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ADVISORY BOARD ON RADIATION AND WORKER HEALTH

NATIONAL INSTITUTE FOR
OCCUPATIONAL SAFETY AND HEALTH

A REVIEW OF NIOSH'S PROGRAM EVALUATION REPORT OCAS-PER-031, "Y-12 TBD REVISIONS"

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Disclaimer

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A PRELIMINARY REVIEW OF NIOSH'S PROGRAM EVALUATION REPORT OCAS-PER-031, "Y-12 TBD REVISIONS"	Page 2 of 24
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Record of Revisions

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0 (Draft)	07/15/2013	Initial issue

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ABBREVIATIONS AND ACRONYMS

Advisory Board or ABRWH	Advisory Board on Radiation and Worker Health
CFR	*Code of Federal Regulations*
DOE	Department of Energy
DOL	Department of Labor
dpm	disintegration per minute
DR	dose reconstruction
IMBA	Integrated Modules for Bioassay Analysis
LOD	limit of detection
MDA	minimum detectable activity
mg	milligram
MPLB	maximum permissible lung burden
nCi	nanocuries
NIOSH	National Institute for Occupational Safety and Health
OCAS	Office of Compensation Analysis and Support
ORAUT	Oak Ridge Associated Universities Team
PEP	Program Evaluation Plan
PER	Program Evaluation Report
POC	probability of causation
SC&A	S. Cohen and Associates (SC&A, Inc.)
SEC	Special Exposure Cohort
TBD	Technical Basis Document
TIB	Technical Information Bulletin

1.0 STATEMENT OF PURPOSE

To support dose reconstruction (DR), the National Institute for Occupational Safety and Health (NIOSH) and the Oak Ridge Associated Universities Team (ORAUT) have assembled a large body of guidance documents, technical basis documents (TBDs), workbooks, computer codes, and tools. In recognition of the fact that all of these supporting elements in DR may be subject to revisions, provisions exist for evaluating the effect of such programmatic revisions on the outcome of previously completed DRs. Such revisions may be prompted by document revisions due to new information, misinterpretation of guidance, changes in policy, and/or programmatic improvements.

The process for evaluating potential impacts of programmatic changes on previously completed DRs has been proceduralized in OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2, dated December 6, 2006. This procedure describes the format and methodology to be employed in preparing a Program Evaluation Report (PER) and a Program Evaluation Plan (PEP).

A PER provides a critical evaluation of the effect(s) that a given issue/programmatic change may have on previously completed DRs. This includes a qualitative and quantitative assessment of potential impacts. Most important in this assessment is the potential impact(s) on the Probability of Causation (POC) of previously completed DRs with POCs of <50%.

As needed, a PEP may be issued that serves as a formal notification of an impending PER. The PEP provides a preliminary description of the issue(s) that will be addressed in the PER, and summarizes the likely scope of the effort required to complete the PER.

S. Cohen and Associates (SC&A) was tasked by the Advisory Board to conduct a review of OCAS-PER-031, *Y-12 TBD revisions*. In conducting a PER review, SC&A is committed to perform the following five subtasks, each of which is discussed in this report:

Subtask 1: Assess NIOSH's evaluation/characterization of the "issue" and its potential impacts on DR. Our assessment intends to ensure that the "issue" was fully understood and characterized in the PER.

Subtask 2: Assess NIOSH's specific methods for corrective action. In instances where the PER involves a technical issue that is supported by document(s) [e.g., white papers, technical information bulletins (TIBs), procedures] that have not yet been subjected to a formal SC&A review, Subtask 2 will include a review of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science. Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, Subtask 2 will simply provide a brief summary/conclusion of this review process.

Subtask 3: Evaluate the PER's stated **approach** for identifying the universe of potentially affected DRs, and assess the **criteria** by which a subset of potentially affected DRs was selected for re-evaluation. The second step may have important implications in instances

where the universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's re-evaluation is confined to a subset of DRs that, based on their scientific judgment, have the potential to be significantly affected by the PER. In behalf of Subtask 3, SC&A will also evaluate the timeliness for the completion of the PER.

Subtask 4: Conduct audits of DRs affected by the PER under review. Based on information contained in the PER (and discussed in Section 5 below), the number of DRs selected for audit for a given PER will vary. (It is assumed that the selection of the DRs and the total number of DR audits per PER will be made by the Advisory Board.)

Subtask 5: Prepare a comprehensive written report that contains the results of the above-stated subtasks, along with our review conclusions.

2.0 SUBTASK 1: ASSESS NIOSH'S IDENTIFICATION OF THE ISSUES AND THEIR IMPACT ON DOSE RECONSTRUCTION

NIOSH has issued six TBDs for the Y-12 site, along with a number of revisions. As stated in OCAS-PER-031, these documents have been utilized to perform DRs for claims from the National Security Complex (Y-12). Each of these documents has been through several revisions. Although many of the revisions only added annotation and attribution or corrected errors that did not affect the DR methods, there were a number of substantial changes made that could affect the outcome of a DR. In preparation of OCAS-PER-031, the technical changes made in the revisions of these documents were reviewed to determine if any previously completed DR would result in an increased dose using the current methods. The review was limited to identifying any increase in assigned dose, rather than any change or an overall increase.

