). Later, it was known as the Fernald Environmental Management Project (FEMP). All three names may be used in this report.

On May 6, 2011, NIOSH posted a draft white paper entitled *Mobile In Vivo Radiation Monitoring Laboratory Calibration and Data Interpretation* (NIOSH 2011) in response to the Board's request. In addition, references related to the calibration of the Y-12 MIVRML were posted on the O-Drive on June 2, 2011. This report provides SC&A's technical response to these documents in the context of data adequacy.

2.0 SUMMARY OF SC&A'S PREVIOUS FINDINGS REGARDING THE ADEQUACY OF IN-VIVO THORIUM DATA

SC&A 2010 identified the following eight findings regarding data adequacy; all are related to the fact that NIOSH has not demonstrated that it is possible to construct a coworker model due to important questions about the reliability of the thorium in-vivo results:

(1) The use of in-vivo samples reported in mg of Th for the period 1968–1978 might significantly underestimate the lung burden of thorium if the result was based on the gamma activity of thorium daughters Ac-228 and/or Pb-212 (SC&A 2010, Sections 2.1 and 2.7).

(2) SC&A questions whether enough evidence exists to justify the conversion factor 1 mg Th = 0.11 nCi, based on the small number of overlapping samples in 1978–1979 that have been used to justify the factor (SC&A 2010, Section 2.2).

(3) There is a high amount of imprecision present in the pre-1979 data, as shown in individual worker records with implausibly large changes in reported lung burden over relatively short time periods. This could be explained by varying exposures to more heterogeneous mixtures of thorium and its daughter products, but may also have implications as to the reliability of in-vivo measurements during this period (SC&A 2010, Section 2.3).

(4) The reported thorium minimum detectable activity (MDA) of 6 mg appears incompatible with actual positive results reported for Fernald workers. Furthermore, the 84th percentile values presented in the coworker study were all below this 6 mg threshold, with the exception of 1968 (SC&A 2010, Section 2.4).

(5) There is no information provided on the counting time and calibration methods for measuring Pb-212, which calls into question how in-vivo results are being interpreted (SC&A 2010, Section 2.5).

(6) Given the lack of information on the MDA and uncertainties on the significance of the in vivo Pb-212 results, SC&A questions the credibility of the positive Pb-212 results. All derived results at the 84th percentile in the period 1978–1989 are positive results, yet are below the plausible MDAs for Pb-212 (SC&A 2010, Section 2.6).

(7) SC&A feels more justification is required to validate the assumed Pb-212: Th-232 activity ratio of 0.71 (the midpoint of the theoretical range of 0.42–1). Studies suggest that the ratio shows considerable variation and, in some cases, has been found to be

significantly smaller than the lower bound of 0.42 assumed by NIOSH (SC&A 2010, Section 2.7).

(8) Data for identified thorium workers suggest a large number of negative results for Pb-212, which may indicate an overestimation of the natural background component of Pb-212 and possibly a systematic underestimation of thorium lung burdens (SC&A 2010, Section 2.8).

3.0 SC&A'S RESPONSE TO NIOSH'S DRAFT WHITE PAPER (NIOSH 2011)

Section 1 of NIOSH (2011) states that the purpose of the paper is to describe the calibration processes associated with thorium chest count data produced by the MIVRML, which was used periodically at FMPC from 1968 through 1988, and to respond to the issues identified by SC&A. Those responses were subdivided into Sections 2 to 11.

In responding to NIOSH (2011), SC&A first provides a summary of the MIVRML and associated issues, followed by topical responses organized by section.

From 1968 to 1988, the Y-12 MIVRML was used at Fernald to obtain the in-vivo chest results for use in calculating thorium lung burdens. From 1968 through 1978, the results were reported as thorium mass (mg of Th-232) in nearly all cases. During 1979–1988, the results were reported as activity [nanocuries (nCi)] of the Th-232 chain members Ac-228 and Pb-212 in nearly all cases. The differences in reporting conventions before and after 1978 were resolved by changing all reporting units to nCi. For the thorium data reported in mg, the mass-to-activity conversion assumed that all of the mass of natural thorium is associated with Th-232. The specific activity factor used for this conversion was 0.11 nCi of Th-232 per mg of natural thorium.

