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ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

National Institute for Occupational Safety and Health

REVIEW OF ORAUT-PROC-0044: *SPECIAL EXPOSURE COHORT (SEC)*, REVISION 00, OCTOBER 7, 2005

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Disclaimer

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ABBREVIATIONS AND ACRONYMS

ABRWH or the Board	Advisory Board on Radiation and Worker Health
AWE	Atomic Weapons Employer
CATI	Computer Assisted Telephone Interview
CFR	Code of Federal Regulations
DCAS	Division of Compensation Analysis and Support
DOE	U.S. Department of Energy
DWE	Daily Weighted Exposure
EEOICPA	Energy Employees Occupational Illness Compensation Program Act of 2000
FMPC	(Fernald) Feed Materials Production Center (referred to simply as Fernald)
HHS	Health and Human Services
IMBA	Integrated Modules for Bioassay Analysis
MDA	minimum detectable activity
MeV	megaelectron-volts
MFP	mixed fission product
mg	milligram
MI/cc	microcuries per cubic centimeter
MIVRML	Mobile In Vivo Radiation Monitoring Laboratory
mrem	millirem
NIOSH	National Institute for Occupational Safety and Health
NOCTS	NIOSH OCAS Claims Tracking System
NTA	nuclear track emulsion, type A
NS	Nevada Site
NTS	Nevadva Test Site
OCAS	Office of Compensation Analysis and Support
ORAUT	Oak Ridge Associated Universities Team
PER	Petition Evaluation Report
PIC	personal ionization chamber; pocket ionization chamber
POC	probability of causation
QA	Quality Assurance
rem	roentgen equivalent man

REX	Radiological Exposure Database
SC&A	S. Cohen and Associates (SC&A, Inc.)
SEC	Special Exposure Cohort
SMT	stable metal tritide
TBD	Technical Basis Document
TLD	thermoluminescent dosimeter
µg/l	microgram per liter

1.0 INTRODUCTION

During its meeting held in Santa Fe, New Mexico, June 19–21, 2012, the Advisory Board on Radiation and Worker Health (Advisory Board or ABRWH) directed SC&A to perform a review of ORAUT-PROC-0044, "*Special Exposure Cohort (SEC)* Revision 00, October 7, 2005" (ORAUT 2005). SC&A's method for reviewing National Institute for Occupational Safety and Health/Division of Compensation Analysis and Support (NIOSH/DCAS[1]) procedures is described in its procedure, *A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction*, which was approved by the Advisory Board in April 2004 (SC&A 2004). In addition, since PROC-0044 deals specifically with SEC petition evaluation reports, this review also takes guidance from *Board Procedures for Review of Special Exposure Cohort Petitions and Petition Evaluation Reports*, Revision 1 (SC&A 2006). Hence, unlike other procedure reviews performed by SC&A, which are concerned primarily with dose reconstructions, this review is uniquely concerned with SEC petition evaluation reports. As such, the criteria used to evaluate this procedure reflect a hybrid of the two SC&A procedures. Nevertheless, SC&A made use of its standard procedure review checklist (appearing in Section 4) as applicable to this situation. In addition to assessing the Oak Ridge Associated Universities Team (ORAUT) SEC procedure against the formal requirement and guidance documents, SC&A made use of its many years of experience as the Advisory Board's technical contractor to inform its review.

The objective of this particular review is to evaluate the degree to which ORAUT-PROC-0044 meets the requirements of 42 CFR Part 83 and sound health physics practice. The procedure provides protocols for (1) determining whether an SEC petition qualifies for evaluation, and (2) evaluating those qualifying petitions. Item (2) is within the scope of the mission of the Advisory Board as defined in the Energy Employee Occupational Illness Compensation Program Act of 2000 (EEOICPA), while item (1) is not (as best we understand the mission of the Advisory Board). Hence, this review is limited to that portion of the procedure that addresses item (2).

ORAUT-PROC-0044, which is a procedure prepared by ORAUT, the technical contractor hired by NIOSH, must be reviewed within the context of a hierarchy of documents, beginning with the EEOICPA and its implementing regulations, 42 CFR Parts 82 and 83, and DCAS guidelines, specifically DCAS-PR-004, OCAS-IG-001, and OCAS-IG-002. Hence, our review tries to address two questions:

(1) Does the procedure materially follow the provisions of the statute, its implementing regulations, and DCAS guidelines?

(2) Are the guidelines scientifically sound and claimant favorable?

Following this introduction, Sections 2 and 3 address these questions.

[1] Formerly known as OCAS (Office of Compensation Analysis and Support).

As described in Section 6.2 of the ORAUT procedure, qualified petitions are evaluated under one of two provisions of Part 83, as follows:

> *First, a 42 CFR 83.13 petition is filed when the petitioner is not a claimant for whom NIOSH has already found that it cannot complete a dose reconstruction. Second, a 42CFR 83.14 petition is filed when the petitioner is one for whom NIOSH could not complete a dose reconstruction.*

ORAUT-PROC-0044 and this review address both types of qualified petitions.

Our review does not attempt to evaluate every statement made in every section of ORAUT-PROC-0044, but is limited to those guidelines considered to be essential to a scientifically sound and claimant-favorable SEC petition evaluation report and the degree to which the procedure faithfully follows Part 83 in significant procedural areas. It should be noted that Part 83 refers only to NIOSH, which will be taken here as referring to the NIOSH operating unit, DCAS. It is assumed that ORAUT is acting on behalf of or supporting DCAS in fulfilling many of its duties, so responsibilities flow down to ORAUT from DCAS in most instances.

Section 2.0 of this report evaluates ORAUT-PROC-0044 for procedural compliance, and Section 3.0 for technical compliance to Part 83 regulations and DCAS-PR-004 guidelines. As mentioned previously, Section 4.0 consists of an SC&A-developed and Board-approved checklist, which is adapted for review of the ORAUT procedure.

2.0 PROCEDURAL EVALUATION

ORAUT-PROC-0044 provides step-by-step instructions to ORAUT for evaluating SEC petitions in accordance with 42 CFR Part 83 and DCAS-PR-004, which are superior to it in the hierarchy of regulations and guidance related to SEC petitions and flowing down from EEOICPA. This section assesses the degree of compliance of PROC-0044 to the procedural steps delineated in Part 83 and DCAS-PR-004 (which provides guidance on compliance with the requirements of Part 83). This assessment will examine closely the DCAS procedure from the point of view of whether the ORAUT procedure complies with its guidance; the DCAS procedure itself, however, will not be assessed for its compliance with Part 83. This assessment will begin at the point after a petition is found qualified, which corresponds to 43 CFR 83.12, Section 6.2 of DCAS-PR-004, and Section 6.1.12 of ORAUT-PROC-0044.

42 CFR 83.12

Since both ORAUT-PROC-0044 and DCAS-PR-004 generally follow the order of topics covered in 42 CFR Part 83, this review will begin with the first applicable section of the latter, namely §83.12, "How will NIOSH notify petitioners, the Board, and the public of petitions that have been selected for evaluation?," which prescribes how NIOSH will notify petitioners, the Advisory Board, and the public of petitions that have been selected for evaluation. As such, all of this section's provisions can be categorized as "procedural," rather than "technical." For convenience, the document review is summarized in Table 1. All relevant material in DCAS-PR-004 is found in Section 6.2, and all relevant material in ORAUT-PROC-0044 is found in Section 6.1.12 and Attachment A (a flowchart).

Table 1: Compliance with 42 CFR Part 83.12

42 CFR 83.12 Requirement	DCAS-PR-004 Section	ORAUT-PROC-0044 Section	Comments
§83.12: *How will NIOSH notify petitioners, the Board, and the public of petitions that have been selected for evaluation?*	6.2	6.1.12 and Attachment A (page 10)	
(a) *NIOSH will notify the petitioner(s) in writing that it has selected the petition for evaluation. NIOSH will also provide the petitioner(s) with information on the steps of the evaluation and other processes required pursuant to these procedures.*	6.2.1	6.1.12.2	
(b) *NIOSH will combine separate petitions and evaluate them as a single petition if, at this or at any point in the evaluation process under §§83.13 and 83.14, NIOSH finds such petitions represent the same class of employees.*	6.2.3	6.1.12.3	

Table 1: Compliance with 42 CFR Part 83.12

42 CFR 83.12 Requirement	DCAS-PR-004 Section	ORAUT-PROC-0044 Section	Comments
(c) *NIOSH will present petitions selected for evaluation to the Board with plans specific to evaluating each petition. Each evaluation plan will include the following elements:* *(1) An initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation conducted under §83.13 or §83.14; and* *(2) A list of activities for evaluating the radiation exposure potential of the class and the adequacy of existing records and information needed to conduct dose reconstructions for all class members under 42 CFR part 82.*	6.2.3	6.1.12.3	
(d) *NIOSH may initiate work to evaluate a petition immediately, prior to presenting the petition and evaluation to the Board.*	6.2.4	N/A	"Permission" is given to DCAS, which then might direct ORAUT to perform work.
(e) *NIOSH will publish a notice in the Federal Register notifying the public of its decision to evaluate a petition.*	6.2.5	6.1.12.4	
N/A	6.2.6	6.1.12.1	DCAS 6.2.6 requires posting notice of the decision on the NIOSH/ DCAS website as well.

As seen from Table 1, ORAUT-PROC-0044 complies fully with the requirements of 42 CFR 83.12, with the note that the procedure could mention that DCAS might ask ORAUT to begin preparing the Petition Evaluation Report (PER) before the petition is presented to the Board. The flow diagram of Appendix A (page 10) of the former procedure adequately reflects, in summary, the steps of the procedure's text.

42 CFR 83.13

The next section of 42 CFR Part 83 that contains procedural requirements applicable to ORAUT is Section 83.13, "How will NIOSH evaluate petitions, other than petitions by claimants covered under §83.14?" Petitions covered under this section are those where the petitioner is not a claimant whose claim NIOSH has already evaluated and determined that it cannot perform a dose reconstruction. This section contains technical items in addition to procedural items; only the latter will be examined here. Most relevant material in DCAS-PR-004 is found in Section 6.4, and all relevant material in ORAUT-PROC-0044 is found in Section 6.2 and is summarized in the Attachment C flowcharts. Table 2 summarizes SC&A's assessment of ORAUT-PROC-0044's compliance with requirements of the higher level documents.

Table 2: Compliance with 42 CFR Part 83.13

42 CFR 83.13 Requirement	DCAS-PR-004 Section	ORAUT-PROC-0044 Section	Comments
§83.13: How will NIOSH evaluate petitions, other than petitions by claimants covered under §83.14?	6.4 (primarily)	6.2 and Attachment C	
(a) *NIOSH will collect information on the types and levels of radiation exposures that potential members of the class may have incurred as specified under 42 CFR 83.14, from the following potential sources, as necessary:* Eight sources of information follow. In summary: (1) the petition; (2) DOE and AWE facility records; (3) potential members of the class and their survivors; (4) labor organizations; (5) witnesses present during the relevant period of employment at the facility; (6) NIOSH records from epidemiological research on DOE populations and from 42 CFR 82 dose reconstructions; (7) Records from research, dose reconstructions, medical screening programs, etc.; and (8) other sources.	6.4.11 (also, 6.4.1, 6.4.4, 6.4.6, 6.4.7, 6.4.8)	6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5	The DCAS procedure mentions data sources in several sections; Section 6.4.11 explicitly addresses the eight sources of information in §83.13(a). The ORAUT procedure explicitly lists the Part 83 sources in Section 6.2.4.1.
(b) *The Director of OCAS may determine the records and/or information requested from DOE, an AWE, or another source[s] to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available.*	6.3.1.3, 6.4.10	N/A	This section is not applicable to ORAUT.
(c) *NIOSH will evaluate records and information collected to make the following determinations:*	6.4	6.2	
(1) Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?	6.4.1ff	6.2.7	
(2) How should the class be defined, consistent with the findings of the analysis discussed under paragraph (c)(1) of this section?	6.4.16	6.2.6	
(3) Is there a reasonable likelihood that such radiation dose may have endangered the health of members of the class?	6.4.15	6.2.8	Both discrete and non-discrete radiation events
(d) *NIOSH will submit a report of its evaluation findings to the Board and to the petitioner(s). The report will include the following elements:* Five elements follow: (1) identification of petition; (2) proposed class definition; (3) justification for including groups who were not specified in original petition; (4) summary of findings concerning adequacy of records and information for reconstructing doses under 42 CFR Part 82; and (5) for a class for which it is not feasible to estimate doses with sufficient accuracy, a summary of the	6.6, 6.7, 6.8, 6.9, Attachment 1	6.2.10	

Table 2: Compliance with 42 CFR Part 83.13

42 CFR 83.13 Requirement	DCAS-PR-004 Section	ORAUT-PROC-0044 Section	Comments
basis for establishing the duration of employment requirement with respect to health endangerment.			
(e) *The NIOSH report under paragraph (d) of this section shall be completed within 180 calendar days of the receipt of the petition from NIOSH. The procedure for computing this time period is specified in §83.5(c). In addition, the computing of 180 calendar days shall not include any days during which the petitioner may be revising the petition to remedy deficiencies identified by NIOSH under §83.11(a) or (b), nor shall it include any days during which the petitioner may request a review of a proposed finding under §83.11(c) or during the conduct of such a review under §83.11(d).*	6.3, 6.7.1	–	The ORAUT procedure does not appear to include the requirements of the CFR and DCAS documents related to establishing a time-line for completion of the Petition Evaluation Report.