A summary of the Y-12 TBDs revisions that are pertinent to the evaluation of OCAS-PER-031 are listed below.

- ORAUT-TKBS-0014-1 - *Introduction* – This TBD was revised as follows:
  - 01/06/2004, Rev. 00
  - 11/24/2004, Rev. 00 PC-1
  - 10/11/2005, Rev. 00 PC-2
  - 10/24/2006, Rev. 01

- ORAUT-TKBS-0014-2 - *Site Description* – This TBD was revised as follows:
  - 11/19/2003, Rev. 00
  - 09/09/2004, Rev. 00 PC-1
  - 01/19/2005, Rev. 01
  - 10/11/2005, Rev. 01 PC-1
  - 10/25/2006, Rev. 01 PC-2
  - 11/08/2007, Rev. 02

- ORAUT-TKBS-0014-3 - *Occupational Medical Dose* – This TBD was revised as follows:
  - 12/15/2003, Rev. 00
  - 09/09/2004, Rev. 00 PC-1
  - 10/11/2005, Rev. 00 PC-2
  - 04/18/2006, Rev. 00 PC-3
  - 06/18/2007, Rev. 01

- ORAUT-TKBS-0014-4 - *Occupational Environmental Dose* – This TBD was revised as follows:
  - 12/05/2003, Rev. 00
  - 05/20/2004, Rev. 00 PC-1
  - 09/09/2004, Rev. 00 PC-2
  - 10/11/2005, Rev. 00 PC-3
  - 07/20/2006, Rev. 01

- ORAUT-TKBS-0014-5 - *Occupational Internal Dose* – This TBD was revised as follows:
  - 03/17/2004, Rev. 00
  - 05/10/2005, Rev. 01
  - 10/11/2005, Rev. 01 PC-1
  - 01/12/2006, Rev. 01 PC-2
  - 02/14/2006, Rev. 01 PC-3
  - 08/03/2006, Rev. 02
  - 10/10/2006, Rev. 02 PC-1
  - 03/12/2012, Rev. 03

- ORAUT-TKBS-0014-6 - *Occupational External Dosimetry* – This TBD was revised as follows:
  - 11/19/2003, Rev. 00
  - 10/11/2005, Rev. 00 PC-1
  - 02/14/2006, Rev. 00 PC-2
  - 05/11/2006, Rev. 00 PC-3
  - 06/02/2009, Rev. 01
  - 12/18/2009, Rev. 02

2.1 ISSUANCE OF OCAS-PER-031

On December 18, 2007, NIOSH issued OCAS-PER-031, which contained the following major sections:

1. Section 1.0 provides a description of the basis for the issuance of OCAS-PER-031. It was determined, after reviewing the Y-12 TBD revisions, that there was the potential for increases in previously assigned claimant internal doses.

2. Section 2.0 provides a summary of the potential for increased internal doses associated with thorium, as described in the following:

   After evaluating the Y-12 documentation, one issue did arise that could increase the dose estimate for some claims. The equilibrium ratio for Th-228/Th-232 was changed from assuming 100% equilibrium to assuming 80% equilibrium. Incorporating this change would increase the dose estimate for claims containing a thorium intake determined from chest count data. This change was included in revision 1 page change 2 (Rev. 1 PC-2) of the internal dose section of the Y-12 TBD (ORAUT-TKBS-0014-5). This change was issued on 1/12/2006.

3. Section 3.0 states that there were 693 Y-12 claims completed prior to the issuance of the January 12, 2006, Occupational Internal Dose TBD (ORAUT-TKBS-0014-5) revision with a POC <50% and identifies the criterion that will be used to determine if a new dose estimate is necessary.

2.2 SC&A'S ASSESSMENT OF THE DEVELOPMENT OF OCAS-PER-031

SC&A's review of the applicable Y-12 TBDs, with their revisions, and OCAS-PER-031 indicates that NIOSH properly outlined the necessary steps to re-evaluate the claims potentially impacted by the revisions in the TBDs as proceduralized in OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans,* Rev. 02. **However, SC&A found that the recommended method of assigning thorium doses from chest counts at Y-12 is both unclear to the dose reconstructors, and technically incorrect, resulting in an underestimate of internal dose being assigned from purified thorium intakes. The recorded thorium data for Y-12 workers were obtained from the same chest counting method as was used for Fernald workers, which was deemed unable to provide sufficient thorium intake information and resulted in the issuance of a Special Exposure Cohort (SEC) for Fernald in June of 2012.**

A detailed analysis of our review is provided in Section 3.0 of this report.

3.0 SUBTASK 2: ASSESS NIOSH'S SPECIFIC METHODS FOR CORRECTIVE ACTION

In instances where the PER involves a technical issue that is supported by documents [e.g., white paper(s), TIB(s), and/or procedure(s)] that have not yet been subjected to a formal SC&A review, Subtask 2 will assess the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science.

Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, Subtask 2 will simply provide a brief summary/conclusion of this review process.

