NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

TASK 3

REVIEW OF NIOSH/ORAUT PROCEDURES AND METHODS USED FOR DOSE RECONSTRUCTION

Review of the Third Set of Procedures (45 procedure reviews)

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ACRONYMS AND ABBREVIATIONS

42 CFR 82	Title 42, Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000, of the *Code of Federal Regulations*
Advisory Board or Board	Advisory Board on Radiation and Worker Health
AMAD	Activity Median Aerodynamic Diameter
AP	Anterior-Posterior
AWE	Atomic Weapons Employer
CAD	Computer-Aided Design
CATI	Computer-Assisted Telephone Interview
CEDR	Comprehensive Epidemiologic Data Resource
CEF	Critical Experiments Facility
CER	Center for Epidemiological Research
Ci	Curies
CTW	Construction Trade Worker
D&D	Decontamination and Decommissioning
DCF	Dose Conversion Factor
(D)HHS	U.S. (Department of) Health and Human Services
DOE	U.S. Department of Energy
DOELAP	Department of Energy Laboratory Accreditation Program
DOL	U.S. Department of Labor
dpm	Disintegrations per Minute
DR	Dose Reconstructor or Dose Reconstruction
EE	Energy Employee
EALER	Elevated Ambient Levels of External Radiation
EDP	Electronic Data Processing
EEOICPA	Energy Employees Occupational Illness Compensation Program Act of 2000
ENSDF	Evaluated Nuclear Structure Data File
ERR	Excess Relative Risk
ESE	Entrance Skin Exposure

ET	ExtraThoracic
FGR	Federal Guidance Report
FIPR	Florida Institute of Phosphate Research
GI	Gastro-Intestinal
GM	Geometric Mean
GSD	Geometric Standard Deviation
HAT	Human Alimentary Tract
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IMBA	Integrated Modules for Bioassay Analysis
IREP	Interactive RadioEpidemiological Program
K-25	Oak Ridge Gaseous Diffusion Plant
LANL	Los Alamos National Laboratory
LLI	Lower Large Intestine
LOD	Limit of Detection
MCNP, MCNP5, or MCNPX	Monte Carlo N-Particle transport codes
MDA	Minimum Detectable Activity
MDL	Minimum Detection Level
MeV	Megaelectron Volt
MPBB	Maximum Permissible Body Burden
NBS	National Bureau of Standards
NDRP	Neutron Dose Reconstruction Project
NIOSH	National Institute for Occupational Safety and Health
n/p	neutron/proton
NTA	Nuclear Track Emulsion Type A film
NTP	Nuclear Track Plate
OCAS	Office of Compensation Analysis and Support
ORAU	Oak Ridge Associated Universities
ORAUT	Oak Ridge Associated Universities Team

ORISE	Oak Ridge Institute for Science and Education
ORNL	Oak Ridge National Laboratory
PA	Posterior-Anterior
PER	Program Evaluation Report
PEP	Program Evaluation Plan
PFG	Photofluorographic
PGDP	Paducah (Kentucky) Gaseous Diffusion Plant
PIC	pocket ionization chamber
PNNL	Pacific Northwest National Laboratory
POC	Probability of Causation
PROC	Procedures
QAP	Quality Assurance Plan
QC	Quality Control
REF	Radiation Effectiveness Factor
REX	Hanford Radiological Exposure Records database
RFETS	Rocky Flats Environmental Technology
RFP	Rocky Flats Plant
SC&A	S. Cohen & Associates (SC&A, Inc.)
SF	Scattering Factor
SRS	Savannah River Site
TBD	Technical Basis Document
TDG	Tools Development Group
TIB	Technical Information Bulletin
TLD	Thermoluminescent dosimeter
TORI	Table of Radioactive Isotopes
USTUR	United States Transuranium and Uranium Registry
V&V	Verification and Validation
WLM	Work Level Month

EXECUTIVE SUMMARY

Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and Title 42, Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000, of the Code of Federal Regulations* (42 CFR Part 82), the Advisory Board on Radiation and Worker Health (Advisory Board or Board) is mandated to conduct an independent review of the methods and procedures used by the National Institute for Occupational Safety and Health (NIOSH) and its contractors for dose reconstruction.

As contractor to the Advisory Board, S. Cohen & Associates (SC&A) has been charged under Task 3 to provide support in this effort. To date the following work products have been completed under Task 3:

(1) **Develop a Formal Review Protocol for the Evaluation of Procedures Used in Dose Reconstruction:** The purpose of a review protocol is to ensure a structured and systematic review process that determines whether procedures are consistent with the philosophy, intent, and/or statutory directives cited in EEOICPA, and comply with the general requirements, methods, and guidance provided in 42 CFR Part 82.

In behalf of the first work product, SC&A submitted a report entitled, *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.

(2) **Conduct a First Round of Critical Reviews of Methods and Procedures Used by NIOSH for Dose Reconstruction:** Under Modifications Nos. 2 through 5 (initially authorized on June 24, 2004), the Advisory Board approved SC&A's proposal of work to perform a review of a total of 33 documents from the Office of Compensation Analysis and Support (OCAS) and the Oak Ridge Associated Universities Team (ORAUT), that included implementation guidelines, procedures, technical information bulletins (TIBs), and plans. This review was completed and a draft report delivered to NIOSH and the Advisory Board entitled *Task 3: The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-Task3, Rev. 0, Final Draft, January 17, 2005. This document and its findings are the subject of an issues resolution process that is currently underway under the direction of an Advisory Board working group.

(3) **Conduct a Second Round of Critical Reviews of Methods and Procedures Used by NIOSH for Dose Reconstruction:** Under Modification No. 6 (authorized on August 30, 2005), NIOSH and the Advisory Board approved SC&A's proposal of work to perform a review of a total of 30 documents that included OCAS and ORAUT procedures and technical information bulletins (TIBs).. This review was completed and a draft report delivered to NIOSH and the Advisory Board entitled *Task 3: The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction, Supplement 1*, SCA-TR-Task3 Supplement 1, Rev. 0, Final Draft, June 8, 2006. This document and its findings are the subject of an issues resolution process under the direction of an Advisory Board working group.

(4) **Conduct a Critical Review of General Workbooks Used by NIOSH for Dose Reconstruction:** This workbook review was completed and a draft report was delivered to NIOSH and the Advisory Board entitled *Task 3, Supplement 2, Review of Nine General Dose Reconstruction Tools,* SCA-TR-Task3, Supplement 2, Rev. 0, Draft, April 13, 2007. This document and its findings are the subject of an issues resolution process under the direction of an Advisory Board working group.

(5) **Conduct a Third Round of Critical Reviews of Methods and Procedures Used by NIOSH for Dose Reconstruction**: The Advisory Board identified 45 documents for SC&A to critically review. The draft work product presented herein is provided in fulfillment of this work assignment.

(6) **Conduct a Critical Review of ORAUT-OTIB-0052, Parameters to Consider when Processing Claims for Construction Trade Workers:** For the review of ORAUT-OTIB-0052, the standard SC&A review has been augmented by additional detailed confirmatory analysis of the data utilized by NIOSH in their development of ORAUT-OTIB-0052. SC&A also interviewed personnel from the Center to Protect Workers' Rights, since they have been deeply involved in providing comments on NIOSH's approach to construction worker dose reconstruction. This review was completed and a draft report delivered to NIOSH and the Advisory Board entitled, *Review of ORAUT-OTIB-0052, Parameters to Consider when Processing Claims for Construction Trade Workers,* SCA-TR-Task3-0004, Rev. 0, Draft, July 3, 2007.

SUMMARY FINDINGS

The 45 documents identified to SC&A for this third round of Task 3 critical reviews represent a sizeable body of written text that embraces a wide array of complex topics and clearly reflects an intense effort by many individuals who are regarded as scientific experts in their fields. These documents were created beginning in 2004 by the OCAS and the ORAUT, and reflect a maturation of the dose reconstruction program that began in 2000, and the first set of guidelines issued in 2002. Like our Task 3, Supplement 1 procedures review report issued in June 2006, this report reveals an integration of the generic OCAS and ORAUT guidelines with the site profiles, to the extent feasible. We believe this aspect of the guidelines helps to avoid inconsistencies between the procedures and the site profiles.

Included in this round of reviews are revised versions of several documents that have previously been reviewed by SC&A for the Advisory Board. In addition to SC&A's 'normal' review of these re-reviewed documents, they were also checked to assess whether the comments/issues/ findings made in the previous review were satisfactory addressed. It is equally important to note that some of the 45 documents have already been revised or are likely to be revised in the future, due to the fact that these documents are regarded as "living documents." The need for living documents, as explained to SC&A by NIOSH, reflects the urgent demand for NIOSH to begin the adjudication of claims by a progressive selection process that started with claims requiring the least amount of procedural guidance and data. Future, more complex dose reconstructions may, therefore, require further procedural revisions and/or the development of additional procedures.

In brief, SC&A's review of the methods and procedures used for dose reconstruction must be viewed with some caution, since these findings are not only limited to documents as they exist currently, but more importantly do not include the role of site profiles in dose reconstruction. However, the latter issue is less of a concern for the procedures reviewed in this supplement, because of the concerted effort made by NIOSH to cross-reference site profiles. An overview of SC&A's findings is given below with respect to the seven general review objectives identified by SC&A in its review protocol. Due to the large number of documents and their heterogeneous contents, some comments may not apply to all documents and, in select instances, may only apply to one or a few of the documents.

Table ES-1 presents a summary of the reviews performed on the 45 documents that were assigned to SC&A by the Advisory Board for this third round of critical reviews.

Table ES-1: Summary of Documents Reviewed

Document Category	Number
Reviewed, results presented herein	32
Re-reviewed, results presented herein	4
Reviewed, including predecessor documents comments	2
Reviewed as QA documents, results presented herein	2
Not reviewed, deferred to an addendum to this report	2
Not reviewed, document not issued	2
Reviewed, results presented in separate report	1

The approach used to perform the reviews contained in this report follows the SC&A procedures provided in "A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction" (SCA-PR-Task3, Rev. 1, Final, April 29, 2004). In brief, SC&A identified seven objectives (including 26 sub-objectives) in its protocol to the Advisory Board, which form the basis for conducting the review. Each of the 38 documents in the top three rows of Table ES-1 was rated as to how well it met each sub-objective using a rating system of 1 through 5, corresponding to the following answers: 1=No (or Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (or Always). The two QA documents had a separate rating system.

Table ES-2 presents a roll-up of the findings of the results of SC&A's review of the 38 documents that constitute the main scope of this third round of critical reviews. As indicated by the number of "fives" that were assigned to individual sub-objectives, it is evident that most documents received very high scores.