As seen from Table 2, ORAUT-PROC-0044 complies with the requirements of 42 CFR 83.13, with the exceptions noted in the following paragraphs. The flowcharts of Attachment C of the former procedure adequately reflect, in summary, the steps of the procedure's text.

Finding 1: ORAUT-PROC-0044 Section 6.2 states:

> ***As seen in OCAS-PR-004, Section 6.3.1, the feasibility evaluation process is guided by 42 CFR 83.13(b)(1). The rule states that doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose that could have* [been] *incurred in plausible circumstances by any member of the class. Sufficient information may also be needed to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose.***

DCAS-PR-004 (Rev. 1), Section 6.3.1 does not refer to the feasibility evaluation process; this incorrect citation may be due to the fact that the ORAUT procedure predates the Rev. 1 DCAS procedure. However, a more important observation is that the referenced Part 83 section, 42 CFR 83.13(b)(1), also does not treat the feasibility evaluation process; rather, it deals with the role of the Director of OCAS. Hence, the citation to Part 83 in the quoted ORAUT-PROC-0044 section should be corrected.

Finding 2: As noted in Table 2, ORAUT-PROC-0044 does not appear to include the requirements of 40 CFR 83.13(e) and DCAS-PROC-004 Sections 6.3 and 6.71 related to establishing and maintaining a timeline for completion of the Petition Evaluation Report.

42 CFR 83.14

The next section of 42 CFR Part 83 that contains procedural requirements applicable to ORAUT is Section 83.14, "How will NIOSH evaluate a petition by a claimant whose dose reconstruction NIOSH could not complete under 42 CFR part 82?" The requirements contained therein relate to steps that are taken when DCAS determines that it is not feasible to reconstruct doses with

sufficient accuracy for members of the class. Table 3 summarizes and lines up the Part 83 requirements, the DCAS guidelines (Section 6.5), and the ORAUT compliance (primarily, Section 6.2.9).

Table 3: Compliance with 42 CFR Part 83.14

42 CFR 83.14 Requirement	DCAS-PR-004 Section	ORAUT-PROC-0044 Section	Comments
§83.14: *How will NIOSH evaluate a petition by a claimant whose dose reconstruction NIOSH could not complete under 42 CFR part 82?*	6.5	6.2.9 (primarily), Attachment C	
(a) *NIOSH may establish two classes for evaluation, to permit the timely adjudication of the existing cancer claim:* *(1) A class of employees defined using the research and analyses already completed in attempting the dose reconstruction for the employee identified in the claimant's petition; and* (2) *A class of co-workers similar to the class defined under paragraph (a)(1) of this section, to be defined by NIOSH on the basis of further research and analysis, using the procedures under §83.13.*	6.5.1, 6.5.3	6.2.9	
(b) *NIOSH will determine the health endangerment criteria for adding the class under paragraph (a)(1) of this section to the Cohort, using the procedures under §83.13. NIOSH will report to the Board and to petitioner(s) the results of this determination, together with its finding under 42 CFR part 82 that there was insufficient information to complete the dose reconstruction. HHS will consider this finding under 42 CFR part 82 sufficient, without further consideration, to determine that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy.*	6.5.2, 6.6	6.2.8, 6.2.9	
(c) *NIOSH will evaluate the petition as it may concern a class of co-workers, as described under paragraph (a)(2) of this section, according to the procedures under §83.13.*	6.5.4, 6.6	6.2.9	ORAUT-PROC-0044 Section 6.2.10 covers reporting evaluation findings.

As seen from Table 3, ORAUT-PROC-0044 complies with the requirements of 42 CFR 83.14. The flowcharts of Attachment C of the former procedure adequately reflect, in summary, the steps of the procedure's text.

42 CFR 83.15, 83.16, 83.17, 83.18. 83.19

Part 83 continues past Part 83.14 with:

- 83.15: *How will the Board consider and advise the Secretary on a petition?*
- 83.16: *How will the Secretary decide the outcome(s) of a petition?*

- 83.17: *How will the Secretary report a final decision to add a class of employees to the Cohort and any actions of Congress concerning the effect of the final decision?*
- 83.18: *How can petitioners obtain an administrative review of a final decision by the Secretary?*

DCAS-PR-004 includes the following sections, which are related to the aforementioned Part 83 sections:

- 6.8: *Schedule a presentation to the Board*
- 6.9: *Establish a proposed decision on the outcome of the petition(s)*
- 6.10: *Transmit proposed decisions to the Board and the Secretary*
- 6.11: *Basis for the Secretary's (or designee's) making and reporting a final decision*
- 6.12: *If a class which the Board has recommended be designated is found not to meet the statutory criteria for adding a class, prepare for the Secretary a determination to be submitted to Congress within 30 calendar days following receipt of the Board's recommendation*
- 6.13: *Transmit and publicize final decisions*
- 6.14: *Transmit and publicize the outcome of congressional review*
- 6.15: *Conduct an HHS administrative review of final decisions, as necessary*
- 6.16: *Review the utility of newly obtained records and information for classes of employees added to the Cohort*

Finding 3: ORAUT-PROC-0044 ends with Section 6.2.10 and does not address any of the Part 83 requirements or DCAS-PR-004 guidelines contained in 43 CFR 83.15–18, and DCAS-PR-004 Sections 6.8–6.16. While it is recognized that DCAS, HHS, etc., may conduct many of the activities without ORAUT involvement, DCAS can and does call on ORAUT for support (i.e., preparing draft responses, recommendations, or other documents) in several of the areas. This should be reflected in the ORAUT procedure.

General Comments

SC&A's review of the ORAUT procedure resulted in the following three general comments/ findings that are not aligned with any particular sections of 42 CFR Part 83 and DCAS-PR-004.

Finding 4: It should be noted that ORAUT-PROC-0044 (ORAUT 2005) antedates the current version of DCAS-PR-004 (2011), so that the references in the former procedure to sections in the latter procedure are often incorrect and should be appropriately corrected in a future revision.

Finding 5: ORAUT-PROC-0044 does not adequately reflect the role of the Advisory Board and the Board's Technical Support Contractor (currently SC&A) in the SEC process. For example, Advisory Board Work Groups for specific sites often become very involved

reviewing, commenting on, and requiring additional analyses for PERs. The Technical Support Contractor reviews and comments on PERs and frequently performs its own independent evaluations and calculations, which are themselves evaluated by the Work Groups, DCAS, and ORAUT; and DCAS and ORAUT often respond with their own, new, or revised analyses and reports. This cycle may be repeated several times before convergence is reached and the Work Group is satisfied. In addition, all four organizations frequently speak to and gather information from claimants and their representatives.

Finding 6: ORAUT-PROC-0044 does not discuss the issue of separating SEC from Site Profile [Technical Basis Document (TBD)] issues that frequently arises when the Advisory Board, Work Groups, and the Board's Technical Contractor review PERs. When this issue arises, ORAUT is often charged with performing supporting work.

3.0 TECHNICAL EVALUATION OF QUALIFIED SEC PETITIONS

3.1 GENERAL CONSIDERATIONS

Section 6.2 of PROC-0044, "Evaluating Qualified Petitions," begins with the statement, "Note that in the SEC process, actual dose reconstruction is not required, only that the feasibility of dose reconstruction can be shown…," and refers to several guidelines developed by DCAS that can be used to help make judgments regarding the feasibility of performing dose reconstructions. SC&A reviewed Part 83 and concurs with this qualifying statement.

Section 6.2 of PROC-0044 states that the SEC petition evaluation process should explicitly evaluate the degree to which "…exposures could have endangered the health of members of the petition class-the maximum exposures." General criteria for judging health endangerment are provided in Section 6.3.11 of DCAS-PR-004. However, because of the very general nature of these criteria, one of the recurring challenges to the SEC petition evaluation process has been the lack of quantitative criteria/guidance that can help in determining exposures or conditions that represent health endangerment. On many occasions, an SEC PER published by NIOSH states that NIOSH was unable to reconstruct exposures with sufficient accuracy. However, in SC&A's opinion, many of these reports are unable to clearly establish, within a regulatory framework established by rule or precedent, that health was endangered. A review of the record of SEC decisions reveals that, once it has been determined that there was, in fact, the potential for at least some radiation exposures associated with weapons complex activities, and that doses could not be reconstructed with sufficient accuracy, health endangerment is presumed. To the extent possible, the program would benefit if additional criteria and/or guidance could be developed that help to define the level of radiation exposure that constitutes health endangerment. SC&A recognizes that efforts have been made by the Advisory Board in the past to establish quantitative criteria defining health endangerment, and that these efforts encountered many challenges. Nevertheless, SC&A believes that these efforts need to continue.

Section 6.2 of PROC-0044 reiterates the "tension" that exists between the need to thoroughly evaluate the issues raised in SEC petitions and timeliness. Timeliness is explicitly addressed in the statute and its implementing regulations and guidelines. In addition, timeliness is clearly of great concern to petitioners, as expressed by petitioners on numerous occasions at Advisory Board meetings. However, issues related to timeliness appear to arise primarily after an SEC PER is submitted to the Advisory Board, wherein NIOSH recommends denial of the petition. Such a recommendation often results in the initiation of a protracted review process by the Board that involves the cognizant Work Group, NIOSH, and SC&A trading reports and assessments, and meeting both in-person and by conference call. However, timeliness does not appear to be an issue with respect to PROC-0044, in that considerable attention is given to protocols that help to ensure that SEC PERs meet the 180-day schedule for delivery to the Advisory Board, and that this schedule is generally met.

3.2 EXAMINE SITE PROFILES, USER GUIDES, AND PREVIOUS DOSE RECONSTRUCTIONS

Sections 6.2.1 and 6.2.2 provide specific guidance to the team reviewing SEC petitions with respect to judging whether doses can be reconstructed with sufficient accuracy through the examination of site profiles, user's guides, and previous dose reconstructions. We understand why these steps in the review process could be useful, but it seems to miss the fundamental issues, which include the adequacy, accuracy, and completeness of the data needed to reconstruct exposures. The fact that there is a site profile, user's guide, and previous dose reconstructions for a given site does not necessarily mean that doses can be reconstructed with sufficient accuracy. SC&A believes that the starting point for an SEC petition evaluation should be an in-depth review of source documents that characterize the operations that took place at the facility, and the nature and extent of the external and internal dosimetry data and other data that might help in determining data accuracy, adequacy, and completeness.

