Draft

SUMMARY OF SC&A CONCERNS REGARDING THE LATEST DOCUMENTS POSTED BY NIOSH TO COMPLEMENT THEIR WHITE PAPERS ON IN-VIVO THORIUM BIOASSAY

Contract No. 200-2009-28555

Prepared by

Joyce Lipsztein, PhD John Stiver, CHP

SC&A, Inc. 1608 Spring Hill Road, Suite 400 Vienna, VA 22182

April 2012

Disclaimer

This document is made available in accordance with the unanimous desire of the Advisory Board on Radiation and Worker Health (ABRWH) to maintain all possible openness in its deliberations. However, the ABRWH and its contractor, SC&A, caution the reader that at the time of its release, this report is predecisional and has not been reviewed by the Board for factual accuracy or applicability within the requirements of 42 CFR 82. This implies that once reviewed by the ABRWH, the Board's position may differ from the report's conclusions. Thus, the reader should be cautioned that this report is for information only and that premature interpretations regarding its conclusions are unwarranted.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	2 of 22

S. Cohen & Associates:	Document No.: Review of In-vivo Thorium Bioassay Issues
Technical Support for the Advisory Board on Radiation & Worker Health Review of	Effective Date:
	Draft – April 6, 2012
NIOSH Dose Reconstruction Program	Revision No.
	0 (Draft)
Summary of SC&A Concerns Regarding the Late	st
Documents Posted by NIOSH to Complement The	eir White Page 2 of 22
Papers on In-vivo Thorium Bioassay	Ū.
	Supersedes:
Task Manager:	
Date:	N/A
John H. Stiver, MS, CHP	
Project Manager:	Peer Reviewer(s):
Tojeet Munuger.	
Date:	John Mauro
John H. Stiver, MS, CHP	John Stiver
	Bob Barton

Record of Revisions

Revision Number	Effective Date	Description of Revision
0 (Draft)	04/06/2012	Initial issue

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	3 of 22

TABLE OF CONTENTS

Abbre	eviations	s and Acronyms	4
Introd	luction		5
	Backg	round	5
1.0	NIOS	H White Papers	7
	1.1	Example of Thorium Intake and Dose Calculation, Tom LaBone, February 24, 2012 (NIOSH 2012b)	7
	1.2	White Paper – Chronic Intake IRFs for Th-232; Calculation of Chronic Intake IRFs for Th-232 Assuming Shared Kinetics, Tom LaBone, February 2012 (NIOSH 2012a)	8
	1.3	NIOSH's White Paper, "Response to SC&A Response to NIOSH White Paper on FMPC MIVRML Calibration, November 2011" (NIOSH 2011d)	9
2.0		Papers Posted by NIOSH on February 24 th (before the February 29 th Board ng)	11
	2.1	SRDB 32612 – Lung Counter Thorium Calibration Runs, Author Unknown 1976	11
	2.2	SRDB 32614 – Mobile Lung Counter Conversion Factors, 1982	12
	2.3	SRDB 11596 – Health Physics Considerations Associated With Thorium Processing, C.M. West (1965)	13
	2.4	Document SRDB 701 – A Technique for Assessing Thorium Body Burdens Utilizing In-vivo Gamma Spectrometry, L.M. Scott, 1966	16
	2.5	Document SRDB 32615 – Rule of Thumb for Computing Thorium Body Burdens from In-vivo Counts, L.M. Scott, 1961	16
3.0	SC&A	Conclusions	18
Refer	ences		20

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	4 of 22

ABBREVIATIONS AND ACRONYMS

ABRWH or the Board	Advisory Board on Radiation and Worker Health
ALI	Annual Limit on Intake
Bq	Becquerel
Ci	Curies
cpm	counts per minute
dpm	disintegrations per minute
FEMP	Fernald Environmental Management Project
FMPC	Feed Materials Production Center
kg	kilogram
ICRP	International Commission on Radiological Protection
IRF	Intake Retention Fraction
keV	kilo electron volt
LLNL	Lawrence Livermore National Laboratory
μg	microgram
MDA	Minimum Detectable Activity
mg	milligrams
MIVRML	Mobile In-Vivo Radiation Monitoring Laboratory
nCi	nanocurie
NIOSH	National Institute for Environmental Safety and Health
ORAUT	Oak Ridge Associated Universities Team
rem	roentgen equivalent man
ROI	Regions of Interest
SC&A	S. Cohen and Associates (SC&A, Inc.)
SEC	Special Exposure Cohort
SRDB	Site Research Database
Sv	Sievert
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	5 of 22

INTRODUCTION

In February 2012, the National Institute for Occupational Safety and Health (NIOSH) presented to SC&A and the Advisory Board on Radiation and Worker Heath (the Board) a set of documents claimed to be, "relevant references related to the estimation of thorium-232 [Th-232] intakes for Fernald workers using in vivo data from the Y-12 mobile counter (MIVRML)." Those references consisted of white papers produced by NIOSH and other documents that describe different approaches that could have been used to calculate Th-232 lung burdens [reported in units of milligrams (mg) of thorium] during the period 1968–1978. NIOSH's white papers are based on the unsupported assumption that Pb-212 was measured and Th-232 burdens in mg were calculated using those measurement results. This memo presents SC&A's interpretation of the relevance of these documents in supporting NIOSH's position.