3.1 SC&A'S EVALUATION OF Y-12 TECHNICAL BASIS DOCUMENTS

In September 2005, SC&A performed a formal review of all six Y-12 TBDs (SC&A 2005), as cited in Section 3.1.1 below. Although there have subsequently been numerous page-change revisions issued for the Introduction (Section 1), Site Description (Section 2), Occupational Medical Dose (Section 3), and Occupational Environmental Dose (Section 4), these changes had no impact on dose or the issuance of OCAS-PER-031. In addition, SEC-related revisions introduced in Occupational External Dose (ORAUT-TKBS-0014-6) after SC&A's 2005 review do not appear to have any increased dose implications, based on our review of information provided in the publication record accompanying each revision.

However, it was the revision to the Y-12 Occupational Internal Dose (ORAUT-TKBS-0014-5) that prompted the genesis of OCAS-PER-031. Therefore, as part of our review of OCAS-PER-031, SC&A also performed a technical evaluation of changes introduced in ORAUT-TKBS-0014-5 since our 2005 review. This assessment focused on revisions that could potentially increase assigned dose as of the issue date (December 18, 2007) of OCAS-PER-031.

3.1.1 SC&A's Previous Evaluation of Y-12 Technical Basis Documents

Y-12 Site technical documents relevant to OCAS-PER-031 previously reviewed by SC&A (SC&A 2005) include the following:

- ORAUT-TKBS-0014-1, *Technical Basis Document for the Y-12 Site – Introduction.* November 24, 2004 *(*Murray 2004a).
- ORAUT-TKBS-0014-2, *Technical Basis Document for the Y-12 Site – Site Description.* January 19, 2005 (Jessen 2005).
- ORAUT-TKBS-0014-3, *Technical Basis Document for the Y-12 Site – Occupational Medical Dose*. September 9, 2004 (Murray 2004b).
- ORAUT-TKBS-0014-4, *Technical Basis Document for the Y-12 Site –Occupational Environmental Dose*. September 9, 2004 (Ijaz and Adler 2004).

- ORAUT-TKBS-0014-5, *Technical Basis Document for the Y-12 Site – Occupational Internal Dose*. May 10, 2005 (ORAUT-TKBS-0014-5 (2005a).

- ORAUT-TKBS-0014-6, *Technical Basis Document for the Y-12 Site – Occupational External Dosimetry* (Kerr 2003).

A short summary of one of SC&A's findings that is relevant to the evaluation of OCAS-PER-031 is provided in Attachment A of this report.

3.1.2 SC&A's Current Evaluation of Y-12 Technical Basis Document Revisions

SC&A reviewed and compared the first three revisions (up to and including the January 12, 2006, that was used in OCAS-PER-031) of ORAUT-TKBS-0014-5 to identify changes. The changes identified were then narrowed down to only those that would impact dose assignments; these changes were then further reduced to only those that could potentially result in an increase in assigned dose. While performing this task, SC&A identified the following documentation errors:

- The "*PUBLICATION RECORD*" (or sometimes labeled "*RECORD OF ISSUE/REVISIONS*") in the front of each ORAUT-TKBS-0014-5 document lists an original ORAUT-TKBS-0014-5 version dated March 17, 2004 (Rev. 00). However, this first version can not be located on any of the databases searched to date. In view of the changes listed for the next version (Rev. 01), the lack of the original version does not appear to impact the evaluation of OCAS-PER-031.

- ORAUT-TKBS-0014-5, Rev. 01 PC-1, of October 11, 2005, retains the old issue information of Rev. 01, May 10, 2005, in the heading on many pages; instead of the correct information of Rev. 01 PC-1, October 11, 2005. This is an error, but would not impact the doses assigned.

- ORAUT-TKBS-0014-5, Rev. 01 PC-2, of January 12, 2006, retains the old issue information of Rev. 01, May 10, 2005, in the heading on many pages; instead of the correct information of Rev. 01 PC-2, January 12, 2006. This is an error, but would not impact the doses assigned.

SC&A's page-by-page comparison of the different versions of ORAUT-TKBS-0014-5 did not identify any changes that would impact the assigned doses, except for the method of determining purified thorium (Th-232 and Th-228) body burdens. Details of this evaluation are provided in Section 3.2 below under the corrective action plan.

3.2 SC&A'S EVALUATION OF NIOSH'S CORRECTIVE ACTION PLAN

According to Section 3.0 of OCAS-PER-031, on December 18, 2007 (the issue date of the PER), NIOSH identified 693 Y-12 claims that were completed prior to that date and had a POC below 50%. NIOSH will review the DRs for each of these 693 claims to determine if the evaluation of dose involved exposure to, and intake from, purified thorium.

NIOSH will provide the Department of Labor (DOL) with the list of 693 claims, as well as a determination for each claim as to whether a new dose estimate is required. Documentation for each claim not requiring a new DR will provide the basis for that determination.

3.2.1 Issues Identified by SC&A

SC&A was able to confirm that the Th-228/Th-232 ratio of 1:1 was changed to 0.8:1 in the January 12, 2006, version of ORAUT-TKBS-0014-5, which concurs with NIOSH's statement for issuing OCAS-PER-031.