Table ES-2: Roll-up of Findings of the Review of OCAS and ORAUT Documents

No.	Description of Objective	5	4	3	2	1	N/A
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**						
1.1	Is the procedure written in a style that is clear and unambiguous?	14	16	6	2	0	0
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	21	14	3	0	0	0
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	15	11	9	3	0	0
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	26	9	2	0	0	1
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	20	10	3	2	0	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?	9	1	0	0	0	28
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	13	0	1	0	1	23
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**						
3.1	Assess quality of data collected via interviews:	-----					
3.1.1	Is scope of information sufficiently comprehensive?	0	0	0	0	0	38
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	0	0	0	0	0	38
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	0	0	0	0	0	38
3.1.4	Is the interview process sensitive to the claimant?	0	0	0	0	0	38
3.1.5	Does the interview process protect information as required under the Privacy Act?	0	0	0	0	0	38
3.2	Adequacy and use of site-specific data pertaining to:	-----					
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	12	5	1	0	0	20
3.2.2	In-vivo/In-vitro bioassays	3	1	4	2	0	28
3.2.3	Missing dosimetry data	13	1	4	3	0	17
3.2.4	Unmonitored periods of exposure	13	4	3	4	0	14
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?	19	10	0	0	1	8
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	27	0	1	0	0	10

Table ES-2: Roll-up of Findings of the Review of OCAS and ORAUT Documents

No.	Description of Objective	5	4	3	2	1	N/A
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?	17	3	5	2	0	11
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	13	3	10	2	1	9
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	11	2	8	1	1	15
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)?	13	6	3	0	1	15
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	4	0	1	0	0	33
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**						
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	27	4	0	1	0	6
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	18	3	0	1	0	16
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	16	8	8	3	1	2

Objective 1: Determine the Degree to Which Documents Support a Process that is Expeditious and Timely for Dose Reconstruction

A well-written procedure presents all required data in a logical, concise, unambiguous, and prescriptive manner. Our review of this set of documents revealed that most were concise, well organized, and provided generally complete and unambiguous guidance. Unlike many of the documents we reviewed in our January 2005 report, the documents reviewed in this report do not require the dose reconstructor to read through voluminous and frequently irrelevant background information, similar to our June 2006 findings. There were 186 applicable rankings under Objective 1, of which 84% received a ranking of a 4 or 5, and none received a ranking of 1.

Objective 2: Determine Whether Documents Provide Adequate Guidance to be Efficient in Select Instances Where a More Detailed Approach to Dose Reconstruction Would Not Affect the Outcome

SC&A understands the benefit of and endorses the need for an efficient dose reconstruction process that, in appropriate instances, either avoids a full-blown dose reconstruction (i.e., when a partial dose reconstruction yields a probability of causation (POC) > 50%) or simplifies a dose reconstruction by means of worst-case assumptions/dose assignments for claims with a low POC. As in our January 2005 report, we found that a sizeable number of documents, while

making reference to the likely or unlikely compensability of a claim, provide little or no guidance to the dose reconstructor for prejudging a claim. However, we have come to believe that it is not always possible to provide explicit guidance on making these judgments, and that it is best to leave these judgments to the dose reconstructor working within a QA/QC framework that ensures consistency in these judgments. However, we have also found that, when it was possible to assist the dose reconstructor in making these judgments, such guidance was provided. There were 25 applicable rankings under Objective 2, of which 92% received a ranking of a 4 or 5. Only OCAS-TIB-013 received a ranking of 1, as SC&A found that TIB-013 understated the maximum correction factor to be applied to the badge readings, and thus, does not provide adequate guidance for defining the claimant-favorable assumptions.

Objective 3: Assess the Extent to Which Documents Account for all Potential Exposures, and Ensure that Resultant Doses are Complete and Based on Adequate Data in Instances where the POC is not Evident

Objective 3 is divided into two parts. The first part applies to the quality of data collected via interviews. In this second set of supplemental documents reviewed by SC&A, none of the documents were associated with data collection via interviews. Therefore, this first part of Objective 3 was not applicable to all of the documents reviewed.

The second part of Objective 3 applies to adequacy and use of site-specific data. We found that, to a large extent, a concerted effort was made in these documents to take into consideration site-specific and time-dependent factors, with appropriate cross-references to site profiles. There were 73 applicable rankings under the second part of Objective 3, of which 71% received a ranking of a 4 or 5, and none received a ranking of 1.

Objective 4: Assess Documents for Providing a Consistent Approach to Dose Reconstruction Regardless of Claimants' Exposures by Time and Employment Locations

In order for the adjudication process to be fair to claimants, the process of dose reconstruction must attempt to remain consistent over time and space. Consistency implies that the same documents are applied to claims that share a high degree of commonality. SC&A's review of the documents found that the documents generally provided a consistent approach to dose reconstruction. There were 58 applicable rankings under Objective 4, of which 97% received a ranking of a 4 or 5. Only ORAUT-OTIB-0015 received a ranking of 1, as SC&A found that OTIB-0015 does not contain any prescriptive information, rather it contains a level of detail far more than is reasonable, needed, or desired, for dose reconstruction. SC&A concluded that OTIB-0015 is not a technical instruction document as much as it is a specific statistical theory document and is not necessary for use, or as a reference, by dose reconstructors.

Objective 5: Evaluate Documents with Regard to Fairness and the Extent to which the Claimant is given the Benefit of Doubt when there are Unknowns and Uncertainties Concerning Radiation Exposures

The statutory requirement of a claimant-favorable dose reconstruction process is achieved by (1) giving the benefit of the doubt when there are unknowns, and (2) defining uncertainties for

measured data and selecting the 99th percentile value of a Monte Carlo distribution when determining the POC.

With few exceptions, the guidelines reviewed in this report give the benefit of the doubt to the claimant. There were 72 applicable rankings under Objective 5, of which 62% received a ranking of a 4 or 5. ORAUT-OTIB-0038 received two rankings of 1. The SC&A review of OTIB-0038 concluded that the uncertainties related to the model were large and, as a consequence, claimant-favorable dose reconstruction was not achieved.

Objective 6: Evaluate Documents for its Ability to Adequately Account for the Uncertainty of Dose Estimates

Generally, it was found that the procedures reviewed in this report adequately address uncertainties, with 82% of the 28 possible applicable rankings under Objective 6 receiving either a 4 or 5. The single ranking of 1 was given to ORAUT-OTIB-0027, because while the OTIB provides uncertainty factors for photon, neutron, and electron Rocky Flats Plant doses, there is no mention of the appropriate probability distribution to use in the IREP input.

Objective 7: Assess the Scientific and Technical Quality of Methods and Guidance Contained in Documents to ensure that they reflect the Proper Balance Between Current/ Consensus Scientific Methods and Dose Reconstruction Efficiency

The seventh and final review objective not only assessed the scientific credibility of procedural methods, but also the EEOICPA directive that the methods and procedures must achieve a balance between technical precision and dose reconstruction efficiency. There were 90 applicable rankings under Objective 7, of which 84% received a ranking of a 4 or 5. As is the case for Objective 2, only OCAS-TIB-0013 received a ranking of 1 under Objective 7. Reasons for this low ranking included (1) SC&A was unable to match NIOSH's results, (2) SC&A took issue with a number of assumptions made by NIOSH, including source spectrum, β-bremsstrahlung, and exposure geometry, and (3) the manner in which TIB-0013 handles direct β and neutron doses.

In summary, for the 38 documents that were evaluated, there were a total of 988 possible rankings, of which 449, or 45.4%, were found to be not applicable. Table ES-3 shows a summary of the rankings for the remaining 539 applicable sub-objectives.

Table ES-3: Summary of Rankings

Ranking	Percentage With Rank
5	60.1%
4	20.6%
3	13.4%
2	4.8%
1	1.1%

As indicated by the large percentage of 5s that were given, SC&A found that most of the documents reviewed were in satisfactory condition, and although SC&A found some areas that could be improved upon, we believe that overall NIOSH and ORAUT should be commended for producing so many highly technical documents of generally high standards.

Finally, SC&A's critical review of the two QA documents found that ORAUT-PROC-0094 provides adequate guidance to conduct and document verification and validation of software tools, and that ORAUT-PROC-0096 provides adequate instructions to perform QA checks of Task 4 claimant communication functions, including CATI, close-out interviews, and dose reconstruction submittals.

1.0 INTRODUCTION

1.1 STATEMENT OF PURPOSE

The purpose of this draft report is to assist the Advisory Board on Radiation and Worker Health (Advisory Board) in fulfilling its mandate to review the methods and procedures used by the National Institute for Occupational Safety and Health (NIOSH) and its contractors in the performance of dose reconstruction, as directed by the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) and Title 42, Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000, of the Code of Federal Regulations.*

Specifically, Section B of 42 CFR Part 82 identifies the following statutory requirement for:

> *… The Advisory Board on Radiation and Worker Health to **independently** review the methods established by this rule and to verify a reasonable sample of dose reconstructions established under these methods.* [Emphasis added.]

Section P of 42 CFR Part 82 restates this requirement, but further directs the Advisory Board to identify those procedures that are to be reviewed by the Board, as stated in the following:

> *As described above under the discussion of statutory provisions related to the rule, EEOICPA requires the Board to conduct an independent review of a sample of NIOSH dose reconstruction. 42 U.S.C. 7348 n(d). Since this review is specified to be independent, the **Board**, rather than HHS, must determine the procedures for the **Board's** review of NIOSH dose reconstructions. Moreover, this level of **autonomy** is important for the credibility of the review.* [Emphasis added.]

1.2 IDENTIFICATION OF DOCUMENTS SUBJECT TO REVIEW

Based on the above-cited statutory and regulatory requirements, the Board provided S. Cohen and Associates (SC&A) with a list of Office of Compensation Analysis and Support (OCAS) and Oak Ridge Associated Universities Team (ORAUT) documents to be assessed in FY2007 to satisfy the requirement of an "independent review." The final list of documents to be reviewed is provided in Table 1.2-1.