BACKGROUND

A considerable amount of material and reports has been exchanged between NIOSH and SC&A on the usability of chest count data to reconstruct Th-232 internal exposures for monitored and unmonitored workers starting in 1968. The original coworker model was delivered in 2008 titled, *Thorium In Vivo Coworker Study for FEMP – A Proposed Attachment for ORAUT-TKBS-0017-5* (ORAUT 2008). In response, SC&A prepared a white paper review of the NIOSH coworker study in June of 2010 (SC&A 2010). Subsequent to this initial review, there have been several work group discussions and exchanges of information in the form of additional white papers and informal responses. The timeline of discussions and additional responses is summarized as follows:

- February 2, 2011: NIOSH releases its initial response to SC&A's review in two documents; *FMPC In Vivo Chest Count Bias Adjustment* (NIOSH 2011a) and *Response to SCA comments on Fernald Th232 coworker study* (NIOSH 2011b).
- February 8, 2011: SC&A review and NIOSH responses first discussed at the work group meeting.
- April 19, 2011: Issues are further discussed at the work group meeting. This work group meeting was the first instance in which the chest count data were discussed in detail.
- May 23, 2011: NIOSH releases report titled, *FMPC Mobile In Vivo Radiation Monitoring Laboratory Calibration and Data Interpretation – Draft 01* (NIOSH 2011c).
- August 3, 2011: SC&A releases second white paper, SC&A Response to NIOSH White Paper on FMPC Mobile In Vivo Radiation Monitoring Laboratory Calibration and Data Interpretation and Associated References (SC&A 2011), in response to previously released NIOSH documents.
- August 8, 2011: Recent exchange of white papers and documented responses are discussed at work group meeting.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	6 of 22

- November 10, 2011: NIOSH releases white paper response titled, *NIOSH Response to SC&A Response to NIOSH White Paper on FMPC MIVRML Calibration*, Rev. 00. (NIOSH 2011d).
- January 30, 2012: SC&A releases third white paper titled SC&A Final Position on the Th-232 In-vivo Data Quality and Adequacy for FEMP Workers (SC&A 2012).
- February 9, 2012: Recent exchange of white papers and documented responses are discussed at work group meeting.
- February 29, 2012: SC&A presents final position on the veracity of mg thorium data at the full Board meeting in Oakland, California.

SC&A has performed a detailed examination of all the documents provided by NIOSH and it does not appear that a plausible upper bound can be placed on the thorium results provided in milligrams of thorium in terms of real exposures to be used to bound thorium lung burdens, body burdens, or doses in a Special Exposure Cohort (SEC) context for the period of 1968–1978.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	7 of 22

1.0 NIOSH WHITE PAPERS

1.1 EXAMPLE OF THORIUM INTAKE AND DOSE CALCULATION, TOM LaBONE, FEBRUARY 24, 2012 (NIOSH 2012b)

SEC Issues

- This example problem illustrates an approach for calculating "worst-case" bounding organ doses from intakes of Th-232 based on Pb-212 chest measurements. Implicit in the approach is that Pb-212 activity was actually measured, and that the characteristics of the calibration standard used at FMPC are known. Despite several work group discussions, white paper exchanges, and extensive historic research, NIOSH has not demonstrated that Pb-212 activity measurements were actually used to calculate the Th-232 chest burden in mg.
- NIOSH has also failed to demonstrate the validity of their assumptions regarding the calibration standard used at Fernald. NIOSH assumed that a specific calibration standard (Scott 1966) was used to determine the activity of Th-232 in the lung based on the ratio of Th-232 to Th-228 (Pb-212) in the standard and Pb-212 measurement results. NIOSH did not demonstrate that this standard was used at FMPC or that this method, which is not correct, was used at FMPC.

Technical Evaluation

NIOSH calculated that a worker's Pb-212 chest burden of 10 mg at 1,095 days after an intake was equal to 32 Bq based on the assumption that the ratio of Pb-212 (Th-228) to Th-232 in the lung at the time of measurement was equal to the ratio in the Scott (1966) calibration standard. This assumption is not correct and there is no information showing that the people in charge of lung monitoring at FMPC made this mistaken assumption. Calibration standards and calibration phantoms are used to calculate the calibration factors that convert net count rates obtained from measurements in specific energy regions of interest (ROI) to an estimate of the radionuclide activity. Energy calibrations and resolution calibrations are also established to provide the energy per channel relationship for each spectrum and the system resolution as a function of energy that is used for peak identification and to establish the size of the energy ROI used in the calculations.

It is possible that a calibration standard similar to the one used by Scott might have been used to transform the counts in the Pb-212 and Ac-228 peak regions into activities in dpm or Ci of Pb-212 and Ac-228, although NIOSH has neither demonstrated that this occurred at Fernald during the 1968–1978 period nor that Pb-212 and Ac-228 activities were calculated. The relation between Th-228 (Pb-212) and Th-232 is not static, and the ratio of activities varies depending on the material that is measured. **The example given by NIOSH is hypothetical and is predicated on unsubstantiated assumptions; there is no information on how mg Th-232 values were calculated at FMPC.**

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	8 of 22

1.2 WHITE PAPER – CHRONIC INTAKE IRFS FOR TH-232; CALCULATION OF CHRONIC INTAKE IRFS FOR TH-232 ASSUMING SHARED KINETICS, TOM LaBONE, FEBRUARY 2012 (NIOSH 2012a)

SEC Issues

NIOSH applies the unsubstantiated assumption that Pb-212 activity was measured as described in Section 1.1 above to derive the Th-232 chest burden results.

Doing these types of calculations allows **conservative estimates of the Th-232 body burden to be made from the Pb-212 measurements** as long as the majority of the Th-232 and Pb-212 (and all daughters in between) is physically locked together in an insoluble particle in the body. [Emphasis added.] (NIOSH 2012a, page 3)

In Appendix A, the "maximum underestimation" of Th-232 chest burden is calculated assuming that Pb-212 activities were measured in the lung

However, if the person had inhaled thorium that had gone through three chemical separations at the worst possible times, **the 1 nCi of Pb-212 observed in the person** represents a chest burden of 47.9 mg of thorium rather than 9.1 mg. In this extremely unfavorable and unlikely case, the chest burden is underestimated by a factor of ~5.25. [Emphasis added.] (NIOSH 2012a, page 21)

Technical Evaluation

The paper is based on the assumption that Th-232 body burdens were calculated by measuring Pb-212, as explained on page 3 of NIOSH 2012a:

In vivo bioassay (whole-body and chest counting) for Th-232 is often performed by quantifying the activity of the Ac-228 or Pb-212 daughters in the body and then calculating the Th-232 (and relatively long-lived daughters Ra-228 and Th-228) present by assuming the material is in secular equilibrium. This is considered to be a reasonable assumption when:

- the inhaled thorium has been locked in an insoluble physical matrix for a long period of time, (e.g., for natural thorium mined from the ground); and
- *the inhaled thorium particulate does not dissolve in the lungs to any great extent.*

Thorium that has been chemically purified will consist primarily of Th-232 and Th-228. Daughters of Th-232 that are not isotopes of thorium will be absent immediately after purification and will begin to grow in. The daughters can exist in various degrees of disequilibrium with the parent Th-232 depending on the timing and number of separations. An example of this is presented in Appendix A

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	9 of 22

where the relative amounts of the Th-232 decay chain members present following three chemical separations are calculated. Doing these types of calculations allows conservative estimates of the Th-232 body burden to be made from the Pb-212 measurements as long as the majority of the Th-232 and Pb-212 (and all daughters in between) is physically locked together in an insoluble particle in the body. [Emphasis added.]

The key assumption that Pb-212 was measured to calculate Th-232 chest burdens as was done in the 1978–1988 timeframe has not been substantiated by NIOSH.

All examples of IRF calculations are correct, although there are available codes that can perform those calculations.

Appendix A has already been presented by NIOSH in *Response to SC&A Response to NIOSH White Paper on FMPC MIVRML Calibration, 2011.* As stated in SC&A (2012), SC&A agrees with NIOSH's bounding assumption of three consecutive separations on the source material for the period of 1979–1988, <u>when Pb-212 measurement results are available</u>. For the period of 1968–1978, there are no documents demonstrating that Pb-212 activities in the lung were measured and used to derive Th-232 chest burdens at FMPC. Despite a lack of supporting documentation for this fundamental assumption, NIOSH continues to base all arguments in favor of using the mg thorium data for dose reconstruction on the assumption that Pb-212 was measured to calculate Th-232 chest burdens. Because this assumption is not substantiated, all conclusions based on it are questionable and highly uncertain. In addition, there is no documentation that a phantom containing known activities of Th-232 and daughters was used to calculate Th-232 mass/activity in the lung, given Pb-212, Ac-228 or Tl-208 measured activities in the chest.

1.3 NIOSH'S WHITE PAPER, "RESPONSE TO SC&A RESPONSE TO NIOSH WHITE PAPER ON FMPC MIVRML CALIBRATION, NOVEMBER 2011" (NIOSH 2011d)

SEC Issues

The uncertainties related to the Th-232 chest burden result in mg span 2 to 3 orders of magnitude. NIOSH suggested that the measurements below the minimum detectable activity (MDA) of 6 mg **"are analytical background and this indicates that these were workers that were "clean" and represent normal thorium burdens that are in workers that were not exposed.**" NIOSH abandoned this position when SC&A demonstrated that normal thorium lung burdens of non exposed people are about 3 orders of magnitude lower, and that the uncertainties on the results in mg of Th-232 are as high as 3 orders of magnitude.

Technical Evaluation

This NIOSH white paper was intended to respond to the SC&A white paper, SC&A Response to NIOSH White Paper on FMPC Mobile In Vivo Radiation Monitoring Laboratory Calibration and Data Interpretation and Associated References (SC&A 2011). SC&A's paper contains

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	10 of 22

various technical concerns related to uncertainties in the Th-232 chest burden results in mg, indicating that depending on the way measurement was made, uncertainties of 2 orders of magnitude or higher could be expected.

NIOSH presented 11 plots of thorium chest count results in mg for Fernald workers for each year from 1968 to 1978 and invoked those plots to support their position:

...the uncertainties are reasonable; particularly for small intakes and that the data available are appropriate for the use of a coworker model. The significant feature of these plots is the large number of persons (2617) counted over these time periods which were measured below the MDA. Most of these counts are analytical background and this indicates that these were workers that were "clean" and represent normal thorium burdens that are in workers that were not exposed. The relative few that were above the MDA could represent potential intakes of thorium. These uncensored data sets, collectively represented as a lognormal distribution, can be used for a co-worker intake model. They do reflect significant and well behaved data sets and suggest that the potential for Fernald workers being exposed to thorium intakes was small. [Emphasis added.] (NIOSH 2012d, page 3)

As pointed out in SC&A (2012), SC&A believes this statement to be misleading. In reality, the preponderance of sub-MDA values in the mg thorium results does not reflect analytical background, but rather an insufficiently sensitive measurement system. The normal thorium lung content in non-exposed populations is around 3 μ g (Watson and Strom 2011, Iyengar et al. 2004, UNSCEAR 2000, Ibrahim et al. 1983, Wrenn et al. 1981), about 3 orders of magnitude lower than the mg amount reported for FMPC workers. If mg levels of Th-232 in the chest represent normal thorium burdens, as stated by NIOSH, then the uncertainties in the chest measurement results are on the order of 1,000. It is noteworthy that the whole body content of thorium in the U.S. population is about 30 μ g (ORNL 2006). Thus, even if the content of Th-232 in other tissues were measured when the detectors were placed in the lung regions, the results would be within about a factor of 10 of the background lung burdens for an unexposed population. The whole body content of 30 μ g is about 100 times less than one-half the assumed MDA for chest burden results. **The uncertainties in the lung counting results in mg of Th-232 are therefore on the order of 100 to 1,000.**

SC&A has also questioned whether the MIVRML was adequately sensitive as used at FMPC for measuring thorium lung burdens. In SC&A (2012), it was demonstrated that intakes at values below the stated MDA of 6 mg, which comprise 97% of the mg thorium data, can nonetheless result in Sv-level organ doses. Intakes corresponding to values at one-half the stated MDA (3 mg Th-232 chest burden) using plausible scenarios can be higher than the ICRP 60 (ICRP 1990) or ICRP 30 (ICRP 1979) annual limit of intakes (ALIs) for thorium. The issue of sufficient accuracy was raised in regards to the range of doses that could result when sub-MDA mg thorium data form the basis for assigned coworker intakes. Those doses could range from zero to hundreds of rem, depending on the target organ.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	11 of 22