As a result of SC&A's evaluation of the impact of the Y-12 ORAUT-TKBS-0014-5 (2006) changes on assigned internal dose, SC&A identified the following findings:

- **Finding #1: Change in Assigned Dose –** This change in the Th-228/Th-232 ratio would actually reduce the assigned dose, not increase it, if thorium intakes, and resulting doses, are based on recorded mg values of thorium from chest counts, as was observed in the case files SC&A has reviewed to date.

- **Finding #2: Chest Counts Conversion to Th-232 Body Burden –** The method NIOSH uses (in both the older ORAUT-TKBS-0014-5 (2005a and 2005b) and the new ORAUT-TKBS-0014-5 (2006) versions) to assign Th-232 body burdens assumes that the gamma counts obtained during the chest counts are directly related to Th-232 (in mg) in the lungs, using an empirically derived calibration factor that applies to all Y-12 workers at all times. This is incorrect since the gammas from Ac-228 and Pb-212 are being counted, and (1) Ac-228 is not in equilibrium with Th-232, (2) Pb-212 is not in equilibrium with Th-228, and (3) Th-228 is not in equilibrium with Th-232. Additionally, a given equilibrium cannot be assumed because it is constantly changing for many years after the purification of thorium.

- **Finding #3: Different Solubility of Thorium and Decay Products in the Lung –** The lung may retain thorium, being relatively insoluble, longer than the more soluble decay products in some cases. Therefore, a lung count based on the decay product (i.e., Ac-228 and/or Pb-212) would not necessarily have a consistent relationship to the thorium (Th-232 and/or Th-228) body burden. Additionally, the solubility of the decay products themselves (inhaled or formed in the lungs) may have different solubility and not have consistent ratios.

- **Finding #4: MDA or LOD Value –** NIOSH assumed a Ra-228 to Th-232 ratio of 0.6 [page 31 of ORAUT-TKBS-0014-5, Rev. 01 PC-2 (2006)] for determining the minimum detectable activity (MDA) of 0.6 nCi; this would require approximately 8 years from purification to counting. This is not a valid assumption for almost all workers and is not constant between each chest count. The limit of detection (LOD) value was not directly based on counting statistics, but it was empirically derived and meant to be used only as a screening tool, not to accurately assign dose (West 1965, Scott 1961).

In order to fully understand the basis for these findings, a brief technical summary of the detection and assignment of purified thorium body burdens is provided.

3.2.2 Technical Summary

The purified thorium project at Y-12 consisted of receiving thorium from outside sources that had recently been purified to remove all but the thorium product, which would consist of Th-232 and Th-228 in equilibrium at the time of purification. The Th-228 activity (with a half-life of 1.9 years) would then decrease faster than the Th-232 (with a half-life of 1.4E10 years), and the Th-228 would grow back in through the Th-232 → Ra-228 (T1/2 = 5.7 years) → Ac-228 → Th-228 decay chain.

Thorium Decay Chain

Figure A illustrates the thorium decay chain (West 1965, page 11); note the 5.7 year half-life of Ra-228.

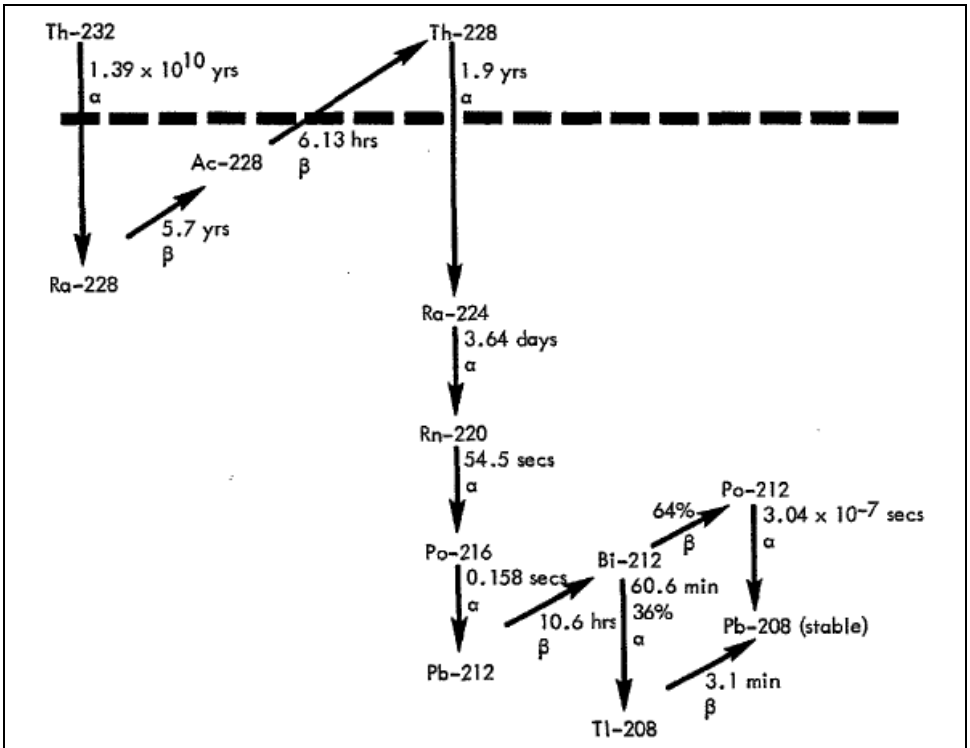

Figure A. Decay Chain of Thorium (from West 1965)

Radionuclide Activity After Thorium Purification

Figure B illustrates the activity of various radionuclides in the thorium decay chain after purification of thorium (West 1965, page 13). Figure 5-4, page 31, of ORAUT-TKBS-0014-5 (2006) is similar, but Figure B contains more details; note that the Ra-228 activity ranges from near zero to 10% of the Th-232 activity during the first year.