Table 1.2-1: Identification of Documents Subject to Review

Document Number	Rev.	Document Title	Date	Comments
OCAS-IG-001	2	External Dose Reconstruction Implementation Guideline	8/25/06	Re-review
OCAS-PER-003	0	Evaluation of Adding Ingestion Intakes to Bethlehem Steel Cases	1/28/05	
OCAS-PER-004	0	Application of Photofluorography at the Pinellas Plant	2/15/05	
OCAS-PER-006	0	External Dosimetry Target Organ for Prostate Cancer	9/15/06	
OCAS-PER-007	0	Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases	11/9/06	

Table 1.2-1: Identification of Documents Subject to Review

Document Number	Rev.	Document Title	Date	Comments
OCAS-PR-008	2	Preparation of Program Evaluation Reports and Program Evaluation Plans	12/6/06	
OCAS-TIB-0013	0	Special External Dose Reconstruction Considerations for Mallinckrodt Workers	10/26/05	
OCAS-TIB-0014	0	Rocky Flats Internal Dosimetry Coworker Extension	12/7/06	
ORAUT-OTIB-0002	2	Maximum Internal Dose Estimates for Certain DOE Complex Claims	2/7/07	
ORAUT-OTIB-0005	02 PC-1	Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code	2/10/06	Re-review
ORAUT-OTIB-0006	3	Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures	12/21/05	Re-review
ORAUT-OTIB-0013	0	Individual Dose Adjustment Procedure for Y-12 Dose Reconstruction	9/9/04	
ORAUT-OTIB-0015	0	Bayesian Methods for Estimation of Unmonitored Y-12 External Penetrating Doses with a Time-Dependent Lognormal Model	9/9/04	
ORAUT-OTIB-0021	1	External Coworker Dosimetry Data for the X-10 Site	11/7/06	
ORAUT-OTIB-0026	0 PC-2	External Coworker Dosimetry Data for the K-25 Site	11/15/06	
ORAUT-OTIB-0027	0	Supplementary External Dose Information for Rocky Flats Plant	5/19/05	
ORAUT-OTIB-0029	0	Internal Dosimetry Coworker Data for Y-12	4/5/05	
ORAUT-OTIB-0030	0	External Coworker Dosimetry Data for the Hanford Site	11/7/06	
ORAUT-OTIB-0032	0 PC-1	External Coworker Dosimetry Data for the Savannah River Site	11/7/06	
ORAUT-OTIB-0034	0	Internal Dosimetry Coworker Data for X-10	12/13/05	
ORAUT-OTIB-0035	0 PC-1	Internal Dosimetry Coworker Data for K-25	7/21/06	
ORAUT-OTIB-0037	0	Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant	9/20/05	
ORAUT-OTIB-0038	0	Internal Dose Coworker for Rocky Flats ETS	8/3/06	
ORAUT-OTIB-0039	0 PC-2	Internal Dosimetry Coworker Data for the Hanford Site	1/31/07	
ORAUT-OTIB-0043	0	Characterization of Occupational Exposure to Radium and Radon Progeny During Recovery of Uranium from Phosphate Materials	1/6/06	
ORAUT-OTIB-0045	—	Historical Evaluation of the Film Badge Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 - Neutron Radiation	—	Not issued by ORAUT
ORAUT-OTIB-0047	0	External Radiation Monitoring at the Y-12 Facility During the 1948-1949 Period	9/20/05	
ORAUT-OTIB-0049	00	Estimating Doses for Plutonium Strongly Retained in the Lung	2/6/2007	
ORAUT-OTIB-0050	00	The Use of Rocky Flats Neutron Dose Reconstruction Project Data in Dose Reconstructions	12/13/05	
ORAUT-OTIB-0051	00	Effect of Threshold Energy and Angular Response of NTA Film on Missed Neutron Dose at the Oak Ridge Y-12 Facility	5/15/06	
ORAUT-OTIB-0052	0	Parameters for Processing Claims for Construct. Workers	8/31/06	Review provided in separate report

Table 1.2-1: Identification of Documents Subject to Review

Document Number	Rev.	Document Title	Date	Comments
ORAUT-OTIB-0055	00	Technical Basis for Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Publication 60 Radiation Weighting Factors for Respective IREP Input Neutron Energy Ranges	6/5/06	
ORAUT-OTIB-0057	00	External Radiation Dose Estimates for Individuals Near the 1958 Criticality Accident at the Oak Ridge Y-12 Plant	5/15/06	
ORAUT-OTIB-0058	1 PC-1	External Coworker Dosimetry Data for Rocky Flats	3/29/07	
ORAUT-OTIB-0060	00	Internal Dose Reconstruction	2/6/07	Incorporates PROC-0003
ORAUT-OTIB-0063	—	Los Alamos National Laboratory Bioassay Data Project	—	Not issued by ORAUT
ORAUT-PROC-0006	1	External Dose Reconstruction	6/5/06	Re-review
ORAUT-PROC-0042	00	Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant Prior to 1961	9/9/04	
ORAUT-PROC-0044	—	Special Exposure Cohort (SEC)	—	To be provided in an addendum
ORAUT-PROC-0060	1	Occupational Onsite Ambient Dose Reconstruction	6/28/06	Incorporates OTIB-0007
ORAUT-PROC-0086	00	Case Preparation - Complex Internal Dosimetry Claims	12/7/05	
ORAUT-PROC-0094	00	Verification and Validation Process for the Tools Development Group	1/5/06	
ORAUT-PROC-0095	00	Generating Summary Statistic for Coworker Bioassay Data	6/5/06	
ORAUT-PROC-0096	00	Claimant Communications Quality Control Process	3/3/06	
ORAUT-PROC-0097	—	Conduct of Worker Outreach Program	—	To be provided in an addendum

1.3 SC&A'S APPROACH FOR TASK 3

The approach used to perform the reviews contained in this report follows the SC&A procedures provided in *A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction* (SCA-PR-Task3, Rev. 1, Final, April 29, 2004). In the original Statement of Work, key technical elements to be addressed in the review included the following:

(a) Review the internal and external radiation dose reconstruction TBDs (including procedures for performing internal dose reconstructions and external dose reconstructions)

(b) Review of methods for estimating "missed dose" and "unmonitored dose" (for cases related to monitoring technology and for cases where monitoring was not performed, monitoring data are not available or incomplete, or otherwise inadequate)

(c) Review of the statistical approaches developed for multiple dose reconstructions

(d) Review procedures used for determining whether data are sufficient to make a reasonable dose estimate

(e) Review methods or procedures used for substituting exposure information for unavailable or incomplete information

(f) Review methods for estimating uncertainty in dose and uncertainty distributions surrounding internal and external dose reconstructions on a facility- and time-specific basis, and evaluate whether the benefit of the doubt was resolved in favor of the claimant where there were uncertainties

(g) Review procedures and questionnaires used for work history telephone interviews (includes review of Computer-Assisted Telephone Interview (CATI), scheduling, performance, and review procedures)

(h) Review quality assurance plan and related procedures

(i) Review procedures related to document acquisition (records request, management, assembly, and handling)

(j) Review procedures related to completing a Site Profile (Site and Exposure Profiles), Worker Profiles, and SEC petition review, and procedures on how Worker Profile and Site Profile data will be used for individual case dose reconstructions

(k) Review the NIOSH methods, procedures, and performance in evaluating, analyzing, and validating all contractor work products

In addition to technical elements, SC&A also recognized that the review of methods and procedures must also address non-technical issues that reflect the philosophy, intent, and/or statutory directives cited in EEOICPA and 42 CFR Part 82.

The Act (as stated in 42 CFR Part 82) requires that "… HHS establish by regulation, methods for arriving at **reasonable estimates** of the radiation doses incurred by covered employees in connection with claims seeking compensation for cancer…" [Emphasis added].

Other directives issued to the U.S. Department of Health and Human Services (HHS) mandated, by regulation, the establishment of methods that are (1) **efficient**, (2) **consistently applied**, (3) **reasonable dose estimates**, (4) **complete**, and (5) **well grounded in the best available science**.

As acknowledged in the Act, the level of effort involved in dose reconstructions depends largely on the quantity and quality of available dose monitoring data, and the extent to which these data are, in fact, complete. The EEOICPA further recognized the complexity of **traditional** approaches for dose reconstruction, which frequently require extensive research and analysis, and in instances of "…health research studies dose reconstruction may take from months to years to complete."

Owing to the large number of claims requiring dose reconstruction, Section 7384 of EEOICPA specifically states that "…one of the purposes of the compensation program is to provide for **timely compensation**" [Emphasis added], and Section E of 42 CFR Part 82 states that "…An additional critical factor affecting how doses are reconstructed is the amount of time available… In compensation programs, however, a balance must be struck between **efficiency** and **precision**." [Emphasis added.]

According to these directives, SC&A's evaluation of documents cannot limit itself to a process that simply determines whether applicable documents are technically correct and make use of the most current ICRP biokinetic models, dose conversion factors (DCFs), cancer risk coefficients, computer codes, etc., but must equally address the more difficult and subjective question of whether a proper balance has been struck between efficiency and precision.

SC&A's review of the technical and scientific methods prescribed in applicable documents must, therefore, also assess non-technical issues and the impacts of scientific detail that are required procedurally, and weigh the incremental precision gained against the reduced efficiency and higher costs for reconstruction and added delay in the adjudication of claims.

In brief, SC&A identified the following objectives in its protocol to the Advisory Board, which form the basis for conducting the review:

Objective 1: Determine the degree to which documents support a process that is expeditious and **timely** for dose reconstruction.

Objective 2: Determine whether documents provide adequate guidance to be **efficient** in select instances where a more detailed approach to dose reconstruction would not affect the outcome.

Objective 3: Assess the extent to which documents account for all potential exposures, and ensure that resultant doses are **complete** and based on adequate data.

Objective 4: Assess documents for providing a **consistent** approach to dose reconstruction, regardless of claimants' exposures by time and employment locations.

Objective 5: Evaluate documents with regard to **fairness** and the extent to which the claimant is given the **benefit of doubt** when there are unknowns and uncertainties concerning radiation exposures.

Objective 6: Evaluate documents for their approach to quantifying the **uncertainty** distribution of annual dose estimates that is consistent with and supports a U.S. Department of Labor POC estimate at the upper 99% confidence level.

Objective 7: Assess the scientific and technical quality of methods and guidance contained in documents to ensure that they reflect the **proper balance between current/ consensus scientific methods and dose reconstruction efficiency**.

1.4 STRUCTURE AND ORGANIZATION OF THE REPORT

Structure: For each of the above-cited seven general objectives, the review protocol was structured on a series of relevant questions contained in a checklist, which the SC&A reviewer used for rating a given procedure. A rating system of 1 through 5 corresponded to the following answers: 1=No (or Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (or Always). For example, Objective 1 focused on timeliness. The need for NIOSH to perform large numbers of dose reconstructions in a timely manner places specific demands on procedures and the dose reconstruction process as a whole. SC&A's evaluation of procedures for their support of a timely reconstruction process was, therefore, based on rating the answers to the following questions:

- Is the procedure written in a style that is concise and unambiguous?
- Is the procedure written in a manner that presents the data in a logical sequence?
- Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?
- Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?
- Is the procedure sufficiently prescriptive to minimize the need for subjective decisions and data interpretation?

Answers that resulted in a rating other than a 5 in the checklist were supported with specific review comments. In some of the more technical issues, the SC&A analyst has provided corroborating information for ratings of "5," when they checked the approach prescribed by the procedure and it was determined to be correct. Table 1.4.1 below identifies the Procedure Review Outline/Checklist that is used in this report to assess the degree to which a given procedure meets the seven objectives, as applicable to the procedure. This table is slightly different than the table used in our original Task 3 report (dated January 17, 2005), in that it includes item 7.3, which explicitly addresses the scientific validity of the methodology employed in the procedure to perform or support dose reconstruction.