One of the recurring findings SC&A has identified in the past is that site profiles, user's guides, and dose reconstructions are often deficient with respect to these issues. Specifically, site profiles are considered working documents that are a convenient tool to help dose reconstructors complete as many dose reconstructions as possible in a scientifically sound, consistent, and claimant-favorable manner. However, they were not conceived as a tool to assess data accuracy, completeness, and adequacy from the perspective of an SEC petition evaluation, though they can be useful for that purpose. For example, Section 1.2 of the Advisory Board's SEC petition review procedures states the following:

> *Site profile and workbook reviews can play a significant role in ensuring consideration of all the issues that may be part of the "full evaluation" of each petition required by 42 CFR 83. While they are helpful, such reviews are not essential to the process of review of SEC petitions and their evaluation reports (see Section 4).*

Finding 7: ORAUT-PROC-0044 should de-emphasize its dependence on site profiles, user's guides, and previous dose reconstructions for evaluating SEC petitions, and emphasize the need to review source documents that will help to achieve a complete understanding of the operations, radionuclides of concern, exposure scenarios, health physics oversight programs, and the accuracy, adequacy, and completeness of the data needed to reconstruct the doses to all workers over all time periods of interest to the petition. Reviews of site profiles, user's guides, and previous dose reconstructions can be helpful in accomplishing these types of reviews, but should not be assumed to be the authoritative documents with respect to SEC petition evaluations.

Continuing with this theme, Section 6.2.1.4 of PROC-0044 provides important direction, as follows: "determine whether a maximum potential exposure scenario can be developed for the defined class in the petition." Section 6.2.3 of PROC-0044 states that, "if reliable monitoring data exists for personnel meeting the class definition in the petition, dose reconstructions can be performed for individuals within the class." Other sections of PROC-0044 refer to judging data adequacy, etc. SC&A believes that the guidance should focus on how the evaluator should go

about identifying a maximum exposure scenario and compiling and evaluating data so that judgments can be made with respect to whether doses associated with a maximum exposure scenario can be reconstructed with sufficient accuracy. The guidance is limited with respect to these matters. SC&A's reviews of many SEC PERs include a suite of strategies designed to accomplish these very tasks. SC&A recommends that NIOSH and ORAUT take advantage of this collective experience and codify these strategies into its protocols for evaluating SEC petitions.

3.3 EXAMINE PERSONNEL AND AREA/FACILITY MONITORING DATA

Sections 6.2.3 and 6.2.4 of PROC-0044 provide guidance on using and researching personnel and area/facility monitoring data for evaluating SEC petitions. The guidance is structured in a manner that follows the hierarchy of data, where primacy is given to personnel monitoring data, such as film badge and bioassay data, followed by facility monitoring data, such as air sampling data, and concluding with source terms and process knowledge.

Section 6.2.3 begins to address SEC petition evaluations in a manner that is more consistent with the fundamental strategies we believe should be employed. For example, Section 6.2.3 of PROC-0044 states the following:

> *If only a portion of the group has monitoring records, reasonable assumptions can be made for the remainder of the group based on job title, work location, and the monitoring records that are available. This approach is identified in OCAS-PR-003, Performing and Reporting Dose Reconstructions. This process requires the ORAU Team to determine if personal monitoring records exist for the group, portions of the group, or individuals within the class identified in the petition for the identified period. This can be done by evaluating existing NIOSH data, including NOCTS, or by evaluating information requested from DOE or an AWE.*

This is the type of guidance that we believe should be emphasized in the procedure and developed to the fullest extent possible. However, a lot more can be done with respect to offering more detailed guidance on how one goes about collecting and analyzing data in the NIOSH OCAS Claims Tracking System (NOCTS).

Appendix A provides four examples of data completeness evaluations that have been completed in the past and describes the different strategies that have been employed to evaluate the use of surrogate or coworker approaches in an SEC context. The examples were chosen to cover different situations and challenges experienced based on the state of available records at individual sites (i.e., electronic databases, site-wide hardcopy records, claimant sampling, and workplace monitoring). In addition, Appendix B provides two examples of strategies that can be used to evaluate the possibility of data falsification, a concern that has been raised in the past by petitioners.

Finding 8: The guidance should be more specific with respect to the evaluation of NOCTS data that will help to determine data adequacy and completeness.

Continuing in this vein, Sections 6.2.3.7 and 6.2.4.2 of PROC-0044 refer to reviewing personnel monitoring data and area/facility monitoring data with respect to flaws. However, no guidance is provided with respect to what types of flaws to look for. Examples of possible flaws include evidence of data falsification, deliberately not wearing film badges, lack of responsiveness of NTA film to neutrons below 0.5 to 1 MeV, need to correct for photon and neutron angle of incidence, unreliable chest count data (such as the challenges experienced with Th-232 chest count data at Fernald), availability of both breathing zone and general air sampling data, and other such examples.

Finding 9: The guidance would benefit from identifying specific types of flaws in personnel and area/facility monitoring data that should be investigated, and examples of how those investigations can be performed.

Section 6.2.3 of PROC-0044 also makes reference to using surrogate data from another site to help fill in gaps that might exist in the data for the facility under consideration. However, the guidance does not mention the surrogate data criteria adopted by the Advisory Board.

Finding 10: The procedure would benefit by referencing the Advisory Board's surrogate data criteria.

4.0 CHECKLIST

The following presents a checklist of findings in accordance with SC&A's requirements for reviewing procedures. Because PROC-0044 focuses on SEC petition reviews rather than dose reconstruction reviews, the checklist is not entirely applicable to this procedure. For this reason, rather than scoring each item as 1 through 5, we simply indicate yes, no, or NA.

Document No.: OCAS-PR-0044		**Effective Date: 10/07/2005**	
Document Title: Special Exposure Cohort (SEC)			
Reviewer: John Mauro, Steve Ostrow, and Bob Barton			
No.	**Description of Objective**	**Rating 1-5**	**Comments**
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	Yes	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	Yes	
1.3	Is the procedure complete in terms of required data?	No	An overarching concern is that specific technical guidance is not provided regarding how to go about making the judgments required in the flow diagrams
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	Yes	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	No	See 1.3
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	NA	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	NA	

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No.	**Description of Objective**	**Rating 1-5**	**Comments**
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via **interview**:		
3.1.1	Is scope of information sufficiently comprehensive?	No	It appears that no steps are included in the process for feedback from the Board or for additional interviews and data capture activities.
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	No	Se 3.1.1
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	Yes	
3.1.4	Is the interview process sensitive to the claimant?	No	See 3.1.1
3.1.5	Does the interview process protect information as required under the Privacy Act?	NA	
3.2	Assess whether the procedure adequately addresses generic as well as **site-specific data** pertaining to:		
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	No	See 1.3
3.2.2	In vivo/In vitro bioassays	No	See 1.3
3.2.3	Missing dosimetry data	No	See 1.3
3.2.4	Unmonitored periods of exposure	No	See 1.3
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	NA	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	Yes	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	NA	
5.2	Is the procedure claimant favorable in instances of unknown parameters effecting dose estimates?	NA	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	NA	

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No.	**Description of Objective**	**Rating 1-5**	**Comments**
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	NA	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	NA	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	NA	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	NA	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	NA	

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APPENDIX A: EXAMPLES OF STRATEGIES USED BY SC&A IN REVIEWING THE COMPLETENESS OF AVAILABLE SITE-SPECIFIC RECORDS IN AN SEC CONTEXT

As stated previously in this document, two of the most important aspects in making an SEC determination are the "adequacy" and the "completeness" of available data sources. In this context, "adequacy" refers to the ability to use available data to accurately reflect real and meaningful exposures incurred by the worker population with sufficient accuracy. For example, during its review of thorium in-vivo (chest count) data for use in reconstructing internal exposures to Th-232 and associated daughter products, the Advisory Board determined that measurements given in units of "milligrams of thorium" were not "adequate" for the purposes of dose reconstruction. The basis of this determination was the lack of raw data and defined analytical methods that were used in arriving at the values of mg of thorium.[2] In this way, the dataset was not "adequate" to establish real and meaningful exposures for the exposed worker population.

"Completeness" of available datasets does not address the technical accuracy of the data, but rather how well the available records are representative of the potentially exposed worker population. The issue of data completeness is the subject of this appendix. The three most important facets of data completeness can be summarized by the following:

- Temporal coverage: Do the records cover the necessary time periods evaluated by the SEC?
- Job type coverage: Are the highest exposed job types covered by the available records?
- Work area coverage: Are the work areas of highest exposure potential represented by the available monitoring data?

Obviously, these facets are not mutually exclusive and are usually interdependent. For example, a particular dataset may have "complete" data as regards the chronology of the site, but is missing data for the highest job types and/or plant areas during some of those years. It must be noted that decisions regarding the "completeness" of a particular dataset in an SEC context are ultimately a judgment call. As such, there is no quantitative way to definitely determine whether particular monitoring records are complete. However, analytical methods have been used by SC&A in the past, which build a "weight of evidence" argument to assist the Advisory Board in making such determinations.

This appendix provides examples of some of the analytical approaches that have been used for SEC deliberations previously for four different sites (Hanford, Fernald, Nevada Test Site (NTS), and Mound). The examples were chosen to reflect many of the different scenarios and potential problems encountered by the Advisory Board in making SEC recommendations. The four chosen examples include analysis of an extensive electronic database (Example 1), compilation

[2] Th-232 cannot be measured directly in the lung and so must be inferred from the relative measurements of associated daughter products. The original daughter product measurements were not available, nor was the exact procedure used in calculating the lung burden of thorium.

of site-wide data from hardcopy records (Example 2), sampling of claimant dosimetry records (Example 3), and use of workplace monitoring in the absence of adequate bioassay records (Example 4).

Example 1: Electronic Internal Dosimetry Database for the Hanford Site

Background Summary:

In 2011, SC&A was tasked with performing a review of the most recent Hanford Site Profile (ORAUT 2010a–2010f) with a focus on remaining SEC issues for the period of July 1, 1972,[3] through December 31, 1990. One aspect of this site profile review was to assess the data completeness of internal monitoring records during this period. Hanford is somewhat unique, in that it has a very extensive electronic database (known as the Radiological Exposure or "REX" Database) of worker records, which are available for analysis. As described below, SC&A used the REX database to assess the extent of worker monitoring for individual radionuclides as it relates to temporal considerations, job title, and work location. The basic methodology and information available are described below. For the full results of the completeness analysis, the reader is referred to SC&A 2011, Appendix A.

Analytical Approach Taken:

SC&A 2011 states the purpose of the completeness analysis as follows:

> *The purpose of this report is to examine the internal monitoring records contained in the Radiological Exposure Database (REX) for adequacy and suitability in constructing the coworker model presented in Appendix C of the Hanford Site internal dose TBD (ORAUT 2010e). Specifically, this report will seek to identify monitoring practices, exposure potential, and potential gaps as they pertain to worker job categories, as well as periods of production and exposure potential during the SEC period.* (SC&A 2011)

As specified previously, a rather extensive database (REX) contains worker monitoring records for the Hanford Site. The REX database itself is made up of nearly 70 individual files; some of these files contain monitoring data, while most others represent reference tables that can be used to interpret the dosimetry files. As an example, the reference files "REX_DOE_OCCUPATION" and "REX_HAN_FACILITY" provide individual codes for job title and some individual work areas to be used in other database files. These reference files are necessary in order to be able to decode and associate the appropriate job titles and work locations with specific workers and monitoring results.

Inspection of the available REX Database files identified five main database files to be used in the internal completeness analysis. These files are described in Table A-1. The first file listed, REX_WORK_HIST, does not actually contain any monitoring data; however, it enables the tracking of individual workers (via an individual ID number) and their respective employment

[3] On October 20, 2009, the Advisory Board accepted the NIOSH recommendation to extend the Hanford SEC to cover all workers who meet the eligibility criteria up to June 30, 1972.

periods across the three internal dosimetry files of interest: 'INV_RESULT,' 'INV_ISO_RESULT,' and 'EXC_RESULT.' The last file in Table A-1, 'DOS_SUM_RESULTS,' is related to external dosimetry; however, it also contains individual worker job title information, which can be used to supplement job title information contained in the internal dosimetry files.