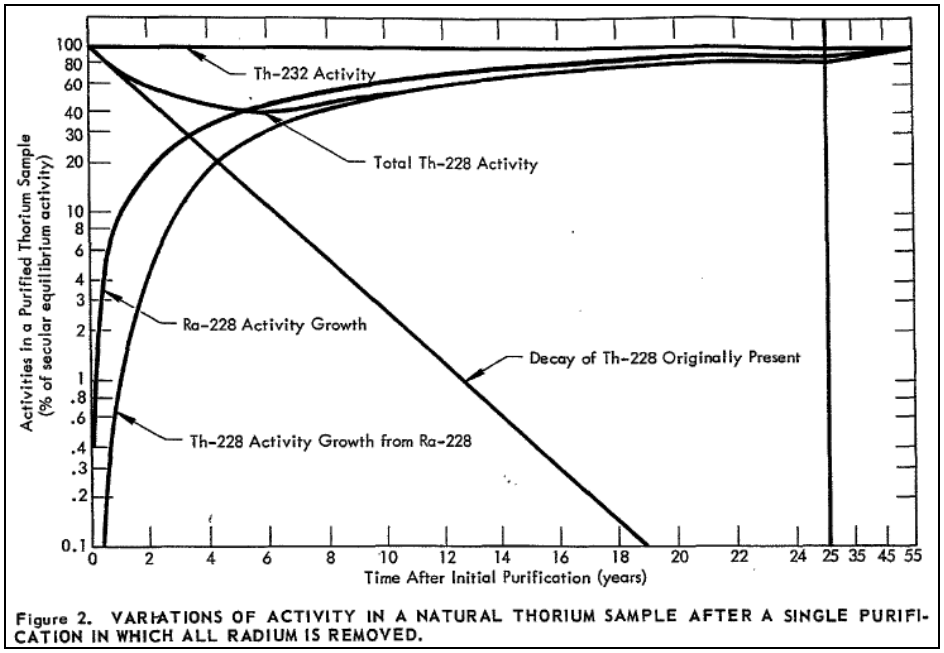

Figure 2. VARIATIONS OF ACTIVITY IN A NATURAL THORIUM SAMPLE AFTER A SINGLE PURIFICATION IN WHICH ALL RADIUM IS REMOVED.

Figure B. Decay and Ingrowth of Various Radionuclides after Purification of Thorium (from West 1965)

Chest Count Gamma Energy Spectra

Figure C below illustrates the gamma spectrum from a chest counter showing (1) a person with no thorium body burden (lower curve), and (2) the simulated spectrum of a worker with a lung burden of thorium in the upper curve (West 1965, page 13).

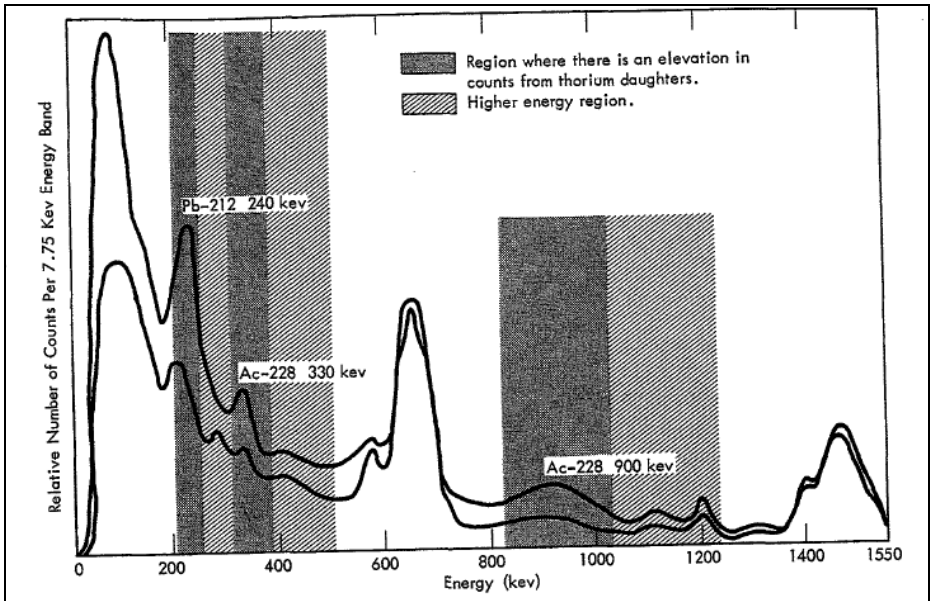

Figure 13. SCHEMATIC REPRESENTATION OF THE THORIUM IN VIVO SCREENING TECHNIQUE.