Organization: The individual procedures/documents for review are grouped by topic in the following sections:

- Section 2.0, Office of Compensation Analysis and Support (OCAS) Documents
- Section 3.0, Oak Ridge Associated Universities Team Technical Information Bulletins (OTIB)
- Section 4.0, Oak Ridge Associated Universities Team (ORAUT) Procedures
- Section 5.0, Oak Ridge Associated Universities Team (ORAUT) Program Evaluation Reports

For a specific section, procedures/documents are sequenced as given in the table of contents for this report.

2.0 OFFICE OF COMPENSATION ANALYSIS AND SUPPORT (OCAS) DOCUMENTS

2.1 OCAS-IG-001: EXTERNAL DOSE RECONSTRUCTION IMPLEMENTATION GUIDELINE

The review of OCAS-IG-001, *External Dose Reconstruction Implementation Guideline*, Rev. 2, dated August 25, 2006, was prepared by Kathleen Behling.

2.1.1 Purpose of the Implementation Guide

The stated purpose of this implementation guide is to provide guidance "… on the components, standards, and methods of external radiation dose reconstruction for probability of causation calculations in support of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). It is to be used as a source to help provide specific guidance and methods which can be found in site profiles and other site-specific documents."

2.1.2 Review Protocol

As part of the first set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated Revision 1 of the *External Dose Reconstruction Implementation Guideline* (August 2002). Our findings were published in *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, dated January 2005 (SCA-TR-Task3). Following the submission of this report and its findings, an expanded review and issues-resolution process was initiated. The process began by NIOSH providing written responses to each of SC&A's findings. Under the direction of a Board-appointed Work Group, a series of meetings was held between representatives of NIOSH and SC&A auditors to discuss and resolve each finding. This process resulted in the preparation of an issues-tracking matrix, whereby the closeout status of each finding is tracked.

The resolution of many findings identified during our review of Revision 1 of the implementation guide required NIOSH to incorporate changes in a future revision of the OCAS-IG-001. These findings were also assigned a resolution priority ranking of high, medium, or low by the Advisory Board. Our evaluation of OCAS-IG-001, Rev. 2, therefore, was designed to ensure that (1) the findings identified in Revision 1 were adequately resolved, and (2) the document adequately supports the dose reconstruction process. Table provides a list of applicable OCAS-IG-001, Rev. 1 findings, the Board-recommended resolution ranking, and our evaluation to assess whether those findings were adequately addressed. Table is a checklist containing SC&A's evaluation of procedural objectives developed as described in the introduction to this report.

Table 2.1-1: Evaluation of Findings Identified in the Review of OCAS-IG-001, Rev. 1

Review Objective	OCAS-IG-001, Rev. 1 Finding Description	Resolution Ranking	Corrected in Rev. 2?	Comments
1.1	Deficiencies with procedure layout include: (1) fragmented structure, (2) excessive amount of useless data and/or historical background in main body, and (3) critical data for dose reconstruction found in Appendices rather than main body. (Finding No. IG-001-01)	Low	Partially	Revision 2 of the Implementation Guide eliminated much of the excessive data, such as examples and historical background information. However, the fragmented structure was not modified. See additional details under Review Objectives 1.1 and 1.2 comments below.
1.3	Guidance for deriving (1) film and TLD dosimeter uncertainty, (2) neutron dose from source term, and (3) occupational medical dose using x-ray machine operating parameters requires data and resources that are not available to the dose reconstructor. (Finding No. IG-001-02)	1–2 Medium 3 Low	Partially	Guidance for dosimeter uncertainty and calculation of occupational medical doses has been modified to include references to site-specific documents. The neutron flux equation has been removed from IG-001 in the section describing assessing neutron dose from source term; however, the recommended method remains the same. See additional details under Review Objective 1.3 comments below.
3.2.1	IG-001 recommends inappropriate methods for estimating TLD uncertainty by (1) recommending the use of present-day (i.e., DOELAP) uncertainty parameters for TLDs of the 1960s and 1970s, and (2) giving the dose reconstructor an option of using the simplified dosimetry uncertainty calculation, even when site-specific data are available. (Finding IG-001-04)	Medium	Yes	Revision 2 of IG-001 eliminates recommending inappropriate methods for TLD uncertainty and includes guidance that directs the dose reconstructor to site-specific documentation, when available.
5.0	IG-001 recommends a range of Limit of Detection (LOD) values for 1956–1960 that the reviewer considers too low for the period. (Finding IG-001-05)	Low	Yes	Table 2.1 that referenced LOD values for the 1956–1960 period has been modified to remove any date-specific LOD values.
5.0	Guidance implies that LOD for deep dose from gamma may also be applied to electron dose, which is inconsistent with historical data that show uncertainty for shallow dose is considerably higher than deep dose. (Finding IG-001-06)	Low	Yes	Revision 2 of IG-001 removes the example that implies LOD for deep dose from gamma is also appropriate for electron dose.
5.0	IG-001 assumes NTA film dosimeters were insensitive to neutrons below 500 kiloelectron volt (keV); however, reviewer contends that the dosimeter is insensitive to neutrons <1 megaelectron volt (MeV). (Finding IG-001-07)	Medium	Yes	Wording in revision indicates that a variety of energy thresholds for NTA film dosimeters are cited in the literature and recommends reviewing site-specific information for determining actual threshold values.

Table 2.1-1: Evaluation of Findings Identified in the Review of OCAS-IG-001, Rev. 1

Review Objective	OCAS-IG-001, Rev. 1 Finding Description	Resolution Ranking	Corrected in Rev. 2?	Comments
5.0	Methods for reconstruction of neutron doses from survey data or source term data do not appear practical, achievable, and defensible for most neutron exposure conditions. (Finding IG-001-08)	Medium	Partially	Revision 2 of IG-001 has eliminated some examples and slightly modified guidance for reconstruction of neutron doses but failed to include the use of more practical methods such as employing neutron-to-photon ratios. A more detailed discussion is provided under Review Objective 5.0 comments below.
5.0	IG-001 does not acknowledge the likely use of neutron/photon ratio methods in neutron dose reconstruction and erroneously states that ". . . at most facilities, neutron exposure were generally less than 20% of the photon exposures." (Finding IG-001-09)	Low	Yes	Section 2.2.2, which discusses missed neutron doses, has been modified to eliminate the statement indicating neutron exposures are less than 20% at most facilities and has introduced a statement acknowledging the use of site-specific neutron-to-photon ratios.
5.0	IG-001, Appendix B, DCFs for bone surface and red marrow are underestimated. (Finding IG-001-10)	Medium	Yes	IG-001, Rev. 2 has added guidance to Section 4.4, which recommends applying a correction factor to the rotational and isotropic dose conversion factors (DCFs) for bone surface and red marrow (as well as esophagus and lung) when the dosimeter is worn on the chest and the worker may have experienced exposure geometries other than anterior-posterior (AP).
6.0	IG-001 does not account for additional laboratory uncertainty for film badge readings associated with exposure less than 200 mrem. (Finding IG-001-11)	Medium	Yes	Guidance has been added to the uncertainty section (Section 2.1.1.3) indicating that site-specific dosimetry data may be available in the site profile.
6.0	IG-001, Appendix B, posterior-anterior (PA) geometry DCFs are in error and underestimate dose. (Finding IG-001-12)	High	No	There has been no modification introduced into Revision 2 of IG-001 to either address the fact that the PA geometry DCFs are in error and should not be used or recommend the use of a dosimeter location correction factor. A more detailed discussion of this issue is provided below under Review Objective 6.0 comments.
6.0	IG-001, Appendix B, rotational and isotropic geometry DCFs are in error and underestimate dose. (Finding IG-001-13)	High	Yes	IG-001, Rev. 2 has introduced a new discussion and table of correction factors to be applied to rotational and isotropic DCFs for bone (surface), bone (red marrow), esophagus, and lung.
6.0	Angular sensitivity not accounted for in 'correcting' measured film or TLD values. (Finding IG-001-14)	High	Yes	A paragraph discussing angular response of dosimeters has been added to Section 4.0 of IG-001, Rev.2. New guidance directs the dose reconstructor to site-specific documentation.

Table 2.1-1: Evaluation of Findings Identified in the Review of OCAS-IG-001, Rev. 1

Review Objective	OCAS-IG-001, Rev. 1 Finding Description	Resolution Ranking	Corrected in Rev. 2?	Comments
6.0	Environmental uncertainty (i.e., heat, humidity, light, etc.) was not addressed (Finding IG-001-16)	Medium	No	There has been no discussion added to the revision of IG-001 that addresses environmental uncertainties. A further discussion of this issue is provided below under Review Objective 6.0 comments.
6.0	Guidance for the selection of uncertainty distributions for total organ dose raises question of consistency and requires professional judgment. (Finding IG-001-17)	Medium	No	Sections 5.1 and 5.2 of IG-001, Rev. 2 have been modified by eliminating previously cited examples, figures, and references to statistical software for determining uncertainty distribution for total organ dose. However, this change does not resolve the issue of consistency or address the need for professional judgment. In fact, the elimination of the examples and figures may have further complicated this issue. A more detailed discussion of the selection of uncertainty distributions is provided below under Review Objective 6.0 comments.

Table 2.1-2: OCAS-IG-001 Review Outline/Checklist

Document No.: OCAS-IG-001, Rev. 2	**Effective Date:** 08/25/2006
Document Title: External Dose Reconstruction Implementation Guideline	
Auditor: Kathleen Behling	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments

Table 2.1-2: OCAS-IG-001 Review Outline/Checklist

Document No.: OCAS-IG-001, Rev. 2	**Effective Date:** 08/25/2006
Document Title: External Dose Reconstruction Implementation Guideline	
Auditor: Kathleen Behling	

No.	Description of Objective	Rating 1–5*	Comments
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	4	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	

Table 2.1-2: OCAS-IG-001 Review Outline/Checklist

Document No.: OCAS-IG-001, Rev. 2	**Effective Date:** 08/25/2006
Document Title: External Dose Reconstruction Implementation Guideline	
Auditor: Kathleen Behling	

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)?	3	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	3	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	4	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.1.3 Review Comments

Review Objective 1.1

SC&A's review of OCAS-IG-001, Rev. 1, identified several deficiencies regarding the clarity and structure of the document that NIOSH indicated would be modified in a subsequent revision of the implementation guide. One of these deficiencies identified the fact that the document contained excessive amounts of data that are not only of limited use to the dose reconstructors, but are time consuming to read and reduce the clarity of the guidance. Revision 2 of IG-001 has eliminated much of the excessive data and generally improved the clarity of the document.

Review Objective 1.2

Another deficiency that was identified under the Revision 1 review was the fragmented structure and illogical sequencing of information. For example, in order to reconstruct photon doses, the dose reconstructor is required to consult (1) Section 2.0 for a discussion of monitoring data, (2) Section 3.0, which provides guidance on handling incomplete, missing, or no monitoring photon data, and (3) Section 4.0 for a guidance on converting photon dose to organ dose. During the findings resolutions process, NIOSH agreed that SC&A's comments were constructive and future revisions would include a change to the structure of the document. However, no such modifications were introduced into Revision 2 of IG-001.