Table A-1: Description of REX Database Files Used in Completeness Study

DATABASE NAME	DESCRIPTION
REX_WORK_HIST	Identifies workers by a 'REX ID,' which allows for the tracking of individual workers across the different database files. Also contains employment start and end dates.
INV_RESULT	Lists in-vivo counting samples by REX ID and date, and assigns a tracking number to each in-vivo sample, which can be used to obtain the results of the count in 'INV_ISO_RESULT' described in the next row.
INV_ISO_RESULT	Uses the tracking number from 'INV_RESULT' and provides the radionuclides and result of the in-vivo sample.
EXC_RESULT	Contains the urinalysis data for workers listed by REX ID.
DOS_SUM_RESULTS	Contains external monitoring results, which are not part of this analysis; however, the database also contains job title information, which can be linked to the internal database files by REX ID

In many instances in the database, work location and/or job title are not specified for each individual internal monitoring result. For example, a worker might have dozens of urinalysis data points available, but only one of those results specifies the job title and work area. SC&A 2011 states the following on this issue:

> *Because taking this information at face value (i.e., only considering worker employment periods with a job title specified or only internal monitoring results that specify a work area) would severely limit the amount of data available for analysis, an approximate approach was developed, so that as much data as possible could be included. To this end, it has been assumed that, if a worker is identified with a specific job title, they held that job title throughout their SEC employment. Similarly, if a worker is identified with a specific area of work, it is assumed they spent their entire employment at that location.* (SC&A 2011)

Clearly this type of approach would result in some "double counting" for cases in which a worker may have held more than one job title or worked in more than one area of the site. SC&A 2011 explored the potential issue of double counting in its completeness study. For example, it was found that over 93% of the surveyed workers were associated with only one job title in the REX_Database. Less than 1% had more than two job titles, and no worker had more than 4 job titles. The effect on work location analyses was less easily quantified; however, it was deemed that the assumption of grouping workers into specific areas for the length of their employment was more beneficial than any potential loss in accuracy.

Using this assumption and available information on job title and work location scattered throughout the database, SC&A was able to modify the information in REX so that the majority

of internal monitoring results could be used in the completeness study. The subsequent analysis was able to draw some of the following conclusion/findings:[4]

(1) For the main radionuclides analyzed (Am, Cs, MFP, Pu, and U), workers associated with the 200 Tank Farms were most likely to be monitored during their employment.

(2) 'Radiation monitors,' 'electricians,' 'operators,' 'pipefitters,' and 'science technicians' were consistently among the five job titles most likely to be monitored during their SEC employment.

(3) In general, the most commonly monitored job titles by area and year were 'managers and administrators' (for the 100, 100-N, 200, and 300 Areas), 'operators' (for the 200, 200 Tank Farms, and 300 Area), and 'scientists' (for the 300 Area).

(4) In-vivo records analysis for americium, cesium, mixed fission products, and uranium monitoring showed a significant decrease in worker sampling in 1975 (generally less than 1% of the worker population was monitored). Other significant decreases in worker monitoring include 1974 (iodine), 1976–1977 (mixed fission products), and 1985 (cesium). Thorium-232 was sparsely monitored throughout the period, and there are very few data points overall. No significant decreases in worker monitoring were identified for plutonium.

(5) Exotic radionuclides with sparsely available records include thorium, iodine, polonium, neptunium, radium, curium, californium/berkelium, and 'total actinides.' Polonium, curium, and 'total actinides' were mostly periodic sampling, while radium and neptunium appear to be incident related.

Finding 1 demonstrates that one of the known areas of highest exposure potential, the 200 Tank Farms, had a higher percentage of workers monitored compared to the other areas. Finding 2 shows that high exposure potential jobs, such as 'operators' and 'technicians,' were often monitored more frequently than many of the other job types. However, Finding 3 also notes that 'managers and administrators' were the most commonly monitored job title for the 100 Area, and it is not likely that they would be among the highest potentially exposed job types.

Finding 4 notes where there are significant temporal gaps by radionuclide. It is important in the context of completeness to establish whether a greater risk for potential exposure might have occurred in those years. As part of its completeness review, SC&A also established what years and areas particular radionuclides are known to have been handled, so parallels can be drawn between any data gaps and any "off-normal" operations. Finally, Finding 5 notes that the available records for some of the more exotic radionuclides are sparse and likely not suitable for the development of a coworker model from a completeness standpoint.

Example 1 Discussion:

One of the major advantages to this type of approach of a completeness evaluation is the sheer amount of information and data contained in the REX database. Though certain assumptions had

[4] It must be noted that findings are meant to be summary conclusions and that much more quantitative information is contained in SC&A 2011 than is appropriate to include here.

to be made when applying the information (such as presumed job title and work location), this allowed for the inclusion of the vast majority of data available and provided a very good overview of the monitoring practices of the site as applied to nearly all workers (nearly 50,000 workers and their associated bioassay records were included in the completeness study). However, the advantages of this type of "site-wide" approach can also be viewed as a drawback, since issues such as the inconsistency of reporting the work location and job type require that workers be "grouped" based on the available information. This results in some "double counting," which can potentially cause the accuracy of conclusions regarding monitoring practices to suffer (for example, if one particular job title was 'reported' more often in the REX database).

One potential solution to this difficulty would be to perform both types of analyses:

- One analysis that only considers job and area information directly related to an individual monitoring result and ignores all other results for that worker
- A second analysis that associates job and area information with a particular worker for their entire employment (as was done in SC&A 2011)

The combined findings and observations from both analyses would likely provide a sufficiently solid analytical base from which to draw conclusions about the completeness of the available records. It should be noted that on May 31, 2012, NIOSH recommended that the SEC class be expanded to also cover the period from July 1, 1972, to December 31, 1983, on the basis of insufficient information to reconstruct doses to enriched uranium, U-233, neptunium or thorium. The Advisory Board agreed with this recommendation during its July 2012 meeting.

Example 2: Fernald In-Vivo Lung Count for Thorium

Background Summary:

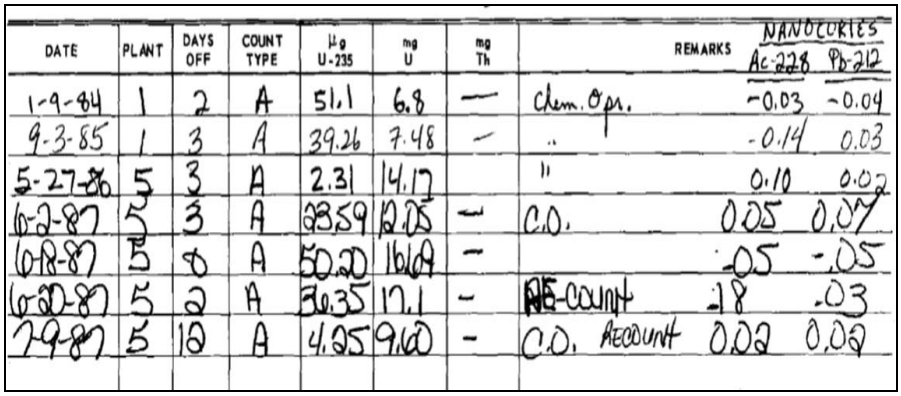
While the majority of processing at Fernald concerned uranium compounds, thorium compounds were also processed at the site, at least up until 1979 and perhaps afterwards in a minimal capacity. Fernald also became the Department of Energy's (DOE's) national repository for thorium compounds beginning in 1972. Therefore, even after the end of most processing in 1979, exposure potential would have existed through stewardship and repackaging operations up through the end of the SEC period in 1989.

From 1953 up through 1967, Fernald utilized Daily Weighted Exposure (DWE) studies to characterize the alpha contamination present in the worker's breathing zone as a way of controlling radiation intakes. Starting in 1968, Fernald began receiving periodic visits from the Mobile In-Vivo Radiation Monitoring Laboratory (MIVRML), which was a mobile lung counter developed at Y-12. Once the MIVRML arrived on site, the practice of performing DWE studies ceased and monitoring for thorium deposition, along with uranium, was assigned to the mobile counter. The MIVRML went through two different periods of reporting conventions for thorium; from 1968–1978, thorium measurements were reported in "milligrams of thorium," while post-1978 thorium measurements were reported as the daughter products of Ac-228 and Pb-212.

In March 2008, NIOSH released its coworker model for thorium exposure entitled, *Thorium In Vivo Coworker Study for FEMP – A Proposed Attachment for ORAUT-TKBS-0017-5, Revision 1* (ORAUT 2008). On April 26, 2012, the Advisory Board determined that Th-232 internal doses cannot be reconstructed with sufficient accuracy for the 1968 to 1978 period (when thorium lung burdens were reported in mg of Th). Therefore, the following completeness study example will focus on the later period of thorium in-vivo monitoring (1979–1988).

Analytical Approach Taken:

No electronic database previously existed to characterize in-vivo monitoring at Fernald. Therefore, ORAUT 2008 developed its coworker model using site-specific hardcopy logbooks, which would document the in-vivo results for individual workers. These logbooks contained the worker's name, a badge number, date of the measurement, number of days off, measurement result, and in most cases the work location (by plant) and job title. An example of a typical logbook is shown in Figure A-1. One vital piece of evidence that the logbooks do not contain is which workers might have handled thorium, and how the in-vivo measurements might reflect these potential exposures. The available hardcopy logbooks contained both claimants and non-claimants, and were compiled into an electronic database by NIOSH/ORAUT.



DATE	PLANT	DAYS OFF	COUNT TYPE	μg U-235	mg U	mg Th	REMARKS	NANOCURIES Ac-228	NANOCURIES Pb-212
1-9-84	1	2	A	51.1	6.8	—	chem. Op.	-0.03	-0.04
9-3-85	1	3	A	39.26	7.48	—	"	-0.14	0.03
5-27-86	5	3	A	2.31	14.17		"	0.10	0.02
6-2-87	5	3	A	23.59	12.25	—	C.O.	0.05	0.07
6-8-87	5	0	A	50.20	16.69	—		-.05	-.05
6-22-87	5	2	A	36.35	17.1	-	RE-count	.18	.03
7-9-87	5	10	A	4.25	9.60	-	C.O. RECOUNT	0.02	0.02

Figure A-1. Example of Thorium Logbooks used in ORAUT 2008

Because the practice of reporting the job title and work area was so prevalent, the approach and assumptions utilized in Example 1[5] were not deemed necessary. The first step in the completeness evaluation involved looking at an overview of records by year to determine the number and relative magnitude of the results. The purpose of this is to determine if there are years with significantly less monitoring, but which might have shown greater exposure potential via the magnitude of available sampling. An example of this analysis is shown in Table A-2, which displays the relative magnitude of results by counting the number of results above the minimum detectable activity (MDA). As seen in the table, the number of total samples generally increased from 1979 onward, with a significant jump in 1984. Meanwhile, the number of "positive" samples decreased from 1979 onward, although they still only constituted a small

[5] The approach taken in Example 1 assumed that if a worker was associated with a specific job title/work area that they held that title and location for their entire employment.

percentage of the overall monitored population. There do not appear to be significant gaps in the number of samples on an annual basis. Based on historical records for Fernald, the large increase in frequency of sampling in the mid-1980s is likely due to the increased focus on radiological protection, which generally coincided with the change in management from National Lead of Ohio to Westinghouse.

Table A-2: Overview of Available In-Vivo Data 1979–1988

Year	# Samples	# Samples with both Ac and Pb Results above the MDA	# Samples with Only the Ac Result above the MDA	# Samples with Only the Pb Result above the MDA	# Samples with no Results above the MDA
1979	177	26 (14.7%)	4 (2.3%)	2 (1.1%)	145 (81.9%)
1980	188	13 (6.9%)	14 (7.4%)	1 (0.5%)	160 (85.1%)
1981	141	8 (5.7%)	3 (2.1%)	1 (0.7%)	129 (91.5%)
1982	180	8 (4.4%)	1 (0.6%)	5 (2.8%)	166 (92.2%)
1983	169	4 (2.4%)	1 (0.6%)	1 (0.6%)	163 (96.4%)
1984	371	9 (2.4%)	3 (0.8%)	0 (0.0%)	359 (96.8%)
1985	382	2 (0.5%)	3 (0.8%)	4 (1.0%)	373 (97.6%)
1986	463	4 (0.9%)	2 (0.4%)	5 (1.1%)	452 (97.6%)
1987	562	4 (0.7%)	1 (0.2%)	5 (0.9%)	552 (98.2%)
1988	108	1 (0.9%)	1 (0.9%)	0 (0.0%)	106 (98.1%)
All In-Vivo Data (1979–1988)	2741	79 (2.9%)	34 (1.2%)	24 (0.9%)	2604 (95.0%)

The next step in the completeness study was to break down the in-vivo records by job title to see which jobs were sampled the most frequently and how their results compare to other less-monitored job types. The results are shown in Table A-3, which demonstrate that the most commonly monitored job title (Chemical Operator) also had the highest results among any other job title. This demonstrates that monitoring was generally focused on the job types with higher exposure potential. However, as mentioned previously, the inability to actually identify which workers handled thorium and to what extent they are reflected in the monitoring records is still somewhat of a concern.