Figure C. Gamma-ray Energy Spectra from Chest Counter (from West 1965)

According to West 1965, page 25, a Th-228/Th-232 (not Th-238 as in the text) ratio of 0.8 and a Ra-228/Th-232 ratio of 0.6 was assumed. This corresponds to the calibration source, quoted in an article by Scott (1966), that was used in deriving the empirical calibration factor of **8.84 mg thorium per sum of net count ratios,** as quoted in a 1961 article by Scott (1961). These ratios are also quoted on page 31 of ORAUT-TKBS-0014-5 (2006). The details of how the empirically derived calibration factor for the chest counter was obtained are not provided in any of these documents (i.e., the placement of the standard source, counting statistics, etc.). However, a Ra-228/Th-232 ratio of 0.6 (corresponding to approximately 8 years after purification) would neither be applicable nor constant for Y-12 personnel working with purified thorium and being chest counted every 6 months.

Y-12 DOE Recorded Chest Count Data

SC&A's preliminary review of a few of the Y-12 claimant files identified five cases that had chest count data recorded. Of these five cases, four Department of Energy (DOE) files recorded the chest count results as mg of thorium during the period 1961–1974, and one DOE file recorded the chest count results as nCi of Ac-228 in 1995. These were the only quantities listed; no Pb-212 or other related data were provided in the DOE files.

DR Use of DOE Recorded Thorium Data

SC&A analyzed the methodology used by NIOSH in these five cases. The specific activity of Th-232 is 0.11 nCi/mg, which corresponds to 244.2 dpm/mg; this is the conversion factor SC&A found in some of the DR worksheets. The following table summarizes the different DR methodologies SC&A found in analyzing the five cases:

Table 1. Units in DOE Records and DR Methodologies Found in Five DR Cases

Year of DR Report	Years of bio	Units in DOE records	Th-232 used in DR*	Th-228 used in DR*	Correct per PER-031
2005 & 2009	1971	Thorium (mg)	60%	40%	No
2006	1964–1974	Thorium (mg)	100%	80%	Yes
2006	1961–1963	Thorium (mg)	100%	80%	Yes
2007	1968	Thorium (mg)	100%	80%	Yes
2010	1995	nCi Ac-228**	100%	25%	No

*Percent of IMBA-derived Th-232 intake from bioassay/MDA data.
**DR assumed Th-232/Ac-228 ratio of 1:1 in the input to the IMBA program.

These methods are not consistent, technically correct, or claimant favorable.

MDA or LOD Value

A brief treatment of the MDA value is provided on page 31 of ORAUT-TKBS-0014-5 (2006), but no detailed analysis is presented. The LOD of 0.6 nCi, for screening purposes, was derived in a fairly complex way in the Scott 1961 and the West 1965 documents.

MDA Value as Derived by NIOSH – From page 31 of ORAUT-TKBS-0014-5 (2006), it appears that NIOSH derived an MDA value of 0.6 nCi by assuming a Th-228/Th-232 ratio of 0.8 [from the Th-228/Th-232 ratio of 80% at 1 year shown in Figure 5-4 on page 31 of ORAUT-TKBS-0014-5 (2006)], which corresponds to a maximum permissible lung burden (MPLB) of

3.2 nCi Th-232, as per Figure 2 on page 13 of the West 1965 document. A Ra-228/Th-232 ratio of 0.6 was then assumed, as stated on page 31 of ORAUT-TKBS-0014-5 (2006). (According to Figure B above, this would correspond to an elapsed period of approximately 8 years, which is not acceptable for DR purposes, as will be discussed later.) The MDA value of 20% of MPLB was then taken from West 1965, page 26, and applied to the 3.2 nCi Th-232 to derive an MDA of 0.2 × 3.2 nCi = **0.6 nCi Th-232**. This would correspond to 0.6 nCi × (1/0.11 nCi/mg) = 5.5 mg Th-232.

Limit of Detectability Derived in Scott 1961 and West 1965 Documents – Pages 25–26 of the West 1965 document outline a method that could use the chest count results for an indication of thorium uptakes, and states a "…*limit of detectability*" of about 20% of the MPLB, using certain assumptions (i.e., Ra-228/Th-232 ratio of 0.6 and a Th-228/Th-232 ratio of 0.8); but states that the sensitivity "…*is dependent upon the ratios of the Th-232 and Ra-228 to the daughters being measured.*" West 1965 further states:

> *Because of this dependency on daughters, a quantitative estimate of thorium or radium is difficult because it depends upon a knowledge of the relationship between the daughters and these parents.*

The main purpose of the work leading to the 1965 West article was to document that safeguards were in place at Y-12 such that workers were not receiving a significant lung burden of thorium from the purified thorium project. This article was not designed to assign lung burdens and resulting doses for determination of compensation. SC&A's understanding of the methodology used in the West 1965 document to illustrate some sort of detection limit for screening (under certain conditions) is as follows:

The LOD value of 20% of MPLB (0.2 × 3.2 nCi = 0.6 nCi; and 0.6 nCi × 1.0 mg/1.1E-1 nCi = 5.5 mg thorium) was derived by:

- Using the results of counting 1,100 persons not exposed to thorium to obtain the gamma energy spectrum represented by the lower curve in Figure C above (Figure 13 on page 13 of West 1965). The sum of the ratio of the thorium peak counts to the adjacent higher-energy region counts for the three major peaks was 3.23 ± 0.7.