NIOSH could not determine the measured quantities and assumptions underlying estimated lung burdens recorded as mg of thorium (NIOSH 2008). Presumably, the measured quantity was gamma emissions from Ac-228 and/or Pb-212. NIOSH noted that measured activity of Ac-228 may not be a useful indicator of Th-232 activity in the lungs of Fernald workers, because chemical purification of thorium occurred as a routine part of thorium processing. Purification would remove Ac-228 and, as a result, a chest count may observe little or no Ac-228, but substantial quantities of Th-232 may nonetheless be present. On the other hand, measured activity of Pb-212 is regarded by NIOSH as a useful indicator of Th-232 activity on the theoretical basis that the activity ratio Th-228:Th-232 would never be less than about 0.422 following chemical separation of the Th-232 chain, and the activity ratio Pb-212:Th-228 is not expected to be substantially less than 1.0 in the lungs for prolonged periods. To convert in-vivo measurements recorded as Pb-212 to an estimated lung content of Th-232, NIOSH assumes a Pb-212:Th-232 ratio of 0.711, representing the midpoint between secular equilibrium (ratio of 1.0) and the minimum theoretical ratio (0.422) for a closed system after chemical separation of Th-232 and Th-228 from other members of the Th-232 chain.

As explained in the introduction of NIOSH (2011) and in NIOSH's papers related to thorium chest measurements, from 1968 through 1977, the amount of thorium in a worker's chest was

reported in units of mg. By 1978, thorium activity in the chest was reported for the thorium isotope progeny, Ac-228 and Pb-212, with activity reported in units of nCi. Although NIOSH (2011) states that the reporting of mg thorium ended in 1977, SC&A found that it was still used for the majority of measurements in 1978. We estimate that in 1978, there were 144 counts in mg Th, and 34/35 counts of Pb/Ac respectively.

3.1 Section 2 (NIOSH 2011)

Section 2 of NIOSH (2011) presents a description of the detectors that were used in the MIVRML. Table 1 of that document shows the minimum limits of sensitivity of the in-vivo system for thorium in 1969, when results were reported in mg of thorium. Table 2 shows the minimum limits of sensitivity in 1987, with the detection for Th-232 daughters Ac-228 and Pb-212. NIOSH does not report what mixture of thorium and daughters is measured to give the minimum sensitivity of 6 mg of thorium in the lung.

According to NIOSH (2011), because thorium cannot be directly measured by in-vivo lung counting, either Ac-228 and/or Pb-212 were used to indirectly measure thorium lung burdens, which were then reported in units of mg thorium. As pointed out in NIOSH (2008), the thorium materials that were sources of exposure to workers had been previously chemically purified. Following chemical purification, the isotopic ratio of daughter products is disrupted and the assumption of approximate equilibration between Th-232 and Th-228 is not accurate until two or three decades have passed. In the interim between chemical separation and equilibration, the isotopic ratios of the radionuclides in the decay chain are variable, as was shown in Figure 3 of NIOSH (2011).

The minimum sensitivity of 6 mg is attributed to the mass of Th-232, because of its very low specific activity. Th-232 activity is determined through the measurement of Pb-212 and/or Ac-228. As a consequence, for fixed limits of sensitivity of Pb-212 and Ac-228, the limit of sensitivity for the Th-232 lung burden will vary, depending on the ratio of Th-232/Th-228 and of Th-232/Ra-228. The following exercise provides an example to illustrate this dependence on the time between thorium purification and measurement. For this example, it is assumed that the Th-232 decay chain members exist in a closed system. If the minimum sensitivity of Pb-212 was ***x*** nCi, the corresponding activity of Th-232 can vary from ***x*** nCi to a maximum of ***x*** nCi / 0.42 = ***2.38 x*** nCi, at 4.5 years after purification, depending on the time that has elapsed between measurement and purification (as shown in Figure 3 of the NIOSH (2011). Thus, if the minimum sensitivity of 6 mg of Th-232 was calculated assuming Th-232 was in equilibrium with the daughters, the minimum sensitivity at 4.5 years after purification would be 14.3 mg of Th-232 lung burden.