A similar analysis was performed based on plant area; however, the results were less conclusive. It is worth noting that a large portion of the results were associated with “other areas” of the site (not Plants 1–9). Repackaging and redrumming operations at Fernald were not generally carried out inside any of the main plants, so these “other areas” likely cover some of the places where these stewardship activities occurred.

Table A-3: Comparison of In-Vivo Results by Job Title (1979–1988)

Job Title	# of Samples (%of Total)	Magnitude of Results	
		95th Percentile* (Ac-228)	95th Percentile* (Pb-212)
Chemical Operator	1207 (55.0%)	0.387	0.330
Unknown	549 (25.0%)	0.150	0.160
Construction Trades	248 (11.3%)	0.096	0.056
Other Operator	156 (7.1%)	0.278	0.194
Millworker	141 (6.4%)	0.100	0.020
Engineer/Technician	81 (3.7%)	0.100	0.030
Supervisor	73 (3.3%)	0.186	0.200
ITO	68 (3.1%)	0.120	0.113
Laborer	59 (2.7%)	0.104	0.071
Inspection/QA	53 (2.4%)	0.084	0.050
Oiler/Degreaser	28 (1.3%)	0.097	0.070
Health and Safety	21 (1.0%)	0.090	0.260
Administrative	20 (0.9%)	0.061	0.057
Mechanic	16 (0.7%)	0.073	0.040
Security	12 (0.5%)	0.183	0.282
Laundry	10 (0.5%)	0.081	0.000

*95th percentile evaluated using Microsoft Excel's Percentile Function

The last analysis performed for this completeness evaluation involved gaining insight into how workers were selected for counting regardless of job type or work area. Specifically, the analysis sought to determine if workers who displayed "positive" lung counts were scheduled to be monitored more frequently than workers whose results were less than the detection limit. It was found that geometric mean number of days that passed between counts for workers with results below the detection limit was nearly a year (364 days), while the number of days for workers with positive results was only 36, nearly 1/10th the time elapsed when compared to results less than the MDA.

In summary, the completeness analysis was able to determine that (1) there were no significant gaps in the monitoring data on an annual basis, (2) higher potential job types (such as chemical operator) were sampled more frequently, and (3) the time elapsed between samples for workers with positive results was approximately 1/10th the elapsed time of those with no positive result. While the work area analysis was generally inconclusive, it also did not demonstrate a bias towards sampling areas with lower exposure potential. SC&A concluded that the dataset was suitably complete for the purposes of dose reconstruction, though cautioned that the implementation of any coworker model should account for the inability to identify the specific workers who handled thorium.

Example 2 Discussion:

This approach used a large cross section of workers (not just claimants, as shown in the next example) and had reasonably extensive work location and job type information included in the hardcopy records. Given these characteristics of the dataset, it is reasonable to conclude that any quantitative analysis including the job and work area was accurate for the group of monitored workers. However, it is not clear to what extent these records reflect the entire affected worker population. As stated previously, the lack of information identifying which workers actually handled thorium and to what extent they were monitored is not currently available. However, reasonable claimant-favorable assumptions regarding the implementation and assignment of thorium intakes using this dataset likely obviates this uncertainty from an SEC perspective.

Example 3: Internal Dose to Workers at Nevada Test Site during the Underground Testing Period (1963–1990)

Background Summary:

The NTS operated from 1951 until 1992 and was one of the primary sites for testing nuclear explosive devices during that time. From the beginning of site operations until 1963, the United States conducted more than 100 aboveground nuclear tests, at which point all further nuclear testing was conducted underground until radiological operations ceased in 1992. In April of 2006, NIOSH evaluated the period of atmospheric testing (1951–1962) and determined that it could not reconstruct doses with sufficient accuracy. The Advisory Board accepted NIOSH's findings and the SEC was granted in May of 2006.

Subsequent to this Advisory Board recommendation, NIOSH produced a new evaluation report covering the period of 1963 through 1992 (NIOSH 2007). In this evaluation report, NIOSH proposed an internal dose coworker model based on the bioassay data from a group of 100 claimants with evidence of radiological exposure at NTS. Specifically, NIOSH 2007 states:

> *NIOSH examined the records supplied by DOE for 100 NS claimants with significant total external whole-body photon exposures (cumulative above 1.0 rem). The nature of the potential exposure scenarios at NTS makes it most likely that significant internal exposure would be associated with significant external exposure.* (NIOSH 2007)

At the time, DOE had supplied records for 1,287 total claims for NTS, and over 400 of those claims contained some internal dosimetry data.

Analytical Approach Taken:

In this example, the proposed coworker model is based on a sample of 100 claimants, which differs from the first two examples that contained an expansive electronic radiological database (Example 1) or site-wide hardcopy records that represent both claimants and non-claimants (Example 2). It must be noted that at the time of the initial evaluation report (NIOSH 2007), no electronic database was known to be available that would encompass a larger portion of the

workers at NTS. It is the absence of a radiological database that necessitated the approach of using claimant records to attempt to characterize the potential dose at NTS.

Since the group of claimants chosen for the basis of the coworker model (henceforth referred to as the "NIOSH 100") only comprise 25% of the NTS claimants with internal dosimetry information, the first step taken in evaluating this approach was to construct an alternate group of claimants for comparison. In order to get a sense for the exposure potential for different job categories, SC&A randomly selected 20 claimants each from 6 job classifications (radiological safety, laborers, welders, wiremen, miners, and security guards). This semi-randomly selected group is comprised of 120 claimants and can be referred to as the "SC&A 120." It should be noted that since the claimants were randomly selected, some of the claimants were included in both the NIOSH 100 and SC&A 120 sampling groups.

SC&A then compiled radiological information provided in the claimant records for both the NIOSH 100 and SC&A 120. From this compilation and analysis, it became clear that the internal monitoring program at NTS was biased, from a frequency standpoint, towards the job titles of radiological safety and security guard. However, there was no evidence from this analysis that those job types exhibited a higher exposure potential than other job types at NTS. Also apparent was the fact that many claimants in the remaining trades analyzed (laborer, welder, wireman, and miner) did not have any available bioassay data.

Subsequent to this comparison, a large electronic database was discovered that contained a significant amount of bioassay data (over 122,000 samples in the evaluated SEC period) which were not previously available to ORAUT. This database did not specify job title; however, SC&A was able to identify the claimants in the database by their social security number and assign them their job titles based on information in the individual claim files. By doing this, SC&A was able to expand on the number of sampled workers in the six job categories of interest. SC&A then analyzed the database by the four major types of internal monitoring at NTS: beta/gross fission products, gamma, plutonium, and tritium. Similar trends to the previous analysis were apparent, in that radiological safety and security guards were sampled much more frequently than the other job types.

An example of the analysis results is shown for tritium in Table A-4, which presents an overview of the frequency that the particular job titles were monitored, as well as providing some indication of the magnitude of the actual results. As shown, though radiological safety workers only compromised 13 of the 134 claimants identified with 1 of the 6 job titles, they accounted for over 50% of the samples taken. Figure A-2 shows a rank order plot of the magnitude of tritium results (MI/cc) for the job categories surveyed. As can be seen, the job categories that had the highest results for tritium were actually the miners, wiremen, and laborers, even though they had significantly less samples present in the dataset. In fact, the magnitude of tritium bioassay for radiological safety was slightly lower than the "all claimant average" at most percentiles and lower than the "all worker average" at the upper percentiles. Similar findings were observed for the other major bioassay categories (beta/gross fission products, gamma, and plutonium); the reader is referred to SC&A 2010 for the full analysis.

Based on this review of job-specific bioassay results, it can reasonably be concluded that the monitoring program was not focused on the most highly exposed workers, and often times did not include those job designations in the sampling program. On January 25, 2010, NIOSH recommended to the Advisory Board that the class of employees at NTS from 1963 through 1992 be included in the SEC. In May of 2010, the Advisory Board accepted NIOSH's recommendation.

Table A-4: Analysis of Electronic Database for Tritium Data Including Data Overview and Characteristics

Tritium Data	Claims							All Workers
	RadSafe	Laborers	Welders	Wireman	Miners	Security	All Claimant Pu	
Data Overview								
Total Samples	1985	221	39	37	817	826	4977	42748
# Individuals	13	17	9	13	48	34	244	4724
Urine Samples	1900 (95.72%)	207 (93.67%)	35 (89.74%)	31 (83.78%)	757 (92.66%)	764 (92.49%)	4673 (93.89%)	40253 (94.16%)
Whole Body Counts	85 (4.28%)	14 (6.33%)	4 (10.26%)	6 (16.22%)	60 (7.34%)	62 (7.51%)	304 (6.11%)	2495 (5.84%)
Data Characteristics								
Number of Positive Results	1718 (86.55%)	202 (91.40%)	29 (74.36%)	28 (75.68%)	717 (87.76%)	755 (91.40%)	4320 (86.80%)	36805 (86.10%)
Number of Results Listed as 'Less than'	148 (7.46%)	3 (1.36%)	2 (5.13%)	2 (5.41%)	23 (2.82%)	3 (0.36%)	276 (5.55%)	2447 (5.72%)
Number of Negative Results	21 (1.06%)	1 (0.45%)	4 (10.26%)	-	1 (0.12%)	6 (0.73%)	41 (0.82%)	-
Number of Zero Results	13 (0.65%)	-	-	-	2 (0.24%)	-	19 (0.38%)	135 (0.32%)
Number of Results listed as 'No Detectable'	-	-	-	-	-	-	-	-
Number of Blank Results	85 (4.28%)	15 (6.79%)	4 (10.26%)	7 (18.92%)	74 (9.06%)	62 (7.51%)	321 (6.45%)	3361 (7.86%)

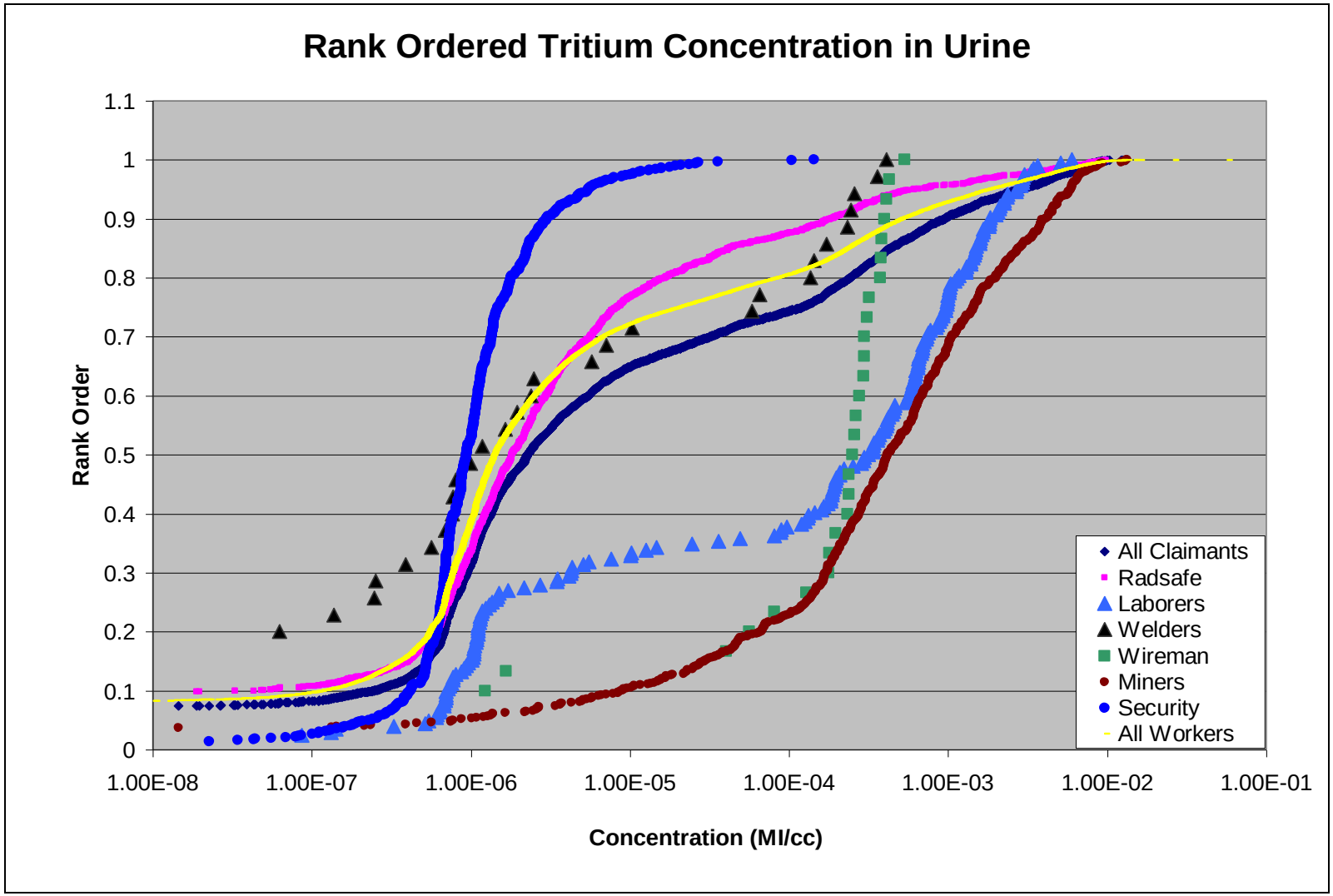


Figure A-2. Rank Ordered Tritium Concentration in Urine (MI/cc) for Surveyed Job Titles