Review Objective 1.3

Review Objective 1.3 addresses the need for this guidance document to be complete and require minimum additional data in order to reconstruct external doses. SC&A's review of IG-001, Rev. 1, identified guidance that required the dose reconstructor to obtain data pertaining to (1) film and TLD dosimeter uncertainty, (2) neutron dose evaluations from source term, and (3) occupational medical data that would not be available to the dose reconstructor. Since the publication of Revision 1 of IG-001, site-specific documents (i.e., Site Profiles) have been developed for most of the DOE sites, as well as numerous OTIBs, which are used to support the more general guidance provided in IG-001. By referencing these technical and site-specific documents, Revision 2 of IG-001 has resolved two of the three concerns raised by SC&A previously identified under Review Objective 1.3. The area where NIOSH did not provide improved guidance is with regard to the assessment of neutron doses using source term data, which is discussed in more detail under Review Objective 5.0 below. Revision 2 simply removes the equation for calculating neutron fluence (Section 3.2.3.2); however, the methodology for assessing neutron dose from source term has not been changed. The revision also neglects to direct the dose reconstructor to site-specific documentation for additional information.

Review Objective 1.5

Review Objective 1.5 evaluates whether the guidance document is sufficiently prescriptive to minimize the need for subjective decisions. During our issues resolution process for findings identified in Revision 1, NIOSH indicated that the IG-001 guidance could be useful in preparation of technical documents (e.g., TBDs, OTIBs, procedures, etc.), which would provide more detailed guidance for the dose reconstructor. As discussed under Review Objective 1.3 comments above, many technical and site-specific documents have been published since the release of IG-001, Rev. 2. However, Revision 2 of IG-001 does not consistently direct the dose reconstructor to these technical documents.

Review Objectives 4.1 and 7.1

Review Objectives 4.1 and 7.1 involve an evaluation of whether the implementation guide provides a prescriptive, sufficiently detailed, and consistent approach to dose reconstruction. SC&A recognizes that IG-001 was designed to provide general guidance and was intended to assist qualified health physicists in determining annual organ dose from external radiation, as opposed to providing step-by-step instructions. However, since this guidance is not intended to be prescriptive or overly detailed, the implementation guide should direct the dose reconstructor to technical and site-specific documentation, which were designed to provide more specific guidance.

Review Objective 5.2

In SC&A's review of IG-001, Rev. 1, we identified some statements under Section 2.2.2.1 Missed Dose regarding neutron exposures that were incorrect and conflict with site-specific documents. SC&A also identified the fact that the implementation guide did not acknowledge the use of neutron-to-photon ratios for estimated neutron doses. During the issues resolution

process, NIOSH agreed with these findings and indicated that IG-001 would be revised to reflect the use of neutron-to-photon ratios. Although IG-001, Rev. 2, has removed the conflicting and erroneous statements, there was no discussion added regarding neutron-to-photon ratios.

Review Objectives 6.1 and 6.2

Under Review Objectives 6.0, the implementation guide is evaluated for its ability to provide guidance on dose estimate uncertainty. Our review of Revision 1 identified six separate issues under this objective, which NIOSH agreed to resolve in a future revision of IG-001. Three of these findings, however, have not been addressed in Revision 2. The unresolved findings include (1) all DCFs associated with posterior to anterior (PA) geometries in Appendix B of Revision 1 are in error and underestimate the dose, (2) environmental uncertainty associated with dosimeters (i.e., heat, humidity, light) was not addressed, and (3) guidance for selection of uncertainty distributions raises questions of consistency and required professional judgment. These three issues are discussed in more detail below.

DCFs for PA Geometries. SC&A concluded that DCF values provided for PA geometries for photons and neutrons were measured with the dosimeter worn on the posterior of the individual. Since personnel dosimeters at the DOE facilities were commonly worn on the chest (anterior), all PA DCFs underestimate the dose. This dose underestimate is particularly pronounced when the organ of interest is the female breast, male testes, eye, and thyroid. Although SC&A acknowledges that the PA geometry is typically not prescribed as a common exposure orientation, NIOSH should have either identified the problem and recommended a badge placement correction factor, as they did for erroneous isotropic and rotational DCFs, or eliminated the use of PA geometry altogether.

Environmental Uncertainty Associated with Dosimeters. In Revision 1 of IG-001, Section 2.1.1.3.1 states that uncertainty in the environmental component of personal dosimeters will be discussed in Section 2.1.3. However, Section 2.1.3 of Revision 1 provides a discussion of occupational medical dose and Section 2.1.4 discusses environmental dose. There is no discussion of the environmental component of personal dosimeters in IG-001, Rev. 1. During the findings resolution process, NIOSH acknowledged that this analysis was erroneously omitted and agreed to revise IG-001. However, Revision 2 does not include any discussion of environmental uncertainty associated with film dosimeters and the reference to the topic in Section 2.1.1.3.1 has not been changed.

Uncertainty Distributions. SC&A's review of IG-001, Rev. 1, questioned whether the guidance for determining organ dose uncertainty distributions could lead to inconsistencies and required professional judgment that may go beyond the knowledge and experience of the average dose reconstructor. NIOSH's resolution of this finding was to eliminate (1) an example of calculating total external organ dose, (2) figures that illustrated uncertainty for each of the external dose components, and (3) references to statistical software in Section 5.0, Annual Organ Dose & Distribution, of Revision 2. SC&A believes that the revision to IG-001 should have directed the dose reconstructor to applicable technical and site-specific documents, which provide clear guidance on the selection of uncertainty distribution for dosimeter, missed, occupational medical, and onsite ambient doses. In addition, Revision 2 should have identified the fact that calculational tools (workbooks) have been developed for best-estimate cases that automate the

process of determining dose uncertainty using Monte Carlo sampling techniques. The use of these calculational tools eliminates inconsistencies and the need for professional judgment. Lastly, it is SC&A's opinion that the examples and figures initially cited in Revision 1 of IG-001 should not have been removed and were useful in providing an understanding of the combined uncertainty for all external dose components.

2.1.4 Conclusions

Revision 2 of OCAS-IG-001 *External Dose Reconstruction Guideline* was issued primarily in response to SC&A's review of Revision 1 of this implementation guide. During our initial evaluation, SC&A identified 15 findings, which NIOSH agreed to resolve in a future revision. Our review of OCAS-IG-001, Rev. 2, identified that NIOSH has not resolved three of the fifteen Revision 1 findings and has partially resolved three additional findings. Of the six issues that were not appropriately addressed in OCAS-IG-001, Rev. 2, only one finding (i.e., erroneous PA geometry DCFs) was ranked as a high priority by the Advisory Board.

In general, SC&A believes that the modifications introduced into OCAS-IG-001, Rev. 2, improve the guidance document and have corrected many previous findings. We would suggest, however, that the remaining unresolved Revision 1 findings be addressed in a future revision of the implementation guide.

2.2 OCAS-PER-003: EVALUATION OF THE EFFECT OF ADDING INGESTION INTAKES TO BETHLEHEM STEEL CASES

The review of OCAS-PER-003, *Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases*, Rev. 0, dated January 28 2005, was prepared by Robert Barton.

2.2.1 Purpose of Program Evaluation Report

The stated purpose of this Program Evaluation Report (hereafter referred to as the PER in this review) is as follows:

> *On 3/31/2003 NIOSH completed a Technical Basis Document assessing exposures to uranium at the Bethlehem Steel Corporation facility. The original document did not assess the intakes of uranium through an ingestion route. The document has since been revised on 6/29/2004 to include this exposure pathway. The purpose of this PER is to evaluate the effect on this additional intake on previously completed claims.* (OCAS-PER-003, pg. 1)

2.2.2 Review Protocol

Our evaluation of OCAS-PER-003 is summarized in Table 2.2-1 below. Table 2.2-1 presents a checklist containing objectives that SC&A developed to evaluate whether a Program Evaluation Report adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 2.2-1: OCAS-PER-003 Review Outline/Checklist

Document No.: OCAS-PER-003, Rev. 0	**Effective Date:** 01/28/2005
Document Title: Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases	
Auditor: Robert Barton	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	N/A	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	

Table 2.2-1: OCAS-PER-003 Review Outline/Checklist

Document No.: OCAS-PER-003, Rev. 0	**Effective Date:** 01/28/2005
Document Title: Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases	
Auditor: Robert Barton	

No.	Description of Objective	Rating 1–5*	Comments
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	3	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.2.3 General Comments

There have been three versions of the site profile for the Bethlehem Steel plant to date: ORAUT-TKBS-0001 Rev. 00, ORAUT-TKBS-0001 Rev. 01, and OCAS-TKBS-0003, which represents the most recent site profile. The purpose of this PER is to analyze the affect on dose reconstruction calculations (particularly the probability of causation) from the source of ingestion that was added to ORAUT-TKBS-0001, Rev. 01. This treatment does not utilize the most recent intake parameters as found in the OCAS document and so the applicability of the treatment found in this PER is no longer the current standard. However, a separate PER report has been generated (PER-007) which deals with the changes of the most recent site profile and will be reviewed in another section. Therefore, this review will concentrate on the validation of PER-003's conclusions in reference to the two older site profiles it references, and will not deal with any comparisons to the newer profile.

2.2.4 Review Comments

Review Comment 1.2

The title of the PER, *Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases*, is misleading, as the PER does not deal solely with the ingestion component. The conclusions of the PER relate not only to the addition of the ingestion component, as prescribed in Revision 01, but also recalculates the probability of causation including the updated occupational x-ray data. The analysis of the ingestion component merely acts as a method to develop which cases should be recalculated. A more appropriate title would be: *Evaluation of the Effect of Revision 01 of the Site Profile on Previously Completed Bethlehem Steel Cases*.

Review Comment 1.3

The PER does not specify which specific intake parameters it utilizes in determining the annual percent increase in dose. In ORAUT-TKBS-0001, Revisions 00 and 01, the inhalation parameters are given in two tables that represent the high-sided and low-sided estimates for annual dose. In addition, each table represents a triangular distribution and so lists a non-zero mode, as well as a maximum value. Therefore, there are four possible inhalation intake parameters listed in addition to the possible use of the average and median intake values that can be calculated from the distribution. Ingestion intakes are found in only one table, which, likewise, contains a mode and maximum value. It would be much easier to independently verify the results of the PER if the specific intake parameters used in determining the percent increase in dose were stated explicitly.