Scott (1966) describes a technique of monitoring for lung-deposited thorium by in-vivo gamma spectrometry, which was used in the Atomic Energy Commission's (AEC's) Y-12 Plant operated by Union Carbide. It states that calibration standards had a Th-232 to Th-228 ratio of 1.27 and a Th-232 to Ra-228 ratio of 1.67, and that the lower limit of detection for such material was 6 mg. **It is noteworthy that the two ratios given in the Scott paper are not possible for a single thorium source that has been purified.** Either there is a mistake on the Th-232/Ra-228 ratio or the calibration source was not a source of purified thorium that decayed for some time before it

was measured. In the latter case, the minimum sensitivity of 6 mg would not apply to the thorium material handled at Fernald. Scott's paper also suggests that an excess of Ra-228 from non-thorium sources may have been present in their standard. Scott (1966) indicates that radium exposures can be distinguished from thorium by evaluation of the decay patterns of Ac-228 and Pb-212. This is done by repeated measurements over a long period of time and observing the decay and in-growth patterns. A thorium assay based on Pb-212 would therefore be biased by the introduction of Ra-228 in amounts in excess of that associated with the decay of the Th-232 source.

SC&A notes that document SRDB 012047 (NLO 1966) contains a letter from 1966 commenting on differences between measurements of a worker who did in-vivo monitoring at Y-12 and at the Wright–Patterson Air Force Base. That document states that the minimum detection at Y-12 was 9.8 mg of Th-232, not 6 mg.

In summary, there does not appear to be precise information on the sensitivity of lung counting results reported in mg for Th-232 materials handled at Fernald.

3.2 Section 3 (NIOSH 2011)

In Section 3, NIOSH describes the three phantoms used for calibration of activities. The paper, *Calibration and Use of a Lung Monitoring Facility Using Sodium Iodide Detectors* (King and Barclay 1983), describes the derivation of conversion factors and the three phantoms that were used. In relation to the REMAB phantom, a torso-shaped plastic shell containing a human skeleton and filled with tissue equivalent organic fluid, the paper describes that sponge material was used in the lung cavity to simulate lung tissue, and that small sources were inserted into holes in the sponge material. The paper points out that past studies have shown that monitoring results can vary by a factor of 3 or more with source positioning inside the lung cavity. The REMAB phantom was used from the early 1970s until 1983, when it was replaced by the Lawrence Livermore Realistic Phantom (Bogard 1999).

In summary, the results from in-vivo lung counting until 1983 might be erroneous by a factor of 3 or more, due to calibration problems.

3.3 Section 4 (NIOSH 2011)

In Section 4, 'Calculation of Thorium Mass from Chest Count Data,' NIOSH presents a description of a methodology proposed by West (1965):

> *The ROIs at 330 and 900 keV include the gamma rays from ^{228}Ac which is directly related to the ^{228}Ra activity. The total counts in the three ROIs were summed. Each of the ROIs was paired with an ROI directly adjacent and higher in energy. The total count in the three adjacent ROIs was also summed and the ratio of the sums was computed. A study of 1,100 people who were not exposed to thorium revealed that the ratio was 3.23 ± 0.70 for unexposed people. A ratio in excess of 3.93 was assumed to indicate the presence of thorium in the lung.*

West's paper does not advocate this method of monitoring for quantitative assessment of thorium burden in the lung, but as a screening method to distinguish exposed from unexposed workers. The paper points out that there are problems associated with monitoring of personnel exposed to thorium, such as the knowledge of the ratio of Th-232 to Th-228, since this ratio changes with time after separation of thorium from its daughters (chemical purification), and the fact that the interpretation of monitoring results depends on:

> *…the metabolic or physical translocation of daughters away from the location of the parent stored in the body.* ***Such translocation can affect the reliability and sensitivity of in vivo interpretation if the gammas measured are those from daughters subject to translocation.*** *On the other hand, translocation could be used in dose estimates if the amount of translocated daughters eliminated from the body can be related to the amount of parent remaining.* [Emphasis added]

There are no excreta measurements of thorium daughters for Fernald workers; thus, the method presented in West (1965) is limited to qualitative assessments of potential thorium intakes. As pointed out in Section 2.7 of SC&A (2010), there are several published papers stating that the behavior of Ra-228 and consequently the retention of the daughters in the lung might be different from Th-232.

Lung Counter Calibration Runs (1976) was posted by NIOSH on the O-Drive among the references related to the calibration of the MIVRML. Pages 6 and 7 of this document illustrate the imprecision of derived thorium lung burdens when the time of purification of the thorium source is not known. It describes measurements with Pb-212 results of 2.85 and 3.15 nCi, with an average of 3.00 nCi, and Ac-228 results of 2.75 and 2.8 nCi, with an average of 2.78 nCi. The ratio of Pb-212/Ac-228 equals 1.08, which leads to the conclusion that the age of the source was 4.3 years. There is a note stating that the exposure source could also be in equilibrium, which would better agree with knowledge of case history. The document further shows:

- A result of 3.962 nCi (36 mg) of Th-232 if 16 years old and 79% equilibrium was assumed
- A result of 3 nCi (27.6 mg) of Th-232, assuming equilibrium
- A result of 56 mg of Th-232 (Th-232= 2.21 Ac-228= 6.14nCi= 56mg), assuming 4.3 years after purification

Based on this example, a factor of 19 error could be introduced by assuming an incorrect in-growth period for a previously purified thorium source.

On page 12 of *Lung Counter Calibration Runs* (1976), there are notes stating that new calibration coefficients caused a 4% difference in the Pb-212 to Ac-228 ratio, which translates into a 16% difference in equilibrium assumptions. There is no precise information on when the new calibration coefficients started to be used, but the dates of the notes in the document indicate that it was near the end of 1977. NIOSH does not give any information on this subject.

In summary, the method used to estimate thorium burdens in mg carries many uncertainties and should only be used for qualitative assumptions about thorium burdens, as indicated in West (1965), the paper cited by NIOSH as the basis document for the calculation of thorium mass from chest count data. In addition, there were new calibration coefficients that affected the interpretation of Th-232 burdens, but NIOSH was silent on this subject.

The lack of knowledge on the in-growth age of the thorium source material at the time of exposure contributes significant uncertainty in estimates of the Th-232 lung burden. In addition, the lack of knowledge on the time after exposure that the workers were monitored, during which time the proportion of daughter products might have changed because of physical decay and or/differences in translocation rates from lung to body fluids and organs, introduces uncertainties in the interpretation of daughter results in terms of Th-232 activities in the lung. This is true for the period when results are given in mg of Th-232 (1968–1978) and for when results are given in activities of Pb-212 (1979–1988).

3.4 Section 5 (NIOSH 2011)

In Section 5, NIOSH describes the efficiencies of the detectors in relation to Ac-228 and Pb-212 and how the activities of those radionuclides were calculated in 1982. SC&A has nothing to add, except for the uncertainties related to the use of the REMAB phantom, described in Section 3.2 of the present document.

3.5 Section 6 (NIOSH 2011)

In Section 6, NIOSH assumed that the limit of sensitivity of Th-232 in lung would be 5.4 mg after 1987, based on comparisons to the limit of sensitivity for uranium in 1967 and 1987. It then concludes that a conversion factor of 0.044 nCi of Ac-228 per mg of Th-232 should be applied, assuming secular equilibrium between thorium isotopes and progeny. **It is significant that those calculations are based on assumptions and not actual measurements.**

As pointed out in Section 3.1 of this report, the 6 mg limit of sensitivity was derived for a material that had a Th-232/Th-228 ratio of 1.27 and excess Ra-228 (Scott 1965), while NIOSH assumed limits of sensitivity of thorium material in equilibrium.