2.0 LATEST PAPERS POSTED BY NIOSH ON FEBRUARY 24TH (BEFORE THE FEBRUARY 29TH BOARD MEETING)

Shortly before the full Board meeting in Oakland, California, held from February 28–29, 2012, NIOSH posted a set of papers for review and discussion. In NIOSH's words, those papers are:

...relevant references related to the estimation of thorium-232 intakes for Fernald workers using in vivo data from the Y-12 mobile counter (MIVRML). Concern was recently expressed by SC&A about the ability to interpret thorium mass lung burden results reported between the years of 1968 and 1978 at Fernald. NIOSH has located references which document the calibration of the MIVRML for thorium (SRDB 32612 [Author Unknown 1976] and SRDB 32614 [Author Unknown 1982]), the interpretation of MIVRML count results (SRDB 11596 [West 1965] and SRDB 701 [Scott 1966]), and also which provide the ratio of disequilibrium of thorium-232 from its progeny (SRDB 701). NIOSH now has the conversion factors used to convert thorium mass results (reported in milligrams) to lead-212 activity, as well as the algorithm used to calculate the thorium mass results (SRDB 32615) from the MIVRML measurement data. [Emphasis added.]

In the following paragraphs, SC&A examines the relevance of these papers for the stated purpose of calculating thorium mass results (lung burdens) from the MIVRML measurement data.

2.1 SRDB 32612 – LUNG COUNTER THORIUM CALIBRATION RUNS, AUTHOR UNKNOWN 1976

This document consists of handwritten notes from several authors, most of them unknown. It has been available to the work group for some time and was previously discussed in the SC&A white paper from August 2011 and in SC&A 2012.

SEC Issue

This SRDB reference consists of a collection of draft handwritten notes. Pages have different dates and some of them have parts that are crossed out and scribbled upon. There are no **documents showing that these draft pages were used as a basis for in-vivo monitoring of workers at FMPC or, for that matter, at any other facility**. Only a few pages are relevant to calculations of chest burdens of Th-232 in mg. Those pages demonstrate how uncertainties in the ratio of Pb-212 to Ac-228 used to estimate the age of the thorium exposure source (the time after purification of the thorium source) impact the derived lung burden. The unknown author shows that if the real ratio is used (1.08), the chest burden would be 56 mg. If the equilibrium ratio of 1.0 is used, the chest burden would be equal to 27.6 mg. SC&A notes that **there are no results equal to 27.6 mg or 56 mg of thorium in any thorium results currently available to NIOSH and SC&A, so it is unclear whether this type of analysis represents a Fernald worker. In addition, there is no indication on how this methodology would have been used if results from either Pb-212 or Ac-228 or both were below detection limits.**

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	12 of 22

Technical Evaluation

The first 2 pages of the handwritten notes describe draft calibration runs of Pb-212 and Ac-228, with no explanation of the numbers, results or labels. On the first page, there is a date (March 26, 1976). The third page shows Cs-137, K-40 and Ac-228 results without explanation. The fourth and fifth pages, dated December 5, 1977, show the uncertainties associated with thorium chest burden calculations based on Ac-228 and Pb-212 activity ratios, as described above, and that Th-232 activities were calculated using Ac-228 results. The sixth page is labeled body counter control runs, but there are no explanations on the results displayed on the page. The seventh page shows draft runs of several nuclides and is dated November 15, 1977. The eighth and ninth pages are dated November 15, 1977, have the name "E. Lance" at the top, and display gross counts and channels for various nuclides—U, U-235, K, Cs, Ac and Pb-212. The tenth page shows some draft Th-232 results and uncertainties related to assumptions about equilibrium. The eleventh page is dated December 2, 1977, and has the title, "New calibration coefficients resulting from thorium in-vivo calculation." It shows nCi/cpm results for Pb-212 and Ac-228, but the bottom of the document is a draft composed of numbers without explanations. The next two pages are drafts, no explanations on the numbers, and a lot of crossed out parts that are scribbled upon. The last page is a memo from A. King to L.M. Scott and I.L. Disney, dated April 22, 1976, an earlier date than the ones on pages 4–13. In summary, there is no documentation that these draft pages were used as a basis for in-vivo monitoring of workers at FMPC and only a few pages are relevant to calculations of chest burdens of Th-232 in mg.

2.2 SRDB 32614 – MOBILE LUNG COUNTER CONVERSION FACTORS, 1982

SEC Issue

There are no documents showing that the results or calculations displayed in these handwritten notes were used at FMPC to calculate Th-232 mass using the daughter's activities in nCi.

Technical Evaluation

The handwritten notes consist of three pages showing draft calculations for thorium and daughters. The first page is signed by King, and displays Th-232-, Pb-212-, and Tl-208-calculated activities in the lung (right, left and both lungs) for natural thorium lung sources supplied by LLNL.¹ Although the document specifies that 100% equilibrium was assumed, the activities of Tl-208 and Pb-212 are different from Th-232. On the second page, counting efficiencies are shown for Pb-212 and Ac-228, and a formula to calculate Pb-212/Ac-228 ratios from the counting rates. On the third page, there are a series of counting results for five different thorium sources, with the label, "Results by Old Body Counter Calibration which assumes chest attenuation." The Ac-228 activity is calculated using the 900 keV region. The ratios of Pb-212/Ac-228 activities are calculated. The only calculation of thorium mass is for a lung in phantom in which equilibrium is assumed. The mass of Th-232 is calculated using the average activity of Ac-228. All pages are draft notes, with some parts crossed out. There is no

¹ The handwritten note in SRDB 32614 only provides the acronym "LLNL." Presumably this is in reference to Lawrence Livermore National Laboratory.

NOTICE: This report has been reviewed for Privacy Act information and has been cleared for distribution. However, this report is pre-decisional and has not been reviewed by the Advisory Board on Radiation and Worker Health for factual accuracy or applicability within the requirements of 42 CFR 82.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	13 of 22

documentation showing that the information contained in these notes was used at FMPC or at any other facility.