Review Comment 6.1

In recalculating the probability of causation (POC) for the individuals deemed effected by the change in dose reconstruction, the PER states that:

> *Once the new dose values were entered, the POC calculation was run 30 times with a different random seed value each time. This was done in order to produce a more precise POC by minimizing minor fluctuations attributable to the computation rather than the actual uncertainty in the POC. The average of 30 runs is reported in the table below.* (PER-003, pg. 3)

It is not immediately clear why 30 runs would significantly reduce computational errors associated with the POC calculation, nor why the average was taken instead of the 90^{th} or 95^{th} percentile value. After further investigation, it appears this method stems from the IREP User's Guide (NIOSH 2007, pg. 14). This document should be referenced in the PER report so that the use of the average of 30 runs does not appear as a discretionary choice. Furthermore, this document specifies that the arithmetic mean of the 99% confidence level is to be utilized; this additional information concerning the "average" value should be added to the PER.

Review Comment 7.3

Selection of Absorption Type

The PER states that it will select the most claimant-favorable absorption type based on the organ of interest; specifically, it will utilize absorption Type M for non-respiratory tract organs and Type S for respiratory organs. SC&A calculated the cumulative dose through 2002 for all organs using both absorption types. The PER assertion is correct in all cases except for the respiratory tract organ, ET1, which showed Type M dominance. The dose for ET1 when calculated for Type M was generally a factor of 4 higher than the Type S dose.

Methodology and Conclusions of the PER

The PER uses the largest assumed difference to calculate the effect this change has on previously calculated POCs. The largest assumed differences were 5.62% for tissues associated with the GI tract, 0.62% for respiratory tract doses, and 0.94% for all other doses. For example, with an increase of 5.62%, the claimant would have to have had an original POC of 48.6% in order to reach a new POC equal to 50%,

The PER then identifies seven claimants who had a POC in the range of 40-50% from December 2004. Of these seven, one already included the ingestion dose in the original POC calculation, five had POC's sufficiently below 50% that the addition of ingestion dose would not have brought them to 50%, and only one of the seven claims had a POC close enough to 50% that using the maximum percent increase (5.62%) would bring them equal to or above 50%. The PER then recalculates the POC with the added ingestion dose and consideration for the updated occupational x-ray information specified in Revision 01. Table 1 of the PER, summarizing this concept, is copied below in Table 2.2-2.

Table 2.2-2: Copy of OCAS-PER-003, Table 1

Claim Identification	Cancer Type	Original POC	New POC
A	Chronic Myelocytic Leukemia	44.90 %	43.72 %
B	Kidney	46.36 %	45.72 %
C	Rectum/Kidney	49.42 % combined	49.11 % combined
D	Testis	47.53 %	46.37 %
E	Chronic and Acute Myelomonocytic Leukemia	48.32 % combined	46.53% combined
F	Kidney	49.27 %	47.11 %

As one can see in the above table, all of the cases involve non-respiratory tract cancers. Therefore, the maximum percent increase for the GI tract organs (5.62%) and all other non-respiratory tract organs (0.94%) would apply. Given this information, only claim "F" would result in a POC equal to or greater than 50% when the original POC is used. However, when the new POC is calculated with the updated x-ray dose, the POC falls to 47.11% and so the addition of the ingestion dose would not bring this POC up to 50% or greater.

Verification of PER Methodology

The following treatment will use the intake parameters specified in ORAUT-TKBS-0001, Rev. 01, and use the methodology outlined in the PER to calculate the increase in dose caused by the addition of the ingestion component (the inhalation parameters for Rev. 00 and Rev. 01 are identical). The site profile specifies that cases where it is suspected that the claimant will be below a 50% POC, the inhalation values found in Table 3 (ORAUT-TKBS-0001, pg. 5) should be used. Since the effect of the additional ingestion intake would only be relevant to this type of claimant, the following treatment will also assume the inhalation intakes of Table 3. The ingestion intakes were taken from Table 4 of the TBD. All intake values used in the IMBA calculation are listed in Table 2.2-3.

Table 2.2-3: Intake Values of ORAUT-TKBS-0001 Used in IMBA Calculations

Intake Year	Daily Intake (pCi/day)*			
	Maximum		Median	
	Inhalation	Ingestion	Inhalation	Ingestion
1949	17,781	466	5,217	137
1950	17,781	466	5,217	137
1951	19,261	493	5,651	145
1952	16,301	411	4,783	121

* To convert to dpm/day multiply by 2.22.

The source radionuclide was assumed to be entirely U-234, an assumption often employed by the NIOSH Dose Reconstruction Project (see ORAUT-OTIB-0004 pg 9). The dose was then calculated for various organs using both Type M and Type S absorptions; the absorption type that produced the maximum cumulative dose for each organ was used. To determine the percentage increase in adding the ingestion dose, the following formula was utilized:

$$\text{Percent Increase} = 100*[((\text{Combined Dose})-(\text{Inhalation Only Dose}))/(\text{Inhalation Only Dose})]$$

In order to compare those values developed in the PER, each stated value of “percent increase” found on page 2 of the PER will be compared to those values calculated via IMBA and displayed in Table 2.2-4. It is clear from the table that the use of both the maximum and median intake values yielded similar results.

Table 2.2-4: Comparison of PER-Developed Results to IMBA Findings

PER Assumptions (found on page 2)	IMBA Finding for Maximum Dose	IMBA Finding for Median Dose
"The highest increase in dose occurred in the first year of exposure for all organs other than the respiratory tract."	True for all organs dominated by Type M absorptions with the exception of the anterior nose (ET1), which had its highest increase in 1998.	True for all organs dominated by Type M absorptions with the exception of ET1 that had its highest increase in 1997.
"The difference in respiratory tract dose continued to increase through 2002, the largest difference being 0.62% increase in the ET2 compartment."	Organs dominated by Type S absorptions showed general increase as time passed; however, once reaching a certain maximum would fluctuate around that value. The largest increase was 0.79%, which occurred to the posterior nose, larynx, pharynx, mouth (ET2) and the basal cells of the bronchial region (BBbas).	Organs dominated by Type S absorptions showed general increase as time passed; however, once reaching a certain maximum would fluctuate around that value. The largest increase was 0.758% that occurred to the ET2, BBbas and secretory cells of the bronchial region (BBsec).
"The majority of organs had an increased dose of approximately 0.94% in the first year and quickly decreased to a 0.74% increase."	In agreement with PER findings.	In agreement with PER findings.
"The largest difference in dose was found in the lower large intestine (LLI) tissue. The largest increase in dose to the LLI was 5.62%, occurred in the first year."	The largest difference in dose was to the lower large intestine (LLI) tissue in the first year. This percent increase was 5.48%	The largest difference in dose was to the lower large intestine (LLI) tissue in the first year. This percent increase was 5.52%

Implications of the IMBA Generated Values for the PER

The largest IMBA calculated percent increase using both the maximum and median intake parameters was lower than 5.62% for GI tract tissues (IMBA calculated them at 5.48% for the maximum and 5.52% for the median), and the IMBA analysis agreed well for all other non-respiratory tract organs as using an increase of approximately 0.94%. Therefore, the conclusions of the PER are consistent with findings of this review. It should be noted, however, that the largest increase for respiratory tract organs (those dominated by Type S) was calculated using IMBA to be 3.45% and 3.41% for the median and maximum intakes; these are much larger than the PER-based value of 0.65%. However, none of the claims previously calculated as being between 40-50% were for respiratory tract doses, and so this does not affect the conclusions of the PER.

2.2.5 References

NIOSH 2007. *User's Guide for the Interactive RadioEpidemiological Program (NIOSH-IREP) Version 5.5.1*. National Institute for Occupational Safety and Health. Prepared by SENES Oak Ridge, Inc. January 2007.

OCAS-PER-003. 2005. *Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases, Rev. 0*, January 28, 2005. Office of Compensation Analysis and Support, Program Evaluation Report: Cincinnati, Ohio.

OCAS-PER-007. 2006. *Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases, Rev. 0*, November 9, 2006. Office of Compensation Analysis and Support, Program Evaluation Report: Cincinnati, Ohio.

OCAS-TKBS-0003. 2006. *Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation, Lackawanna, New York; Period of Operation: 1949–1952, Rev. 00,* July 27, 2006. Office of Compensation Analysis and Support (OCAS): Cincinnati, Ohio. July 27, 2006.

ORAUT-OTIB-0004. 2006. *Technical Information Bulletin*: *Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employers Facilities, Rev. 03 PC-2*, December 6, 2006. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

ORAUT-TKBS-0001. 2004. *Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation, Lackawanna, New York; Period of Operations: 1949-1952, Rev. 01*, June 29, 2004. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

2.3 OCAS-PER-004: APPLICATION OF PHOTOFLUOROGRAPHY AT THE PINELLAS PLANT

The review of OCAS-PER-004: *Application of Photofluorography at the Pinellas Plant*, Rev. 0, dated February 15, 2005, was prepared by Harry J. Pettengill, PhD.

2.3.1 Purpose of the Program Evaluation Report

The purpose of this report was to re-evaluate previously completed cases for the Pinellas Plant to assure that claimant files properly assessed occupational medical doses, given the new information indicating that photofluorography may have been used and contributed to potential claimant doses. Prior reviews of claims before February 15, 2005 did not assume that photofluorography was used at Pinellas Plant. The observation of a photofluorography film in a claimant's file on January 23, 2005, necessitated the re-evaluation of prior claims.

2.3.2 Review Protocol

SC&A's evaluation of PER-004 is summarized in Table, below. Table is a checklist containing objectives that SC&A has developed to evaluate whether the Evaluation Report adequately supports dose reconstruction of potentially missed dose for Pinellas Plant claimants.

Table 2.3-1: OCAS-PER-004 Review Outline/Checklist

Document No.: OCAS-PER-004, Rev. 0	**Effective Date:** 02/15/2005
Document Title: Application of Photofluorography at the Pinellas Plant	
Auditor: Harry J. Pettengill, Ph.D.	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	

Table 2.3-1: OCAS-PER-004 Review Outline/Checklist

Document No.: OCAS-PER-004, Rev. 0	**Effective Date:** 02/15/2005
Document Title: Application of Photofluorography at the Pinellas Plant	
Auditor: Harry J. Pettengill, Ph.D.	

No.	Description of Objective	Rating 1–5*	Comments
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.3.3 General Comments

The evaluation was necessitated to determine if prior claims would have been approved (i.e., exceeded 50% POC) if the original dose reconstruction had considered a higher dose due to the potential use of photofluorography. A search of prior claims by NIOSH showed that 11 prior claims should be re-evaluated.

Our review found that the evaluation of prior claims properly assessed the potential added contribution to dose to all organs that would have been exposed had a photofluorographic chest exam been provided. The newly calculated organ dose was then applied to the 11 potential claims to determine if the new calculation would result in a POC of greater than 50% when applied to the diagnosed cancer reported by the claimant.