As pointed out in Section 3.3 of this report, new calibration coefficients for Pb-212 and Ac-228 were introduced in 1977, causing a difference in the mass calculation of the Th-232 lung burden.

In summary, SC&A believes that uncertainties in the conversion of activity to mass for Th-232 have not been satisfactorily resolved.

3.6 Section 7 (NIOSH 2011)

In Section 7, NIOSH proposes to replace the equilibrium ratio of 0.71 for Th-232/Th228, with the theoretical low value of of 0.42 for a closed system, to ensure claimant favorability.

The use of the 0.42 ratio of Th-232/Th-228 can be considered claimant favorable only for the period for which there are Pb-212 in-vivo results.

3.7 Section 8 (NIOSH 2011)

SC&A has no comments on Section 8 of NIOSH (2011).

3.8 Section 9 (NIOSH 2011)

SC&A (2010) and SC&A (2011) provide examples of large variations and uncertainties in the thorium in-vivo results. As NIOSH pointed out in Section 9, the results in mg theoretically below detection limits carry a lot of uncertainties. In addition, as explained in Section 3.1, there are uncertainties related to the value of the minimum sensitivity of the Th-232 in mg. NIOSH has acknowledged the large variations and uncertainties in these data, and in Section 9 (page 12) suggests that they:

> *…could also be explained by other means such as surface contamination, large particle clearance from the upper respiratory tract, and possible ingestion exposure…*

This suggestion by NIOSH was discussed at the February 9, 2011,[2] and April 19, 2011, Work Group meetings. It was the general consensus among the Board members that radiation safety personnel were well aware of the influences of surface contamination, and that specific procedures and siting measures were taken to prevent it (ABRWH 2011, pp. 225–227) . Also, it has been stated in some documents (such as Scott et al. 1969) that the MIVRML be located next to a building where the worker would have access to showers and a specific set of clothing to be used only during in-vivo counting for the specific purpose of avoiding those kinds of false counts, so surface contamination does not seem like a viable option. Finally, SC&A questions whether an ingestion intake would necessarily show up in a chest count.

In summary, NIOSH has not suggested a method to account for large variations and uncertainties in the data that underlie the coworker model. Rather, they have indicated that they believe the data are adequate for use in a coworker model 'as is.'

NLO (1966) illustrates the variability in estimated thorium lung burdens for a worker monitored at two different sites. The document shows an exchange of correspondence describing a difference in monitoring results from a worker that was monitored at Y-12 and at the Wright-Patterson Air Force Base. One of the letters from 1966 states that the minimum detection at Y-12 is 9.8 mg of Th-232 (not 6 mg). It further states that Y-12 has re-evaluated the results and have come up with the following results:

- 7 mg, using Y-12 calibration and Wright-Petterson data
- 3 mg, using Y-12 routine technique and Wright-Petterson data
- 1 mg, using Y-12 routine technique and Y-12 data

[2] Transcript unavailable at the time of this draft (August 3, 2011)

In summary, SC&A believes that the data used by NIOSH to derive the coworker intake rates carry uncertainties and imprecisions that have not been resolved in a satisfactory manner.

3.9 Section 10 (NIOSH 2011)

Section 10 of NIOSH 2011 amounts to a short paragraph asserting that a large proportion of data below the MDA do not impugn the veracity of the coworker model. As explained in Section 3.1 of this report, SC&A still questions the MDA for thorium in mg, as well as the reported lung burden results in mg, which were assumed positive. These concerns are summarized in Findings #4 and #6 in SC&A (2010). NIOSH indicated in the April 19, 2011, Work Group meeting that they intend to assign missed intakes (LOD/2) for results less than the MDA, based on a chronic intake scenario. While NIOSH believes that this approach is claimant favorable, it calls into question the utility of a coworker model wherein only about 3% of the results are above the detection limit and can actually be used to reconstruct intakes (other than missed dose).