2.3 SRDB 11596 – HEALTH PHYSICS CONSIDERATIONS ASSOCIATED WITH THORIUM PROCESSING, C.M. WEST (1965)

This paper has been available to the work group for some time and has been discussed before. It is cited in the SC&A document from August 2011.

SEC Issue

- There is no documentation showing that the method described in this paper was used at FMPC from 1968–1978.
- The methodology proposed is only adequate for the particular composition of Th-232 and daughters in exposure material at Y-12. In addition, the workers at Y-12 were monitored at the fixed in-vivo facility constructed at Y-12, as a low-background counting chamber [Y-12 Radiation Safety Manual (MacRee et al. 1965)]. The background of the MIVRML chamber is higher than the levels inside the Y-12 stationary room (Scott et al. 1969). The background influences the gamma spectrum and thus the methodology could not have been applied directly as described.
- There are a great number of reported results below the sensitivity of the method, between 1-6 mg of Th-232. If this methodology was applied at FMPC, without modifications, the results of Th-232 chest burdens below the sensitivity of the method should be equivalent to non-exposed populations (mean of about 3 µg in lung and 30 µg in the body), and the burdens would have been overestimated by 2 to 3 orders of magnitude.

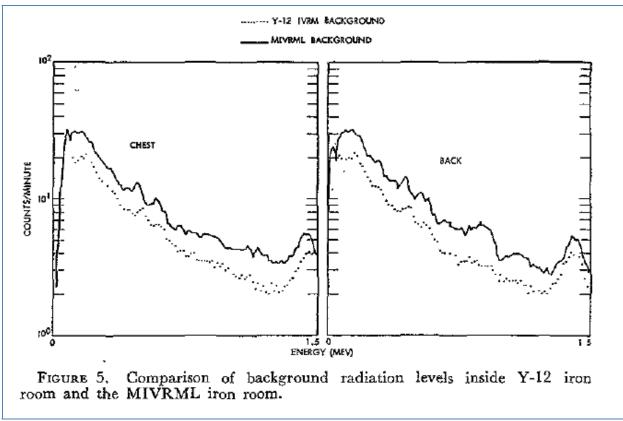
Technical Evaluation

Neither NIOSH nor SC&A have found any documents showing that the interpretation of MIVRML counting results was based on a technique similar to the one described by West, or how it may have been modified for application at FMPC. The technique could not have been applied directly at FMPC, because it depends on the specific mixture of thorium and daughters present in the source material being measured, in this case the workers' lungs, and on the background spectrum of the counter.

The workers at Y-12 were monitored at the fixed in-vivo facility constructed at Y-12 as a lowbackground counting chamber (MacRee et al. 1965). This counting chamber was constructed with special shielding materials and thickness to "keep the levels of naturally occurring radiation as low as possible since the lower limit of detectability for radioactive isotopes is governed to a large degree by the level of background radiation." The background inside the MIVRML counting room is higher than the background inside the fixed facility at Y-12.

In the paper by Scott et al. 1969, Figure 5 (reproduced below) shows the difference on the background spectrum inside the Y-12 iron room and the MIVRML iron room.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	14 of 22



Source: Scott et al. 1969

The dependence of the West (1965) method on the proportion of daughters in the source material is explained in the document as follows:

Figure 13 shows two in vivo gamma spectrum curves. These curves were obtained by plotting the number of counts from gamma photons as a function of the energy of the photons from 0–1550 kev. The spectrum shown by the lower curve is representative of that from persons with no thorium exposure. The peaks in this curve are in the 90, 660, and 1460 kev. The upper curve simulates the spectrum of an individual with a lung burden of a thorium material with a Th-228:Th-232 ratio of 0.8 and a Ra-228:Th-232 ratio of 0.6...

A screening tec[h]nique has been developed for determining who, if anyone, of the Y-12 thorium workers has a chest burden of thorium or radium warranting further investigation. [Emphasis added.]

The screening technique sums the counts under the curve in the areas that include the peaks in the 240- (Pb-212), 330- (Ac-228), and 900-keV (Ac-228) regions, and the sum is divided by the sum of counts in adjacent higher-energy regions.

The ratio obtained in each individual counted is compared to 3.23±0.70 *obtained for some* 1100 *unexposed persons...*

NOTICE: This report has been reviewed for Privacy Act information and has been cleared for distribution. However, this report is pre-decisional and has not been reviewed by the Advisory Board on Radiation and Worker Health for factual accuracy or applicability within the requirements of 42 CFR 82.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	15 of 22

A rise in ratio of 1 is equivalent to 33% of the **lung burden of the listed mixture**. Since a rise of 0.7 is statistically significant, this technique limit of detectability is about 20% of the **lung burden for this mixture**. The method's sensitivity for any particular lung burden is dependent upon the ratios of Th-232 and Ra-228 to the daughter being measured. [Emphasis added.]

Workers at FMPC during 1968–1978 were exposed to materials with different concentrations of Th-232 and daughters, depending on the assigned jobs and depending on the time of exposure. The length of the exposures varied among different workers, different jobs and different years. The length of time between a worker's exposure period and time of counting also varied. For example, some workers could have been monitored at 30 days, 60 days, 100 days, 300 days, etc., after the last day of exposure or in the middle of the exposure period. There is no information available to quantify those variables, yet they profoundly influence the activities of the mixture in the lung, which is the source that was measured. In addition, the solubility of the inhaled particles influences the transport of material from the lung to the rest of the body and excreta. The sum of counts in the 240, 330 and 900-keV ROIs are dependent on all of those unknown variables. Thus, the methodology for interpretation of lung monitoring results could not have been applied at FMPC exactly as described in this paper, unless the screening ratio of the workers' spectral sum was modified for each source of exposure, length of exposure, length of time between counting and exposure, and for the solubility of the material in the lung.