Example 3 Discussion:

The approach described above was clearly an iterative process due to the unavailability of an electronic database in the beginning stages of the completeness evaluation process. Nevertheless, the methodology of using claimant samples can be an effective instrument in gathering information and insight into the monitoring practices of a particular site. This is illustrated by the corroborating analysis of the electronic database later uncovered, though care must be taken to put such claimant sample-based analyses in their proper frame of reference. Though it is always preferable to analyze data that are representative of the workforce as a whole, absent the availability of such information, claimant sampling is a useful tool to gain insight into the completeness of available data in an SEC context.

Example 4: Bounding Internal Exposures to Stable Metal Tritides at the Mound Plant

Background Summary:

Stable metal tritides (SMTs) are a form of insoluble tritium that do not metabolize from the lung like normal tritiated compounds, and, as a result, it is not possible for traditional bioassay methods, such as urinalysis, to accurately reflect the actual exposure to SMTs. It has been established that SMTs were handled in specific known areas of the Mound Plant, and it is also known who the primary workers are who handled the material. Air monitoring data are available; however, it is equally problematic, because this material would have been caught in the air filters prior to being counted by the detector.

Since it is known who the primary handlers of the material were, maximizing assumptions can be made to adjust those individual urinalysis results to effectively bound the potential exposure to these workers. However, this type of bounding model would be inappropriate to use on ancillary or support workers whose exposure to the material would likely have been infrequent and the potential for intake minimal. Therefore, an alternate method was constructed, which used area swipe samples to model the resuspension and intake of the tritiated material. This method was finalized in the NIOSH report: *Potential Stable Metal Tritide Exposures at the Mound Laboratory* (NIOSH 2012a).

Analytical Approach Taken:

As stated in the previous section, the proposed model is not based on actual bioassay or in-vivo monitoring of workers, but rather workplace sampling in the form of swipe data. Though the specific areas/rooms where the work was performed are known, there is still the potential that particular areas of the room may not have been sufficiently monitored via swipe samples. Fortunately, the original swipe sample reports are available and inspection of these reports shows that swipes were taken all over the rooms of interest (an example of one such report is shown in Figure A-3). Therefore, it is not likely that an area within the room had significantly higher contamination and was routinely missed by the swipe sampling program.

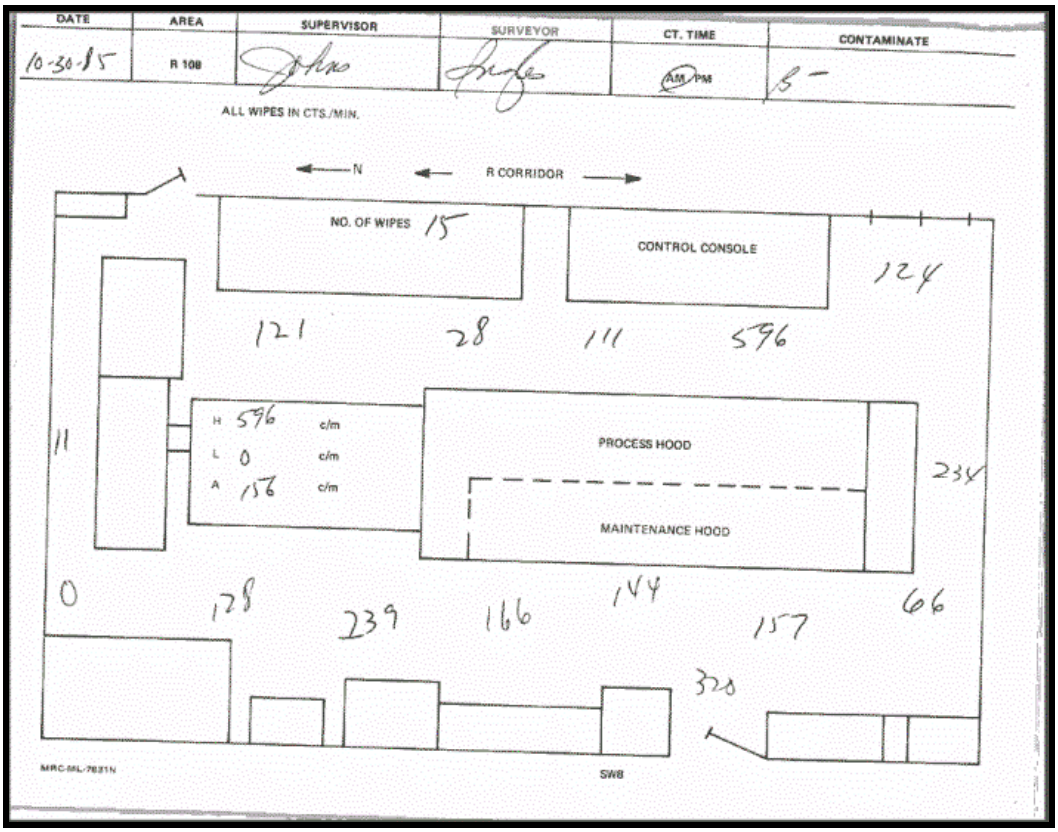
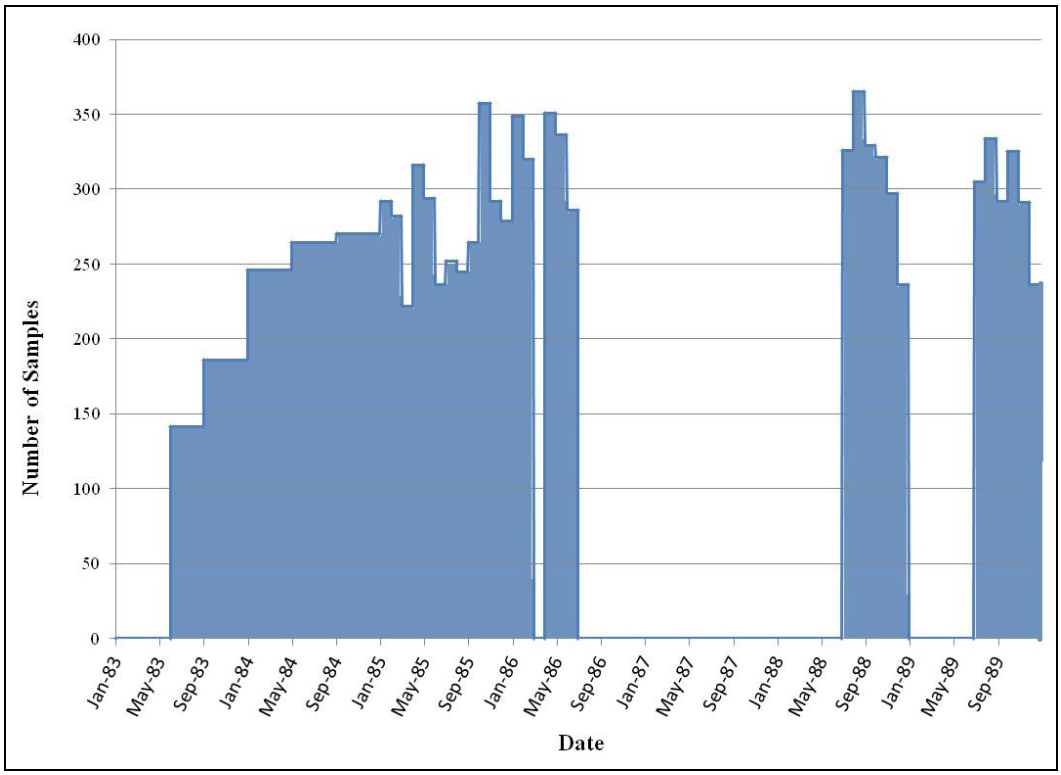


Figure A-3. Example of a Swipe Sample Report Showing the Layout of the Room and Areas that were Sampled

The primary handlers of the SMT material have been identified and a bounding approach has already been developed; therefore, the proposed resuspension model only applies to ancillary or support workers. Since it is not possible to identify which of these workers might have been exposed, the model applies to all workers who entered radiological areas. At Mound, if a worker entered a radiological area, then a tritium urinalysis sample was mandatory. As a result, anyone with tritium bioassay is considered to have been potentially exposed to SMTs. Therefore, any evaluation of the completeness of the proposed approach need only consider the temporal coverage of the available swipe results and not the job types and areas of interest (which are both known).

SC&A presented its completeness study in SC&A 2012 and found that there were significant temporal gaps in the available swipe data. One example is shown in Figure A-4, which plots the number of available swipe samples for Room R-108 during the period of interest. As seen in the figure, there is a gap in the swipe data that extends over 2 years, as well as a few other smaller data gaps. It is important to determine whether a surrogate data approach is appropriate to use during these gaps in data coverage, and that no off-normal operations involving SMTs occurred. Any off-normal operations or conditions might have posed a higher exposure potential, which would make using surrogate data from surrounding periods problematic.