- The gamma energy spectrum in the upper curve of Figure C was simulated as an individual with a lung burden (the amount of lung burden was not stated). The details of how this spectrum was obtained were not presented in the West 1965 document; only that the following conditions were assumed:

  - A Th-228/Th-232 ratio of 0.8 (from the Th-228/Th-232 ratio of 80% at 6 months) as shown in Figure B (Figure 2 on page 13 of West 1965), which corresponds to a MPLB of 3.2 nCi.

  - A Ra-228/Th-232 ratio of 0.6, as stated on page 25 of West 1965 (according to Figure B, this would correspond to an elapsed period of approximately 8 years, which is not acceptable for DR purposes, as is discussed later).

- An empirically derived conversion factor was created by summing the ratio of the counts in one Pb-212 and two Ac-228 gamma energy peaks to those in the next higher energy region of each peak, and then subtracting out the sum of these same ratios from the 1,100 workers with no industrial thorium intakes. The resulting ratio is then multiplied by a factor of 8.84 mg thorium. This is illustrated below:

$$mg_{Th} = \left(\left(\frac{ROI_{0.208-0.248}}{ROI_{0.249-0.295}} + \frac{ROI_{0.299-0.395}}{ROI_{0.396-0.547}} + \frac{ROI_{0.775-0.930}}{ROI_{0.931-1.077}} \right) - 3.23 \right) * 8.84$$

  Note: The method used to derive the factor of 8.84 mg thorium is not provided.

- According to the West 1965 article, page 26, the sum of the ratios of the background Pb-212 and Ac-228 peaks counts to the adjacent higher-energy region counts for the 1,100 workers was 3.23 + 0.7 at the 95th percentile confidence interval, and a rise of 0.7 represents about 20% of one MPLB. Therefore, the corresponding LOD was derived as follows:

$$LOD = 0.20 \times 3.23\ nCi = 0.6\ nCi = 5.5\ mg = 1{,}332\ dpm$$

  Note: Details on how an increase in the sum of the ratios by 0.7 represents 20% of the MPLB are not provided.

3.2.3 Summary of Findings

As discussed above, SC&A has identified four findings regarding the technical merit of changes introduced in ORAUT-TKBS-0014-5, Rev. 01 PC-1, which resulted in the issuance of OCAS-PER-031. These findings are summarized below:

Finding #1: Change in Assigned Dose – The change in the Th-228/Th-232 ratio from 1:1 to 0.8:1 would actually reduce the assigned dose, not increase it, if thorium body burdens are based on chest counts [i.e., using 80% of the Th-232 intake to assign Th-228 intake will result in a lower body burden (and dose) than using the previous value of 100%]. The only instance where a Th-228/Th-232 ratio of 0.8/1.0 would increase the overall dose is if only the counts from Pb-212 were used to determine the Th-228 body burden, and then the Th-232 body burdens were derived from those results. This method was not used by NIOSH and cannot be used with the data provided in the DOE records because the detail of the gamma energy spectrum counts is not recorded.

Finding #2: Chest Counts Conversion to Th-232 Body Burden – The method NIOSH uses [in both the older ORAUT-TKBS-0014-5 (2005a and 2005b) and the new ORAUT-TKBS-0014-5 (2006) versions] to assign Th-232 body burden most likely assumes that the Pb-212 and Ac-228 counts obtained during the chest counts are directly related to Th-232 in the lungs on a consistent basis. This is incorrect because the gammas from Pb-212 and Ac-228 are actually being counted and then recorded as mg of thorium, or nCi of Ac-228. However, by definition, purified thorium less than 1-year old is not in equilibrium with the parent Th-232 because the Ra-228 in the decay chain has a half-life of 5.7 years (see Figure A). The use of an Ac-228/Th-

232 ratio of 1.0 would require an elapsed period over 30 years (see Figure B) because of the Ra-228 half-life of 5.7 years; even the use of an Ac-228/Th-232 ratio of 0.6 would require an elapsed period of approximately 8 years. Both time periods are too long for Y-12 personnel working with purified thorium during the first year after receipt. The Ac-228/Th-232 ratio ranges from near zero to 10% during the first year (see Figure B), with a value of approximately 6% at 6 months; this would increase the assigned dose by a factor of 10, when compared to using an Ac-228/Th-232 ratio of 0.6. Additionally, chest counts taken at later times will have a different Ac-228/Th-232 ratio because of Ra-228 ingrowth. Therefore, the most important issue is not the Th-228/Th-232 ratio, but the unknown (and changing) Ac-228/Th-232 ratio when using chest count data derived from counting Ac-228 gamma rays. A similar analysis applies to the Pb-212 counts.