In addition, 97% of results were reported below the stated detection limit (20% of the lung burden), in the range 0–6 mg. If this methodology was applied at FMPC, results below the sensitivity of the method would be interpreted as chest burdens equivalent to non-exposed persons, as proposed by NIOSH 2011d. The lung content of the non-exposed U.S. population, as explained in Section 1.3, is about 3 μ g, and the total body content about 30 μ g. **Those chest burden results are thus overestimated by about 2 to 3 orders of magnitude for unexposed workers.**

It is noteworthy that at the full Board meeting held in Oakland, California, on February 28–29, it appeared that there was some misunderstanding as to the meaning of SC&A's contention that NIOSH had "not demonstrated that Pb-212 activity was used to derive mg thorium lung burdens from 1968–1978." SC&A understands that counts in the 240 keV ROI were used at Y-12 to derive a sum of counts from three ROIs for calculating a screening ratio, as described in West (1965).² However, SC&A's concern is that NIOSH has not demonstrated that those counts were transformed into a Pb-212 activity value that was then used to correct the age of the source, as was done post-1978.

 $^{^{2}}$ It is not known if this screening ratio was used at FMPC. If it was, the ratio would have to have been modified, because this method was derived for the fixed counter and not the mobile one used at FMPC. As the background was different, the counts below the peaks and adjacent areas had to be different, and also the ratio for non-exposed individuals.

NOTICE: This report has been reviewed for Privacy Act information and has been cleared for distribution. However, this report is pre-decisional and has not been reviewed by the Advisory Board on Radiation and Worker Health for factual accuracy or applicability within the requirements of 42 CFR 82.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	16 of 22

2.4 DOCUMENT SRDB 701 – A TECHNIQUE FOR ASSESSING THORIUM BODY BURDENS UTILIZING IN-VIVO GAMMA SPECTROMETRY, L.M. SCOTT, 1966

SEC Issues

This paper is based on the methodology discussed in Section 2.3. The same SEC issues apply; i.e., there is no documentation showing that the method described in this paper was used at FMPC from 1968–1978 or for any other period.

The methodology proposed is only adequate for the particular composition of Th-232 and daughter exposure material at Y-12 and for the low-background counting chamber of the fixed in-vivo facility constructed at Y-12. The methodology could not have been applied directly as described in the paper. NIOSH has not provided any documentation showing that the interpretation of MIVRML counting results was based on a technique similar to the one described by West, or on how it was modified for application at FMPC. Also, SC&A has not found any documents on this subject.

In addition, NIOSH correspondence from February 24th claims that this paper "provides the ratio of disequilibrium of thorium-232 from its progeny," which is incorrect. The paper provides the ratio of Th-232/Th-228=1.27 and Th-232/Ra-228=1.67 for a specific standard used at Y-12 when the chest burden is below 10 mg of Th-232. **There is no information indicating that a methodology similar to that described in the paper was used at FMPC or if the same calibration standard was used.** In reality, the methodology could not have been used at FMPC without modification to account for differences in the counting systems and variability in site-specific source terms, conditions of exposure, and counting times relative to intake. As described in SC&A 2011, the two ratios presented in the paper are not possible for a single purified source of thorium. An excess Ra-228 might have been present in the source.

2.5 DOCUMENT SRDB 32615 – RULE OF THUMB FOR COMPUTING THORIUM BODY BURDENS FROM IN-VIVO COUNTS, L.M. SCOTT, 1961

SEC ISSUES

This document consists of a letter from L. Max Scott to C.M. West dated November 21, 1961. There is no documentation showing that the method described in this paper was used at FMPC from 1968–1978. NIOSH claims without supporting documentation that this letter contains "<u>the</u> <u>algorithm used to calculate the thorium mass results from the MIVRML measurement data</u>." **SC&A notes that the MIVRML was received from vendor in the summer of 1967 (Author unknown 1968, page 16).** Thus, the rule of thumb, written in 1961, was not meant to calculate the thorium mass results from the MIVRML measurement data and depends on the background spectrum of the Y-12 counter; the background levels at the MIVRML were higher than the ones at the in-vivo counting fixed facility at Y-12 (Scott et al. 1969). In addition, as explained in the letter, the rule of thumb method gives a "rough idea of the dose." The rule of thumb is only adequate for its intended purpose as a rough approximation of lung burden for the particular composition of Th-232 and daughter exposure material used by Scott in its derivation. As

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	17 of 22

explained in the letter, "If the activity ratio of Th-232/Th-228 is less than 1.27, the dose will be underestimated. If the activity ratio is greater than 1.27, then it will be an overestimation."

Technical Evaluation

On a conceptual level, SC&A does not believe that a "rule of thumb" approximation to dose such as that described in Scott (1961), which depends to a great extent on the specific characteristics of one particular source and counter combination, is scientifically sound or necessarily claimant favorable in an SEC context. Even if such an approach was deemed acceptable, there are no documents showing that this rule of thumb was applied for the MIVRML at FMPC. The letter containing the rule of thumb description is meant to give a "**rough idea of the dose**." It was written in 1961, and the MIVRML was received from the vendor in the summer of 1967. The method described in this 1961 letter depends on the ratio of Th-232 to its daughters present in the source material being measured, and on the background spectrum of the counter. This dependence was described in detail in Section 2.3 (West 1965). It could not have been applied at FMPC without modifications. Thus, it is not "**the algorithm used to calculate the thorium mass results from the MIVRML measurement data**," as suggested by NIOSH. There are no documents that have been made available to SC&A that indicate that a similar methodology was applied at FMPC.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	18 of 22

3.0 SC&A CONCLUSIONS

The references provided by NIOSH in February 2012 and those cited in previous exchanges describe different approaches that could have been used to calculate Th-232 lung burdens. NIOSH's white papers are based on the unsupported assumption that Pb-212 was measured and Th-232 burdens were calculated using those measurement results. Author Unknown (1976) and Author Unknown (1982) are handwritten notes, which contain some calculations using Pb-212/Ac-228 activity ratios to estimate the age of the Th-232 source (time since purification) and Ac-228 results to calculate Th-232 activity. West (1965), Scott (1961) and Scott (1966) describe another approach to calculate thorium lung burdens; counts in the spectral regions of Pb-212 and Ac-228 are used and compared with those from non-exposed population. The sum of the counts under the curve in the areas, which includes the peaks in the 240- (Pb-212), 330-(Ac-228), and 900-keV (Ac-228) regions is divided by the sum of counts in adjacent higherenergy regions. The ratio obtained in each individual counted is compared to 3.23±0.70 obtained for some 1,100 unexposed persons. A rise in ratio of 1 is considered to be equivalent to 33% of the lung burden of the listed mixture. These methods are inconsistent with one another, and there are no documents to corroborate NIOSH's assertion that any of those methods were applied at FMPC.