The approach being applied was referenced to and is totally consistent with ORAUT PROC-0061, Rev. 00 (December 1, 2004): *Occupational X-ray Dose Reconstruction for DOE Sites* and also ORAUT-OTIB-0006, Rev. 03 PC-1 (December 21, 2005): *Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures*. It is noteworthy that OTIB-0006 has been

revised three times since its publication; however, these revisions would not affect a change in these claims' re-evaluations. Consistent with OTIB-0006, Rev. 3, this review considered that photofluorography may have been used prior to 1960 and a conservative dose estimate was used.

2.3.4 Review Comments

Review Objective 1.2

OCAS-PR-008 provides guidance on the preparation of PERs, including specifying a six section format to be followed. The structure of PER-004 does not strictly follow the guidance provided by PR-008. In particular, PER-004 has a single Evaluation section, rather than separate Issue and Probability of Causation Evaluations.

2.3.5 Conclusions

As a consequence of the PER, the Pinellas Medical TBD section of the site profile was revised to ensure that all future claims would consider the potential dose from photofluorographic exams prior to 1960. The result of the evaluation report demonstrates that all prior claimants that had not exceeded a POC factor 50% still did not exceed that value after dose re-calculation. This evaluation assures that Pinellas' future claimants will have their medical dose calculated in a manner that is claimant favorable, and is totally consistent to other sites where the use of photofluorography cannot be excluded.

2.3.6 References

OCAS-PER-004. 2005. *Application of Photofluorography at the Pinellas Plant*, Rev. 0, Office of Compensation Analysis and Support, Program Evaluation Report: Cincinnati, Ohio. February 15, 2005.

OCAS-PR-008. 2006. *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2, Office of Compensation Analysis and Support, Program Evaluation Report: Cincinnati, Ohio. December 6, 2006.

ORAUT-PROC-0061. 2004. *Occupational X-ray Dose Reconstruction for DOE Sites*, Rev. 00, December 1, 2004. Oak Ridge Associated Universities Team (ORAUT): Cincinnati, Ohio.

ORAUT-OTIB-0006. 2005. *Technical Information Bulletin: Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures*, Rev. 03 PC-1, December 21, 2005. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

2.4 OCAS-PER-006: EXTERNAL DOSIMETRY TARGET ORGAN FOR PROSTATE CANCER

The review of OCAS-PER-006, *External Dosimetry Target Organ for Prostate Cancer*, Rev. 0, dated September 15, 2006, was prepared by Stephen F. Marschke.

2.4.1 Purpose of the Program Evaluation Report

The purpose of OCAS-PER-006 was to evaluate the impact on completed dose reconstructions of changing the prostate's surrogate target organ from the testes to the bladder.

2.4.2 Review Protocol

SC&A's evaluation of OCAS-PER-006 is summarized in Table, below. Table is a checklist containing objectives that SC&A has developed to evaluate whether the Evaluation Report performs its intended purpose.

Table 2.4-1: OCAS-PER-006 Review Outline/Checklist

Document No.: OCAS-PER-006, Rev. 0	**Effective Date:** 09/15/2006
Document Title: External Dosimetry Target Organ for Prostate Cancer	
Auditor: Stephen F. Marschke	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required	N/A	

Table 2.4-1: OCAS-PER-006 Review Outline/Checklist

Document No.: OCAS-PER-006, Rev. 0	**Effective Date:** 09/15/2006
Document Title: External Dosimetry Target Organ for Prostate Cancer	
Auditor: Stephen F. Marschke	

No.	Description of Objective	Rating 1–5*	Comments
	under the Privacy Act?		
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.4.3 General Comments

OCAS-PER-006 does not evaluate the appropriateness of changing the prostate's surrogate organ from the testes to the bladder. Rather, it assesses the impact of that change on previously performed dose reconstructions. Similarly, this review of OCAS-PER-006 does not evaluate the

appropriateness of using the bladder as the prostate's surrogate organ. As OCAS-PER-006 indicates, NIOSH's guidance on target organ selection is provided in OCAS-IG-001 and ORAUT-OTIB-0005. SC&A has reviewed both these documents, and those reviews show that SC&A agrees with the use of the bladder as the surrogate organ for the prostate.

2.4.4 Review Comments

Review Objective 1.2

OCAS-PR-008 provides guidance on the preparation of PERs, including specifying a six-section format to be followed. The structure of PER-0006 does not strictly follow the guidance provided by PR-008. In particular, PER-006 has a single Evaluation section, rather than separate Issue and Probability of Causation Evaluation sections, and its Summary section is missing.

Review Objective 7.3

Since the prostate is deep in the body cavity and would not be exposed to non-penetrating radiation, the use of the testes as a surrogate organ, which are very close to the body surface, would result in a significant and unrealistic overestimate of the prostate exposure to external beta and low energy photon radiation. Hence, SC&A concurs that the bladder, which is deep in the body cavity and close to the prostate, is a more appropriate surrogate for the prostate, as compared to the testes. Federal Guidance Report (FGR) 12, Tables II.4 through II.16, present organ dose factors, including testes and urinary bladder, due to various external exposure configurations. Table reproduces four of the FGR tables, and demonstrates the scientific validity of the PER-006 statement, i.e., for all four Table cases, the testes and bladder FGR 12 dose factors for the highest energy photons are nearly the same, while for the lowest energy photons, the four bladder factors are about 2 orders of magnitude smaller than the testes factors.

Table 2.4-2: Federal Guidance Report 12 Testes and Bladder Dose From External Exposure

Photon Energy (MeV)	Semi-infinite Cloud Source (Gy per Bq s m^{-3})		Infinite Pool Source (Gy per Bq s m^{-3})		Plane Source at the Air-ground Interface (Gy per Bq s m^{-2})		Source Uniformly Distributed to an Infinite Depth (Gy per Bq s m^{-3})	
	FGR 12, Table II.4		FGR 12, Table II.5		FGR 12, Table II.6		FGR 12, Table II.15	
	TESTES	BLADDER	TESTES	BLADDER	TESTES	BLADDER	TESTES	BLADDER
0.010	6.587E-19	8.251E-21	1.521E-21	1.905E-23	3.597E-19	2.426E-21	7.714E-23	4.235E-25
0.015	2.666E-17	6.043E-19	6.233E-20	1.412E-21	9.241E-18	1.360E-19	3.982E-21	5.153E-23
0.020	1.296E-16	1.220E-17	3.050E-19	2.861E-20	2.566E-17	2.367E-18	2.289E-20	1.637E-21
0.030	5.509E-16	1.616E-16	1.297E-18	3.778E-19	4.481E-17	1.479E-17	1.074E-19	2.863E-20
0.050	1.689E-15	9.478E-16	3.919E-18	2.173E-18	5.672E-17	3.808E-17	4.411E-19	2.570E-19
0.070	2.857E-15	1.947E-15	6.522E-18	4.392E-18	6.917E-17	5.672E-17	9.841E-19	6.965E-19
0.100	4.432E-15	3.337E-15	9.968E-18	7.432E-18	9.669E-17	8.493E-17	2.005E-18	1.542E-18
0.200	9.354E-15	7.432E-15	2.062E-17	1.630E-17	1.996E-16	1.715E-16	5.582E-18	4.470E-18
0.500	2.341E-14	1.940E-14	5.099E-17	4.215E-17	5.197E-16	4.550E-16	1.663E-17	1.311E-17
1.000	4.859E-14	3.973E-14	1.054E-16	8.606E-17	1.004E-15	8.783E-16	3.518E-17	2.950E-17
2.000	1.014E-13	9.174E-14	2.195E-16	1.985E-16	1.830E-15	1.805E-15	7.718E-17	6.564E-17
5.000	2.818E-13	2.530E-13	6.145E-16	5.516E-16	3.965E-15	4.038E-15	1.997E-16	1.806E-16

2.4.5 Conclusions

SC&A agrees with the statement made in PER-006 that:

> *The change in prostate surrogate organ from testes to bladder will result in lower organ doses, and consequently lower POC [probability of causation] values. Therefore, this change will not result in an increase in POC value for any completed claims, and no cases will need to be re-evaluated.* (PER-006, pg. 2)

2.4.6 References

OCAS-IG-001. 2002. *External Dose Reconstruction Implementation Guideline*, Rev. 01, National Institute for Occupational Safety and Health, (NIOSH), Office of Compensation Analysis and Support: Cincinnati, Ohio.

OCAS-PER-006. 2006. *External Dosimetry Target Organ for Prostate Cancer*, Rev. 0, Office of Compensation Analysis and Support: Cincinnati, Ohio. September 15, 2006.

OCAS-PR-008. 2006. *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2, Office of Compensation Analysis and Support, Program Evaluation Report: Cincinnati, Ohio. December 6, 2006.

ORAUT-OTIB-0005. 2006. *IMBA Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code*, Rev. 02 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 10, 2006.

ORAUT-PROC-0003, 2003. *Internal Dose Reconstruction*, Rev. 0, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 1, 2003.

FGR 12, 1993. *External Exposure to Radionuclides in Air, Water, and Soil*, Keith F. Eckerman and Jeffrey C. Ryman, Federal Guidance Report No. 12, EPA-402-R-93-081. September 1993.

2.5 OCAS-PER-007: EVALUATION OF THE EFFECT OF REVISION 2 OF THE SITE PROFILE ON PREVIOUSLY COMPLETED BETHLEHEM STEEL CASES

The review of OCAS-PER-007, Rev. 0, dated November 9, 2006, was prepared by Robert Barton.

2.5.1 Purpose of the Program Evaluation Report

The stated purpose of this PER is as follows:

> *…to evaluate the magnitude of the effect these changes* [to the Bethlehem Steel Site Profile] *made on the probability of causation for previously reconstructed cases. That is, all cases reconstructed using the previous version of the site technical basis document were evaluated to determine if the magnitude of the change in dose is sufficient to move the probability of causation (PC) to greater than or equal to 50% at the 99% credibility interval.* (PER-007, pg. 2)

2.5.2 Review Protocol

The SC&A evaluation of OCAS-PER-007, *Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases,* Rev. 0, is summarized in Table. This table presents a checklist containing objectives that SC&A developed to evaluate whether a procedure adequately supports the dose reconstruction process, as described in the introduction to this report. All instances in which the procedure was found to be deficient are explained in the subsequent text.

Table 2.5-1: OCAS-PER-007 Review Outline/Checklist

Document No.: OCAS-PER-007, Rev. 0	**Effective Date:** 11/09/2006
Document Title: Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases	
Auditor: Robert Barton	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	2	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	2	See Review Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	See Review Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

Table 2.5-1: OCAS-PER-007 Review Outline/Checklist

Document No.: OCAS-PER-007, Rev. 0	**Effective Date:** 11/09/2006
Document Title: Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases	
Auditor: Robert Barton	

No.	Description of Objective	Rating 1–5*	Comments
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.5.3 General Comments

The PER identifies two major changes in the site profile that would have a significant effect on previously performed dose reconstructions. In order to estimate the effect that this will have on

the "Probability of Causation" (POC), the PER establishes the relationship between the increase in dose values and the "Excess Relative Risk" (ERR). The PER states the following relation:

$$POC=ERR/(1+ERR)*100\%$$

The PER also states that the "ERR varies essentially linearly with the dose" (PER-007, pg. 3). Therefore, a difference in the POC value can be obtained by estimating the change in the excessive relative risk based on the difference between doses.