Finding #3: Different Solubility of Thorium and Decay Products in the Lung – The lung may retain thorium, being relatively insoluble, longer than the more soluble decay products in some cases. Therefore, a lung count based on the decay product (i.e., Ac-228 and/or Pb-212) would not necessarily have a consistent relationship to the thorium (Th-232 and/or Th-228) body burden.

Finding #4: MDA or LOD Value – To attain a Ra-228 to Th-232 ratio of 0.6 [page 31 of ORAUT-TKBS-0014-5 (2006)] for determining the MDA of 0.6 nCi would require approximately an 8-year period from purification to counting. This is not a valid assumption for most workers and is not constant between each chest count.

3.2.4 Conclusions

SC&A finds the use of OCAS-PER-031 and the Y-12 ORAUT-TKBS-0014-5 (2006) thorium dose assignment procedures to be inappropriate for the following reasons:

- Neither OCAS-PER-031, nor the ORAUT-TKBS-0014-5 (2006) it is based on, is technically correct.
- The application of OCAS-PER-031 in past DRs that have been reviewed is incorrect and inconsistent in many cases.
- The application of OCAS-PER-031 and ORAUT-TKBS-0014-5 (2006) (as worded) actually decreases the assigned thorium dose compared to the previous method.
- Changes in the thorium equilibrium ratios using original count data cannot be performed because the raw count data are not recorded in the DOE files.
- A consistent relationship between thorium and decay products cannot be assumed in the lung because of possible changes in solubility.
- The assumptions of a constant Th-238/Th-232 ratio of 0.8 and a Ra-226/Th-232 ratio of 0.6 made in deriving the calibration factor and MDA value are not applicable to personnel working with purified thorium at Y-12 during the first year, and having chest counts every 6 months.

It is also relevant to compare the similarities of the chest-counting equipment and data collected/recorded for the Y-12 facility to that of the Fernald facility. Y-12 equipment and counting techniques were used at the Fernald facility; however, as the result of numerous reviews and analyses (as summarized in SC&A 2012), it was determined that the thorium data for Fernald were not adequate to allow for sufficient accuracy in DR and an SEC was granted in 2012 for the period 1968–1978 for all workers at Fernald. The same issues are pertinent to the Y-12 thorium chest-counting data.

4.0 SUBTASK 3: EVALUATE THE PER's STATED APPROACH FOR IDENTIFYING THE NUMBER OF DRs REQUIRING RE-EVALUATION

Section 3.0 of OCAS-PER-031 identified the set of criteria used to determine the total population of claims that had the potential of being affected by changes in the Y-12 TBDs. At the time that OCAS-PER-031 (2007) was issued, NIOSH identified 693 Y-12 claims that were completed prior to that date and had a POC below 50%. This established an upper-bound estimate of the number of claims that may be impacted. NIOSH intends to screen these claims to determine if the evaluation of dose involved any of the methods outlined in Section 3 of this report concerning NIOSH's corrective action plan.

The application of these screening criteria will undoubtedly exclude many of the 693 potential claims from impacts associated with OCAS-PER-031 and the need for the reconstruction of the organ dose. However, until NIOSH reviews all of these claims, the actual number of cases that will be affected by OCAS-PER-031 and require a new dose assessment remains unknown.

In addition, based on the outcome of the findings identified as a result of our technical review of ORAUT-TKBS-0014-5 (2006), there may be a need to cancel OCAS-PER-031 and reissue a PER after this document is appropriately revised.

5.0 SUBTASK 4: CONDUCT AUDITS OF A SAMPLE SET OF DRs AFFECTED BY OCAS-PER-031

In behalf of the four subtasks evaluated under OCAS-PER-031, SC&A identified four findings that question the technical merit of the *Y-12 Occupational Internal Dose* TBD and corrective actions taken by NIOSH in OCAS-PER-031.

SC&A recommends that the selection of Subtask 4 cases be delayed until the Subcommittee on Procedures Review can further investigate SC&A's findings and concerns.

6.0 REFERENCES

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ATTACHMENT A – SC&A'S PREVIOUS FINDINGS IN Y-12 TECHNICAL BASIS DOCUMENTS

On September 19, 2005, SC&A issued a draft report (SC&A 2005) SCA-TR-TASK1-0007 titled, *Y-12 National Security Complex Site Profile Review*. This draft report presents SC&A's evaluation of the National Institute for Occupational Safety and Health (NIOSH) Site Profile for the Y-12 National Security Complex, which was issued as six separate technical basis documents (TBDs) numbered ORAUT-TKBS-0014-1 through ORAUT-TKBS-0014-6.

The finding most relevant to the evaluation of OCAS-PER-031 is stated on page 72 of that document (SC&A 2005):

> *The TBD should provide additional information to the dose reconstructor relating to operations involving thorium and its daughters, including consideration of concentrating daughter products during processing and waste management. Chemical and metallurgical processes can displace the equilibrium existing in the original source material. Further guidance on when to assign thorium uptakes and what default assumptions should be used during various phases of thorium processing should be provided.* [Emphasis added.]

SC&A's current evaluation of the Y-12 ORAUT-TKBS-0014-5 (2006) document and PER-031 concurs with this statement.