Another issue that was not resolved in the April 2011 meeting is the apparent paradox of granularity in the mg thorium data at levels below the MDA. That is, differences in intakes for subgroups of workers are readily identifiable at levels below the MDA. SC&A performed a preliminary examination of the distributions of mg thorium for all workers vs. those identified as chemical operators and thorium workers for the year 1968. We noted that all percentiles for the latter two groups are higher than for the all worker group. The 95% confidence intervals for the chemical operator and thorium worker group means are higher than and do not overlap the 95% confidence interval for the mean of the all-worker distribution. This indicates that the means of the thorium and chemical operator groups are significantly higher than the mean of the 'all other worker' group. The magnitude of the differences in the percentiles ranges from 0.5 mg at the 5^{th} percentile up to 1.5 mg at the 95^{th} percentile, and the difference at the mean, median, and 75^{th} percentile is approximately 1.3 mg. **This confirms that the differences noted in the graphs SC&A presented at the April 19, 2011, Work Group meeting are significant.** Subsequent analysis of the 95% confidence intervals for the mean in years from 1969 to 1978 failed to find significant differences in the mean values for the three groups of workers. Analysis of the nonparametric 95% confidence intervals for the 95^{th} percentiles of the three groups also failed to find significant differences.

The obvious question, then, is how can there be a significant difference of 1.3 mg in the means of the two groups of workers when the MDA is 6 mg? SC&A believes that the discussion in Section 3.1 and the example in Section 3.8 of this report cast serious doubt on the veracity of a 6 mg MDA. However, if one assumes for the moment that the true MDA is significantly higher (nominally 6 mg) than the mean difference of 1.3 mg, this becomes a special type of "non-detect" problem. Usually the non-detect values below the MDA are censored data, noted only by some notation such as "<LOD." In this case, the values below the MDA are not censored, but are "contaminated" by noise. The datasets all include both a noise component and a signal $x_{i,j} = m_j + e_{i,j}$, where the each group j has mean m_j with workers $i=1,\ldots,n_j$ and e is the noise term, which may have a non-zero mean somewhere between 0 and the MDA, and a standard deviation around 3 or 4 mg. **It is important that the noise term be the same for both groups of workers.** The difference in means between groups j and k is $\Delta \equiv E(x_{i,j}) - E(x_{i,k}) = m_j - m_k$.

If we estimate Δ using the difference in the arithmetic means, the variance of Δ will be determined by the sample sizes of the two groups. With a sufficiently large sample size, the estimated value of Δ will be statistically different from 0, indicating a significant difference in the means of the two groups.

Thus, under ideal conditions, it might be feasible to distinguish statistically significant subgroup differences at levels below the MDA. However, as noted above, the inconsistencies identified in NIOSH (2011) and associated references regarding the MDA for mg thorium cast serious doubt on the cited MDA of 6 mg.

In summary, SC&A believes that NIOSH has not adequately determined the veracity of the presumed MDA of 6 mg thorium. Furthermore, the high proportion of values below the reported MDA (nominally 95% or more) casts doubt on the utility of the proposed coworker model.

3.10 Section 11 (NIOSH 2011)

Section 11 of NIOSH (2011) consists of a brief statement asserting their belief that the chest count data are adequate for dose reconstruction, and that any issues are tractable in the dose reconstruction (technical basis document) context.

SC&A does not agree with NIOSH's assertion that the uncertainties in the in-vivo results have been solved, and that the existing chest measurement data can be used to reconstruct workers' doses.

4.0 CONCLUSION

Significant issues remain that raise questions about NIOSH's ability to construct a coworker model and whether the available data are adequate for that purpose. SC&A believes that these issues are important in both the dose reconstruction and Special Exposure Cohort (SEC) context.

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