Source: SC&A 2012

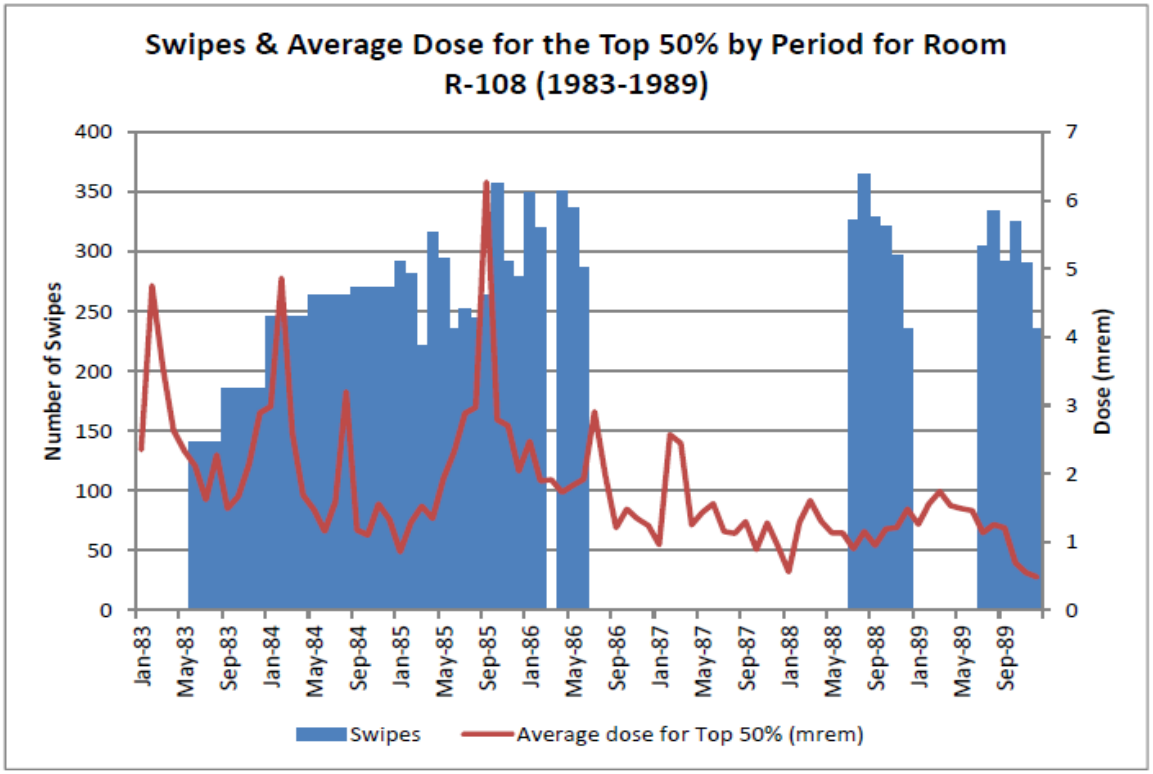
Figure A-4. Number of Samples by Year for Room R-108 during the Period of Interest

NIOSH 2012b addressed these gaps in the data using two different approaches. First, NIOSH conducted further interviews with former workers who had direct knowledge of the SMT operations. These workers were shown the gaps in the available data and were asked if there was any reason to believe that operations would differ from the periods when swipe data were available. NIOSH 2012b states:

> *Interviews with the research chemists and radiological health personnel that have firsthand knowledge of the operations were specifically asked if any working situations occurred or they were made aware of that would have caused the missing swipe data to be different than the data on either side of the gap. The overall agreement was the data from both sides of the gaps should be adequate to extrapolate the data within the gaps.*

In the second approach, NIOSH analyzed the tritium urinalysis data during the entire period of interest, which included the periods with swipe data gaps. Though tritium urinalysis data are not indicative of exposure to SMTs, they do indicate whether site-wide tritium operations might have increased during the periods with no swipe data. This type of indirect test helps build a weight of evidence argument, since it is not unreasonable to assume that operations involving SMTs would generally parallel the other tritium operations at the site from a production and exposure standpoint. An example of this is shown in Figure A-5 for Room R-108, which essentially takes the plot shown in Figure A-4 and overlays the average tritium doses during the period. As seen in the figure, overall tritium doses at the site during periods with swipe data gaps were not

significantly different than the periods with swipe data. In fact, the period with the highest tritium doses (late 1985) is covered by the swipe data. Therefore, reasonable application of surrogate data is likely appropriate to bound SMT exposures during the periods with no data. Similar results were found for the other room of interest (SW-8) that had identified data gaps.



Source: NIOSH 2012b

Figure A-5. Number of Swipe Samples Plotted against the Average Dose Based on Tritium Urinalysis

Example 4 Discussion:

While it is always preferable to use worker bioassay data to reconstruct doses and develop coworker models, in some situations, the bioassay information is unavailable or is not adequate for the task. In the case of Mound, urinalysis data are available, but are inappropriate for the purpose of reconstructing doses to the support workers. Therefore, the alternate approach of using workplace monitoring was adopted to bound doses to this group of workers.

This type of approach still requires the ability to identify the specific areas and workers that were involved in the operation of interest. Fortunately in this case, the pertinent information was available. Therefore, the main concern from a completeness perspective is the temporal considerations. Although there were significant data gaps identified, worker interviews and characterization of the overall site production during the gap mitigate any potential issues arising from the unavailability of swipe data.

APPENDIX B: EXAMPLES OF STRATEGIES USED BY SC&A IN ANALYZING ALLEGATIONS OF DATA FALSIFICATION IN AN SEC CONTEXT

Example 1: Internal Monitoring Record Falsification at Fernald

Background Summary:

During the Work Group meeting on January 29, 2010, the concern was raised by petitioner and others as to the integrity of the Feed Materials Production Center (FMPC or Fernald) bioassay program. Specifically, the integrity of the uranium urinalysis data entered onto logsheets and other hardcopy records was questioned. It was felt that the available data did not reflect the actual uranium exposures and was systematically manipulated to avoid recording high internal exposures. During that Work Group meeting, SC&A was tasked with developing potential strategies to evaluate this issue. The subsequent effort was documented in SC&A 2010.

Analytical Approach Taken:

SC&A investigated the feasibility of three different approaches for evaluating the potential for data falsification:

(1) Comparison of uranium urinalysis and in-vivo lung counting records for individual workers to assess the consistency between the two forms of internal monitoring.

(2) Perform a biokinetic analysis on available urinalysis sampling for a group of workers to determine if the observed fluctuations in uranium concentration are biologically feasible.

(3) Review available daily weighted exposure (DWE) reports to identify the job titles and areas of the site with the highest exposure potential; then compare the DWE reports to the dosimetry records of claimants who can be identified with those jobs and areas.

While data falsification is a difficult thing to prove quantitatively, SC&A explored these analytical approaches to determine if there was an appropriate "test" that might indicate the possibility of widespread record fabrication. For each of the three analytical methods, SC&A 2010 provides a description of the theory behind the proposed approaches, evaluated their feasibility, provided an example (or "proof of concept"), and discussed the advantages and disadvantages of each method.

As stated above, the first strategy involves comparing two different types of internal monitoring for a group of workers. The theory behind the method is that the relative magnitude of in-vivo uranium measurements for exposed workers would closely mirror their urinalysis results at the time. For example, if a worker consistently had a significantly elevated uranium lung burden, but the associated urinalysis results were all "zeros," this might indicate that the bioassay program was corrupt.

The first step in addressing the feasibility of this approach was to determine how many workers can be identified that have a sufficient number of both urinalysis and in-vivo results. Based on

an analysis of the electronic dosimetry database for Fernald (also known as the "HIS_20"), SC&A was able to determine that there were 53 workers who had at least 10 results for both forms of internal monitoring. SC&A also presented two figures that provided examples of the comparison between in-vivo and urinalysis results for individual workers. One such example is shown in Figure B-1 below. As seen in the figure, the worker had one instance where the in-vivo uranium result spiked significantly compared to neighboring measurements; however, no change was witnessed in the urinalysis data, and there was also an instance where the urinalysis result spiked significantly with no associated change in measured lung burden.

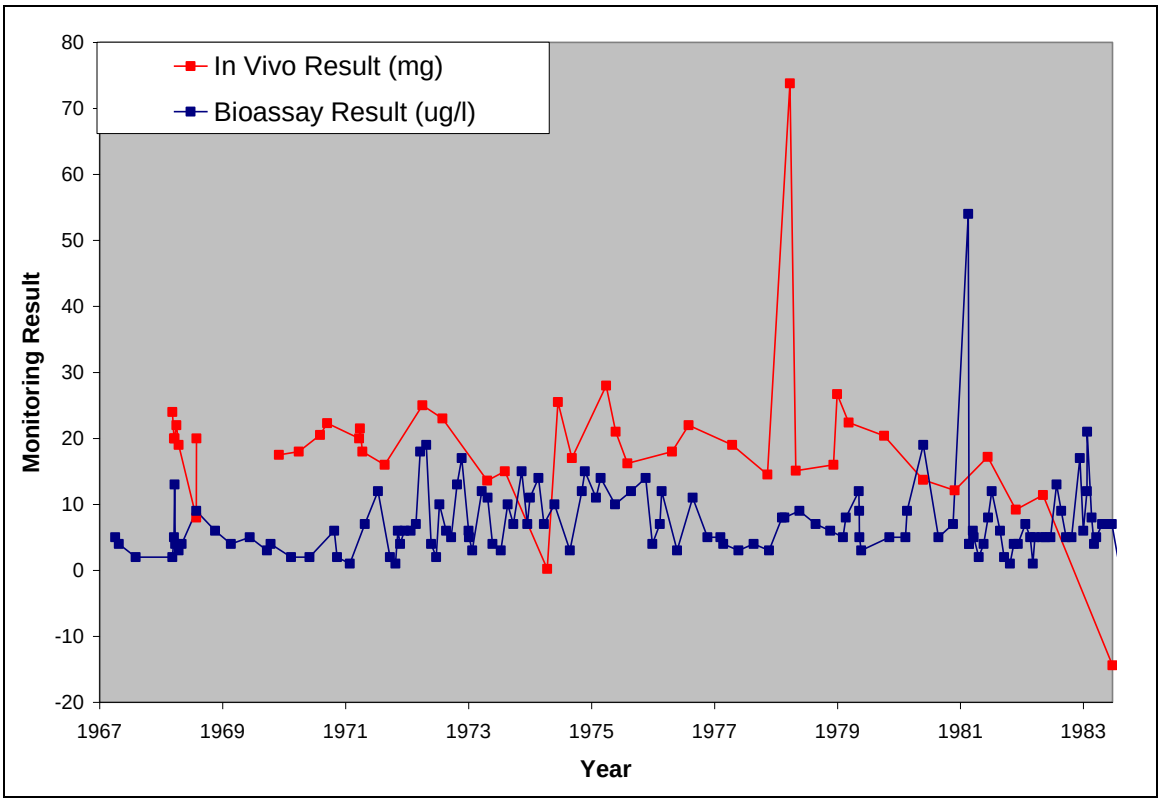


Figure B-1. Comparison of In Vivo (mg U Total) and Bioassay Results (µg/l U Total) for a Select Worker

Some of the benefits identified for this approach include the fact that it is a direct comparison of individual worker dosimetry records. Also, the workers who would be included in the analysis are likely to have had the highest exposure potential, since they were targeted for both the urinalysis and in-vivo program. However, there were also many deficiencies identified including:

- The individual in-vivo and urinalysis results were not often in close proximity chronologically, which could make it difficult to compare and interpret the two monitoring techniques.
- In-vivo monitoring at Fernald was not available prior to 1968.
- The analysis would be restricted to only about 50 workers.

- Without specific information regarding uranium solubility type and the exact sampling methods employed, accurate interpretation of the available data would be problematic.

The second proposed approach involved analyzing individual worker urinalysis results to see if there were instances of biokinetically infeasible declines in uranium concentration in urine as a function of time. If part of a worker's uranium urinalysis record was being purposely under-reported, then these unrealistic drops in urine concentration might be evident.

Similar to the first strategy, this method requires that a worker have a significant number of urinalysis results available for analysis. To address the feasibility of such an approach, SC&A analyzed the HIS_20 database to determine the frequency of uranium monitoring by decade at Fernald. The results are recreated in Table B-1.

Table B-1: Frequency of Worker Sampling by Decade

Number of Records in Period	Number of Workers with Listed Number of Records by Period			
	1950s	**1960s**	**1970s**	**1980s**
1–10	2442	1342	933	3317
11–20	741	516	263	428
21–30	371	392	64	246
31–40	242	472	40	122
41–50	149	253	88	91
>50	293	369	90	337

Based on Table B-1, it is apparent that there are a significant number of workers who could be selected for analysis. As an example, SC&A selected a worker who had multiple urinalysis results and also at least one significantly high concentration reported. This high urinalysis result was analyzed using the IMBA program (Integrated Modules for Bioassay Analysis) to predict what subsequent urinalysis concentrations should be. These predicted concentrations can then be compared to the worker's actual bioassay record. One such example is presented in Figure B-2, which shows that subsequent urinalysis results were not unrealistic compared to the high result.