The approaches put forth in NIOSH's white papers, as described in Sections 1.1, 1.2, and 1.3, are all based on the unsupported assumption that Pb-212 was the measured radionuclide used to calculate Th-232 lung burdens in mg. In SC&A (2012), a table was compiled from the few results where both mg thorium and daughter activity in nCi were reported. The table is presented here to stress the questionable veracity of this critical assumption by NIOSH.

In Table 1, 9 results are reported as 2.1 mg of Th-232 (below the 6 mg detection limit) in June 1979 and in October 1979. The June results are from a group of workers in the same plant who were presumably exposed to the same source. Thus, one would expect proportionality between the Pb-212 activity and mg thorium if, in fact, Pb-212 activity was used to derive the mg result. However, the results of Pb-212 varied between 0.25 nCi and 0.40 nCi, all above the MDA of 0.23 nCi for Pb-212. The Ac-228 results varied between 0.35 and 0.7 nCi, all above the 0.24 nCi MDA for Ac-228. The five 2.1 mg results reported in October 1979 are from a group of workers from Plant 4 who were likely exposed to the same source. The Pb-212 results for that set varied from 0.19 nCi (the only result below detection limit) to 0.40 nCi, and the Ac-228 results varied from 0.33 nCi to 0.5 nCi. Finally, the three highest mg Th-232 correspond to negative Pb-212 results.

SC&A concerns expressed in SC&A (2012) remain unchanged. The existing documentation on the mg thorium data is inconsistent and does not clarify how the thorium chest burden results were calculated. The values in mg of thorium might have been underestimated by 2 or more orders of magnitude if Ac-228 was used to calculate Th-232 chest burdens, as exemplified in the papers discussed in Sections 2.1 and 2.2 and reviewed in Finding 1.3 of SC&A (2012). On the other hand, the values in mg of Th-232 might have been overestimated by 3 orders of magnitude, if the values below 6 mg of Th-232 were considered background levels of non-exposed people or/and the ratios on the Pb-212 and Ac-228 spectral regions of workers and of non-exposed populations were used to calculate the Th-232 chest burden below detection limits.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	19 of 22

Reported Thorium Result (mg)	Reported Pb-212 Activity (nCi)	Reported Ac-228 Activity (nCi)	Monitoring Date	Location or Plant #
-5.00	-0.04	-0.02	8/29/1974	7 or Pilot
-0.60	-0.08	0.03	06/08/88	Maintenance
-0.54	-0.18	-0.01	06/12/86	5
-0.16	-0.16	-0.09	06/23/87	5
-0.12	0.06	0.01	07/10/73	6
-0.05	-0.05	0.02	05/02/87	Maintenance
-0.01	-0.01	0.05	12/09/86	No Information
0.01	-0.06	-0.08	05/02/77	Mech
0.30	0.15	0.06	04/06/77	6
1.81	-0.10	0.04	08/09/85	5
2.10	0.25	0.35	06/02/79	7 or Pilot
2.10	0.30	0.5	06/09/79	7 or Pilot
2.10	0.40	0.7	06/12/79	7 or Pilot
2.10	0.40	0.65	06/19/79	7 or Pilot
2.10	0.40	0.5	10/08/79	4
2.10	0.19	0.33	10/22/79	4
2.10	0.27	0.33	10/29/79	4
2.10	0.28	0.41	10/17/79	4
2.10	0.29	0.39	10/15/79	4
2.20	-0.10	-0.1	04/13/77	Mech
4.30	-0.04	0.05	04/26/71	Inspection
5.10	-0.04	0.01	06/04/80	Mech

Table 1: Comparison of Contemporaneously Reported Thorium Mass (mg),
Pb-212 and Ac-228 Activities (nCi)

In addition, as pointed out in SC&A (2012), the Th-232 data are consistent with a nonquantitative "screening" approach, which is the position still held by FMPC in the 1997–2001 timeframe, as seen in the Technical Basis for Internal Dosimetry at FEMP (Soldano 1997 and Tomes 2001):

Currently, in vivo measurements for Th-232 are performed by determining the amount of Ac-228 and Pb-212 present in a measurement and assuming radioactive equilibrium with the parent. Since the degree of equilibrium is rarely known, this technique is only useful for screening type measurements and should not be used as the only indication of a Th-232 intake. [Emphasis added.]

In conclusion, SC&A believes that coworker models and dose calculations can only yield meaningful results when they are based on quantities that have some inherent meaning in terms of intakes experienced by workers. SC&A believes that the thorium lung burdens reported in units of mg from 1968–1978 cannot be reconstructed or associated with meaningful intakes and, therefore, it does not appear possible to place a scientifically sound and plausible upper bound on the thorium body burdens for some workers.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	20 of 22

REFERENCES

Author Unknown 1968. Collection of documents, page 16, dated November 4, 1968. SRDB 0099712.

Author Unknown 1976. *Lung Counter Thorium Calibration Runs, March 26, 1976.* March 26, 1976. Document Capture No. Y/AB-NIOSH-2007-067. SRDB 32612.

Author Unknown 1982. *Mobile Lung Counter Conversion Factors, December 1982.* Document Capture No. Y/AB-NIOSH-2007-045. SRDB 32614.

Ibrahim, S.A., M.E. Wrenn, N.P. Singh, N. Cohen, and G. Saccomano, 1983. *Thorium concentration in human tissues from two U.S. populations*. <u>Health Physics</u> 44:213–220.