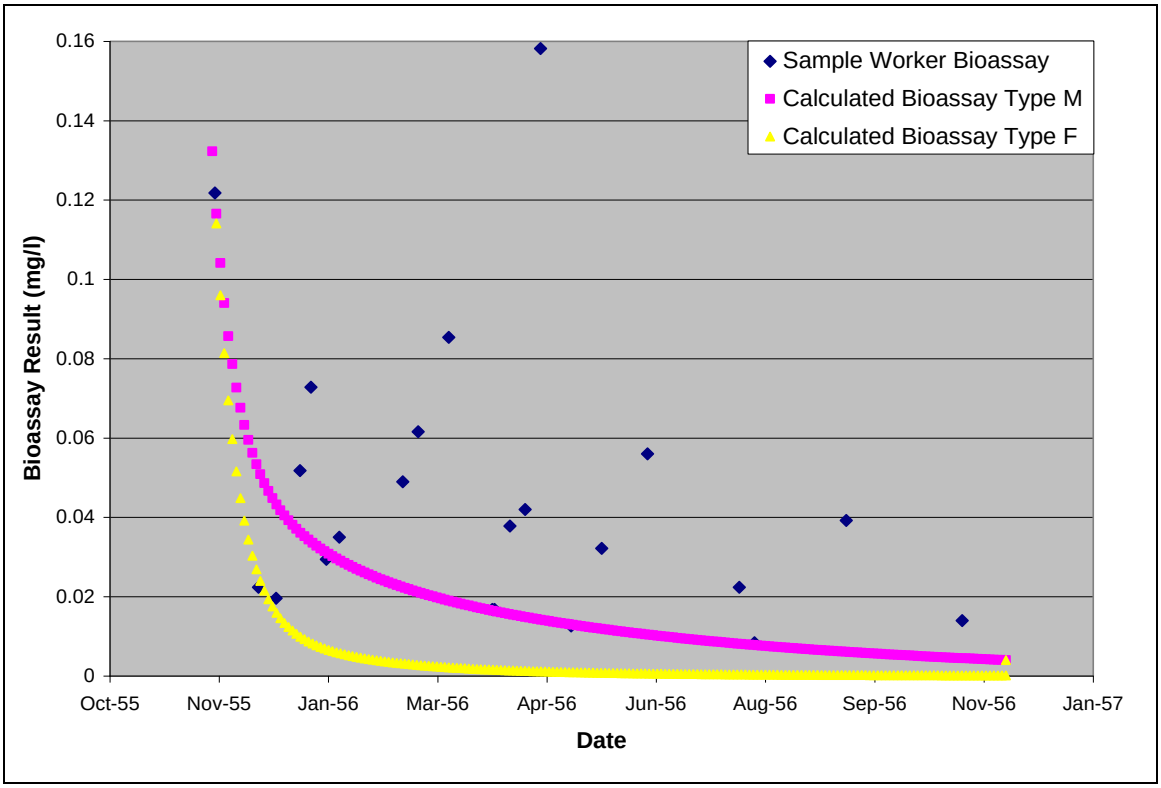


Figure B-2. IMBA Predicted Bioassay Results Based on First High Sample for Select Worker Compared to Actual Bioassay Results

One of the main benefits of this second strategy is that it would cover the entire SEC period at Fernald and utilizes individual bioassay records. Also, this method allows for a larger pool of workers that could be analyzed than the first approach. However, some of the drawbacks are that the strategy still is only applicable to workers with a significant number of urinalysis results. In addition, implausibly large drops in uranium concentration may not be evidence of data falsification, but rather an error in the original sample analysis. Similarly to the first approach, uranium solubility has a major effect on observed urine concentrations, and accurately interpreting the available data would be problematic.

The third and final approach involves identifying the work areas and job titles with the highest exposure potential based on the DWE reports. These higher-risk jobs can then be matched to available claimant records and analyzed to determine if these claimants have unusually low urinalysis results. Logically, if data falsification was prevalent at Fernald, then these higher-risk workers would likely be targeted, and their results falsified.

The first step in determining the feasibility of this strategy was to evaluate the number of claimants who could be matched to facilities and years with available DWE data. The analysis is restricted to claimants, because there are no job title designations available in the HIS_20 database. Also, the pool of workers available for the proposed analysis is further restricted by the limited amount of work area information available. The number of workers available for analysis is in Table B-2.

Table B-2: Plants and Years in Which Claimant Urinalysis Can be Matched and DWE Data Exist

FEMP Location	# of Claimants (# of Samples)*								
	1953	1954	1955	1956	1957	1958	1959	1960	1961
Pilot Plant	-	-	-	20 (184)	11 (53)	-	-	-	-
Plant 1	-	-	14 (42)	39 (140)	22 (49)	-	-	-	-
Plant 2	-	-	21 (85)	42 (127)	32 (67)	1 (1)	-	-	-
Plant 2-3	-	-	-	-	-	-	-	-	-
Plant 3	-	-	31 (93)	23 (43)	27 (64)	1 (1)	-	-	18 (18)
Plant 4	-	5 (13)	16 (30)	26 (112)	27 (148)	4 (4)	-	-	-
Plant 5	8 (11)	5 (11)	48 (343)	61 (135)	69 (257)	9 (9)	-	-	1 (1)
Plant 6	6 (6)	7 (21)	48 (167)	73 (444)	121 (822)	7 (7)	-	-	-
Plant 7	-	-	42 (629)	25 (154)	-	-	-	-	-
Plant 8	-	-	15 (66)	35 (197)	42 (387)	2 (2)	-	-	-
Plant 9	-	-	5 (8)	-	21 (58)	-	-	-	-

*Dashes indicate that either no claimant samples could be identified or no DWE report is available for that plant and year.

Additionally, it was noted that many of the DWE reports contained an appendix with urinalysis samples taken for the workers involved in the DWE study. These appendices would allow for a more direct comparison of the working conditions and available bioassay data. Another benefit of the approach, as noted before, is that it targets the workers with the greatest exposure potential, and therefore the most likely target for any falsified monitoring.

However, one of the major limitations of the strategy is its restriction to plants and years with available DWE reports. The approach is also limited by the number claimants that can be identified with the specific job type, area, and year. The method is further complicated by a lack of information on whether sampled workers might have worn respiratory protection. Similar to the first two proposed strategies, a lack of information on the solubility type of the uranium exposure makes appropriate interpretation of the urinalysis results problematic.

Discussion:

The strategies presented in the previous section were discussed at the Fernald Work Group meeting on November 9, 2010. The consensus of that discussion was that the limitations of each of the three strategies were too great and the results of pursuing any of the approaches would likely be inconclusive. As such, it was determined that it was not feasible to construct an appropriate analytical approach to investigate the potential for records falsification at Fernald. However, by crafting these three approaches and evaluating their feasibility, the Work Group, SC&A, and NIOSH performed the required due diligence in examining this SEC issue.

Example 2: External Badging Practices at the Nevada Test Site

Background Summary:

One major facet of the Nevada Test Site (NTS) SEC petition (HHS 2007) called into question the representativeness of external film badging records due to the stated practice of "hiding" film badges to avoid reaching the regulated external dose limits. The petition covered the period of September 1, 1963, through September 30, 1992, and specifically stated:

> *It was common practice that workers, apparently at the direction of management, did not wear and/or hid dosimeter badges to prevent registering doses that would cause them to exceed project, monthly, or cumulative doses. Consequently, film badge data will underestimate the exposure of individuals and groups of workers.* (HHS 2007)

NIOSH reviewed the petition and released its evaluation report (NIOSH 2007), which addressed the potential issue of whether film badge records accurately reflect the external exposure potential for workers at NTS. In the report, NIOSH utilized the available Computer Assisted Telephone Interviews (CATIs) to show that only about 1% of the NTS claimants confirmed the practice of hiding film badges to keep reported external doses at an allowable level. The results of this analysis were shown in Table 7-16 of NIOSH 2007 and are recreated below in Table B-3.

Table B-3: Results of Interviews regarding Defeat of the Universal Badging Policy
(Source: NIOSH 2007, Table 7-16)

Job Title	Number of CATI Results Reviewed	Number of Additional Interviews	Number of Interviews by Job Category	Number of Interviewees Indicating Monitoring Defeat
Administrative	9	1	10	1
Drill Worker/Engineer	32	1	33	3
Tunnel Worker/Miner	66	1	67	1
Plumber/Pipefitter	48	1	49	0
Carpenter/Welder	36	0	36	1
Surveyor/Civil Engineer	7	0	7	2
Laborer	71	0	71	2
Other	932	10	942	3
Total	**1,201**	**14**	**1,215**	**13 (1.1% of total)**

During SC&A's review of NIOSH 2007, the concern was raised that CATI reports do not specifically ask whether workers might have hidden their badges or misrepresented their accrued external exposure. Therefore, the use of these interviews was not a strong basis to conclude that the practice was not widespread. As a result, the NTS Work Group directed SC&A to perform an additional investigation to gain more information on the potential that external monitoring policies had been compromised.

Analytical Approach Taken:

SC&A's investigation into the allegations of external badge tampering was two-phased:

(1) Perform additional interviews with former workers and specifically address the practice of hiding film badges in order to keep external exposures low.

(2) Review a sample of claimant dosimetry records to determine if film badge records are consistent with other forms of external monitoring, such as pencil dosimeters or pocket ionization chambers (PICs).

It is this second facet of the investigation that is the subject of this example and was documented in SC&A 2008. That report described the sampling and review of dosimetry records for 10 NTS claimants to assess the consistency between the official film badge records and other forms of external monitoring, such as the pencil dosimeters or PICs. Specifically, SC&A 2008 states:

> *SC&A investigated the issue of the "hidden badges" by carefully reviewing the records of 10 workers (referred to as case studies). For each of these cases, SC&A compared area access register data to the yearly and monthly film badge doses reported in the DOE records. Since SC&A had already gathered much of the dosimetry data from 120 randomly selected NTS cases for another petition issue investigation, the 10 cases for this analysis were chosen from that group. SC&A chose cases based on three criteria: (1) job category, (2) availability of area access register data, and (3) employment during the 1963–1967 time period.* (SC&A 2008)

The job categories selected include three Miners, two Radiation Safety workers, two Welders, one Laborer, one Security Guard, and one Wireman. The emphasis on the "miners" in the selected sample was due to their generally higher exposure potential and, therefore, increased motivation to tamper with the external dosimetry results. The 1963–1967 timeframe was chosen because during this time, a worker's film badge and security/ID badge were separate items. At some point in 1966, the film and security badges were integrated. After this time, it would have been much more difficult to gain access to radiological areas without also wearing the film badge. However, SC&A extended the investigation into 1967 to gain insight into the period after the badges were integrated.

The review of each individual case is described in SC&A 2008 to include the following:

> *For each case, SC&A reviewed the area access register information and created spreadsheet tables which included the register date, the shift, the PIC reading, and whether the film badge had been pulled for analysis. We also included any film badge readings that were reported during the dates of the area access registers. In addition, SC&A closely reviewed the area access registers for any inconsistencies or missing information.* (SC&A 2008)

It was found that each case generally fit into one of three categories.

(1) The worker had PIC readings that were all zero or nearly zero (3 cases). For these claimants, no further investigation was warranted.

(2) The worker had positive PIC readings that were less than 100 mrem (2 cases). In these cases, the worker's film badge would not have been pulled for immediate analysis, so the monthly totals for the PIC readings could be directly compared to the film badge result for that month.

(3) The worker had positive PIC readings that were greater than 100 mrem and/or that worker's film badge was pulled for immediate analysis prior to the 1-month interval typical at NTS (5 cases). In these cases, dosimetry records were specifically reviewed to ensure that pulled badges were, in fact, analyzed on the day in question. If so, then the film badge reading was compared to the PIC readings taken up until the date the badge was pulled.

SC&A found no significant inconsistencies for 9 out of the 10 claimant dosimetry files reviewed. However, for the remaining case, it was found that there were multiple incidents where PIC readings were not entered into the area access registers. Also, one of the years showed a discrepancy of approximately 750 mrem between the reported film badge and PIC annual doses. The results for this worker are shown in Table B-4. For the complete analysis of the 10 claimants, please refer to SC&A 2008.

Table B-4: Comparison of PIC and Film Badge Annual Totals for an NTS Claimant

Year	PIC total (mrem)	Film badge total (mrem)
1965	355	4415
1966	935	2365
1967	2701	1945

Discussion:

Similar to Example 4 in Appendix A, an approach utilizing the sampling of claimant documents was necessitated due to the unavailability of a site-wide database (electronic or hardcopy) of worker dosimetry records. This investigation also demonstrated a numerical approach to the issue that can be used to supplement the valuable information gathered from worker interviews. Ultimately, the issue concerning the validity of available film badge records was rendered moot in an SEC context. On January 25, 2010, NIOSH recommended to the Advisory Board that the class of employees at NTS from 1963 through 1992 be included in the SEC on the basis of an inability to reconstruct internal doses during that period (NIOSH 2010). This recommendation was accepted by the Advisory Board in May of 2010.

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