ICRP 1979. *Limits of Intakes of Radionuclides by Workers*. ICRP Publication 30; Ann ICRP 2(3/4); International Commission on Radiological Protection. Oxford: Pergamon Press; 1979.

ICRP 1990. *1990 Recommendations of the International Commission on Radiological Protection.* ICRP Publication 60; Ann ICRP 21(1/3); International Commission on Radiological Protection. Oxford: Pergamon Press; 1991.

Iyengar, G.V., H. Kawamura, H.S. Dang, R.M. Parr, J.W. Wang, S.Y. Cho, and E.S. Natera, 2004. *Contents of Cesium, Iodine, Strontium, Thorium, and Uranium in Selected Human Organs of Adult Asian Population*. <u>Health Physics</u> 87: 402-416.

MacRee, P.C., C.M.West, and J.D. MacLendon, 1965. Y-12 Radiation Safety Manual, Y-1401 Revised. SRDB 008577.

NIOSH 2011a. *FMPC In Vivo Chest Count Data Bias Adjustment*. National Institute for Occupational Safety and Health, Cincinnati, Ohio. January 19, 2011. Transmitted February 3, 2011.

NIOSH 2011b. *Response to SCA comments on Fernald Th232 coworker study*. National Institute for Occupational Safety and Health, Cincinnati, Ohio. Transmitted February 3, 2011.

NIOSH 2011c. Morris, R., *FMPC – Mobile In Vivo Radiation Monitoring Laboratory Calibration and Data Interpretation – Draft 01*. National Institute for Occupational Safety and Health, Cincinnati, Ohio. May 6, 2011. Transmitted May 23, 2011.

NIOSH 2011d. Morris, R., Smith, B., LaBone, T., *Response to SC&A Response to NIOSH White Paper on FMPC MIVRML Calibration*. National Institute for Occupational Safety and Health, Cincinnati, Ohio. November 8, 2011. Transmitted November 10, 2011.

NIOSH 2012a. *Calculation of Chronic Intake IRFs for Th-232 Assuming Shared Kinetics*. T. LaBone, National Institute for Occupational Safety and Health, Cincinnati, Ohio. February 17, 2012.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	21 of 22

NIOSH 2012b. *Example of Thorium Intake and Dose calculation*. T. LaBone, National Institute for Occupational Safety and Health, Cincinnati, Ohio. February 24, 2012.

NIOSH 2012c. e-mail from M.R. Rolfes (NIOSH) to the Fernald Work Group, February 24, 2012.

ORAUT 2008. *Thorium In-Vivo Coworker Study for FEMP – A Proposed Attachment for ORAUT-TKBS-0017-5*, Revision 1. Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 8, 2008.

ORNL 2006. Radiological Toolbox, Version 2.0. Prepared by K.F. Eckerman and A.L. Sjoreen, Oak Ridge National Laboratory. Available from U.S. Nuclear Regulatory Commission for download.

SC&A 2010. Review of "Thorium In-Vivo Coworker Study for FEMP – A Proposed Attachment for ORAUT-TKBS-0017-5, Rev. 1. SC&A, Vienna, Virginia. June 2010.

SC&A 2011. SC&A Response to NIOSH White Paper on FMPC Mobile In-Vivo Radiation Monitoring Laboratory Calibration and Data Interpretation and Associated References. J.L. Lipsztein, SC&A, Inc., Vienna, Virginia. August 3, 2011. Transmitted August 3, 2011.

SC&A 2012. SC&A Final Position on the Th-232 In-vivo Data Quality and Adequacy for FEMP Workers. J.L. Lipsztein, SC&A, Inc., Vienna, Virginia. January 30, 2012.

Scott, L.M. 1961. Letter from L.M. Scott (Union Carbide) to C.M. West (Union Carbide): *Rule of Thumb for Computing Thorium Body Burdens from In-Vivo Counts, November 21, 1961,* Document Capture No. Y/AB-NIOSH-2007-046. SRDB 32615.

Scott, L.M., 1966. A Technique of Assessing Thorium Body Burdens Utilizing In-vivo Gamma Spectrometry, <u>Health Physics</u>, Vol. 12, 1966. SRDB 701.

Scott, L.M., H.M. Abele, E.H. Bryant, H.H. Cromwell, and C.M. West, 1969. *Design and Development of a Mobile In-Vivo Radiation Monitoring Laboratory*. American Industrial Hygiene Association Journal, Volume 30, March–April 1969. Union Carbide Corporation, Nuclear Division, Y-12 Plant, Oak Ridge, Tennessee. SRDB REF ID: 4140.

Soldano, M., 1997. Technical Basis for Internal Dosimetry at FEMP, Rev. 0. SRDB 003521.

Tomes, T., 2001. Technical Basis for Internal Dosimetry at FEMP, Rev. 01. January 4, 2001. SRDB 003292.

UNSCEAR 2000. Report to the General Assembly: *Sources and effects of ionizing radiation: United Nations scientific committee on the effects of atomic radiation report to the General Assembly, with scientific annexes.* New York: United Nations.

Effective Date:	Revision No.	Document No.	Page No.
April 6, 2012	0 Draft)	Review of In-vivo Thorium Bioassay Issues	22 of 22

Watson, D. J., and D.J. Strom, 2011. *Radiation Doses to Members of the U.S. Population from Ubiquitous Radionuclides in the Body: Part 3, Results, Variability, and Uncertainty*, <u>Health Physics</u> 100: 151-159.

West, C.M., 1965. *Health Physics Considerations Associated with Thorium Processing*, Report Number Y-KB-53, Union Carbide Corporation, Nuclear Division, Oak Ridge, Tennessee, Y-12 Plant, 1965. SRDB 11596.

Wrenn, M.E., N.P. Singh, N. Cohen, S.A. Ibrahim, and G. Saccomanno, 1981. *Thorium in human tissues*. Washington, DC: U.S. Nuclear Regulatory Commission.