The PER identifies several groups of workers who would be affected by the changes to the site profile in different ways. The first class, denoted as Category 1, would be the group affected by the change to the external shallow dose parameters. The PER also identifies three classes of workers who would be impacted by the change in internal dose parameters; these are denoted as Categories 2–4. Category 2 deals with workers who were present for all 4 years, and Categories 3 and 4 deal with workers who were present for only the first 2 years or last 2 years, respectively.

2.5.4 Review Comments

Review Objective 1.1

The PER does not specify which intake parameters were utilized to calculate the dose from the original site profile. The original site profile (ORAUT-TKBS-0001 Rev. 00) gives the inhalation values in two tables (Tables 2a and 2b on pp. 5 and 6). Each table represents a low-sided estimate of intake and a high-sided estimate of intake. The PER does specify that it used the median value for the defined triangular distribution; however, it does not specify whether it used the high-sided distribution or low-sided distribution. This is only an issue for the older site profiles, as the newer version (OCAS-TKBS-0003) gives a discrete value for the inhalation and ingestion intake. In addition, no guidance is given as to what absorption types were used in calculating the change in dose. A claimant-favorable method would be to use the maximizing absorption value for each organ under consideration.

In addition, the PER compares the newer profile (Revision 2) to both of the previous versions of the profile (Revisions 0 and 1), and contains no additional discussion as to why one comparison was used over the other. Specifically, the PER compares Revision 2 to Revision 0 of the site profile for the workers classified as Categories 1 and 2, it compares Revision 2 to Revision 1 for workers classified as Category 4, and does not specify what comparison was made for Category 3. The main difference between Revision 0 and Revision 1 is that Revision 1 added an ingestion intake to the internal dose, while the inhalation intake values remain the same. It would be logical to compare Revision 2 to Revision 0 when considering cases where the claimants POC value is likely to increase (Categories 1–3), as this comparison would yield the larger percent difference in dose. Likewise, in cases where the original POC is going to be reduced (Category 4 worker), the use of Revision 1 instead of Revision 0 would yield a smaller percent difference in dose and therefore would benefit the claimants. Therefore, the PER would benefit from a brief discussion as to why each older site profile was selected.

Review Objective 1.2

OCAS-PR-008 provides guidance on the preparation of PERs, including specifying a six section format to be followed. The structure of PER-007 does not strictly follow the guidance provided by PR-008. In particular, PER-007 is missing the Resolution or Corrective Action section, and its Conclusion section should be entitled Summary.

Review Objective 1.4

The closest analog to PER-007 is PER-003, which actually deals with the effect that Revision 01 of the Bethlehem Steel site profile had on dose reconstructions completed using Revision 00 (as opposed to this PER which deals with the effect of Revision 02). However, the methodology between the two documents does not match in a few key places.

Specifically, PER-007 makes reference to the median intake values found in the older site profiles, while PER-003 does not specify how to interpret the various distributions. PER-003 calculates the percent increase in dose for each organ and year and takes the maximum increase for three specific classes of cancer (GI tract tissues, respiratory cancers, all other non-respiratory cancers). PER-007 is not clear as to how the percent increase was reached for Categories 3 and 4-type worker. PER-007 does, however, state that it used the maximum dose totaled to 4 years in developing its percent increase for Category 2 workers. PER-003 states that Type M absorptions should be used for non-respiratory tract tissues, Type S absorptions should be used for the respiratory tract, and an f(1) value of 0.02 should be used for both cases—PER-007 does not specify any of these parameters.

Review Objective 1.5

When describing the process of choosing threshold POC values for different categories of workers, the PER is not consistent in how it describes the results of its analysis. For example, the PER states that for Category 2 workers the intake parameters should be taken from Revision 00 of the site profile, the doses were totaled after 4 years, the limiting organ was the liver, and the threshold POC was 41.49%. For Category 3 workers, it gives the threshold POC as 37.58%; however, it is not stated which version of the site profile should be used, what the limiting organ was, or at what point the doses were totaled. For Category 4 workers, it states to use Rev. 1 of the site profile; however, it does not list a limiting organ, threshold POC, or at what point the doses were totaled. Lack of a consistent format for developing and documenting the PER's conclusions makes it difficult for independent verification of the methodology.

Review Objective 7.3

External Exposure Treatment for Category 1 Worker

The Category 1 worker, as defined in the PER, is a worker who would be affected by the changes in the external treatment of dose, which include the addition of residual contamination and contaminated clothing for natural uranium. The exposure parameters shown in Table were considered.

Based on the average of the total shallow dose received, it was calculated that a POC of 36.56% would now result in a POC equal to or greater than 50%. This is in good agreement with the findings of the PER, which estimates the threshold POC value at 36.52%. No justification was given for using the median value for exposure, as opposed to the mean value. However, use of the mean value of the distribution results in a threshold POC of 37.38%, and so the use of the median value is a more claimant-favorable method.

Table 2.5-2: External Exposure Parameters

Rev. 02 Values (rem)					
	Unat Dust	**Unat Direct Contact**	**Residual Contamination**	**Contaminated Clothing**	**Total Shallow Dose**
1949	0.0020	5.4501	1.77	1.80	9.02
1950	0.0020	5.4501	1.77	1.80	9.02
1951	0.0010	5.9043	1.77	1.80	9.48
1952	0.0000	6.8127	1.77	1.80	10.38
				Average:	9.48
Rev. 00 Values (rem)					
	Unat Dust	**Unat Direct Contact**	**Residual Contamination**	**Contaminated Clothing**	**Total Shallow Dose**
1949	0.0028	5.4501	Not Treated	Not Treated	5.45
1950	0.0028	5.4501	Not Treated	Not Treated	5.45
1951	0.0030	5.9043	Not Treated	Not Treated	5.91
1952	0.0026	4.9960	Not Treated	Not Treated	5.00
				Average:	5.45

IMBA Treatment of Internal Dose

The IMBA software was utilized by SC&A in its verification of the PER's analysis on the effect of using the revised version of the site profile (OCAS-TKBS-0003) in regards to internal dose for both inhalation and ingestion of uranium.

The IMBA analysis utilized the following intake parameters, which are found in Table. The ORAU ingestion parameters are italicized because they are only included in Revision 01 of the site profile and are not treated in Revision 00.

Table 2.5-3: Intake Parameters Used in IMBA Treatment

Exposure Period	**OCAS Rev. 02**		**ORAU Rev. 00, 01**	
	Inhalation Intake (dpm/day)	**Ingestion Intake (dpm/day)**	**Inhalation Intake (dpm/day)**	**Ingestion Intake (dpm/day)**
1/1/1949–12/31/1949	22043	2544	11581.2	303.58
1/1/1950–12/31/1950	22043	2544	11581.2	303.58
1/1/1951–9/30/1951	9864	1156	12544.83	321.43
10/1/1951–12/31/1951	3288	385	12544.83	321.43
1/1/1952–12/31/1952	3288	385	10617.59	267.86

The doses were calculated for each year spanning from the first year of exposure (1949) through 2002, for each organ allowed in the IMBA software. The dose was also calculated for both absorption Types "M" and "S," where the maximum for a given organ and year was the value used. Each organ considered is listed in Table. The doses were summed at 4 years or 2 years

after the initial exposure, based on what category of worker was being analyzed; in addition, the total dose for all the years leading up to 2002 was also considered.

Table 2.5-4: Organs Considered in IMBA Analysis

Adrenals	Urinary Bladder	Brain	Breast	Gall Bladder
Heart Wall	Kidneys	Liver	Muscle	Ovaries
Pancreas	Testes	Thyroid	RBM	Bone Surface
Stomach	SI	ULI	LLI	Skin
Spleen	Thymus	Uterus	ET	Lung
Colon	ET1	ET2	LN(ET)	Bbsec
Bbbas	Bb	AI	LN(TH)	Esophagus

The results of this analysis, along with any associated PER generated component, are shown by worker category in Table through Table, below.

Table 2.5-5: Category 2 Worker

	IMBA Analysis	PER Analysis
4-Year Total Dose Values		
Maximum Percent Difference	71%	-
Average Percent Difference	46%	-
Limiting Organ	Lower Large Intestine	Liver
Threshold POC	36.92%	41.49%
Total Dose Thru 2002 Values		
Maximum Percent Difference	30%	-
Average Percent Difference	24%	-
Limiting Organ	Lower Large Intestine	-
Threshold POC	43.48%	-

Table 2.5-6: Category 3 Worker

	IMBA Analysis	PER Analysis
2-Year Total Dose Values		
Maximum Percent Difference	133.78%	-
Average Percent Difference	98.57%	-
Limiting Organ	Lower Large Intestine	Not Given
Threshold POC	29.96%	37.58%
Total Dose Thru 2002 Values		
Maximum Percent Difference	104.41%	-
Average Percent Difference	95.48%	-
Limiting Organ	Lower Large Intestine	-
Threshold POC	32.85%	-

Table 2.5-7: Category 4 Worker

	IMBA Analysis	PER Analysis
2-Year Total Dose Values		
Maximum Percent Difference	- 49.58%	-
Average Percent Difference	- 42.97%	-
Limiting Organ	Bbsec	Not Given
Threshold POC	66.48%	Not Given
Total Dose Thru 2002 Values		
Maximum Percent Difference	- 50.42%	-
Average Percent Difference	- 49.24%	-
Limiting Organ	ET	-
Threshold POC	66.85%	-

Implications of IMBA Analysis

As shown in Table through Table, the IMBA analysis did not agree well with the conclusions of the PER. For worker Categories 2 and 3, the PER threshold POCs were 5% to 8% higher than those calculated using IMBA. This means that the Category 2 workers with POCs in the 36% to 41% range would have been excluded from recalculation, as would the Category 3 workers with POCs in the 29% to 37% range. Judging by the values listed in Tables 2 and 3 of the PER, there is no clear-cut correlation between an older POC and the newer calculated POC. Therefore, it is recommended that OCAS revisit the analysis to include the workers falling into the lower POC threshold ranges. No threshold POC is given for Category 4 workers; however upon inspection of Table 3 of the PER it can be seen that the POC values ranged from 51%–80%. Since the IMBA-calculated POC was approximately 66%, this does not appear to be an issue; however, a more detailed discussion as to what criteria were used in the selection of Category 4 cases is warranted.

The reason for the discrepancy between the IMBA and PER results is not clear. It may be attributable to the selection of absorption types, the specific organs used in the calculation, or inconsistencies related to data interpretation (see Sections 2.5.4.1-2 for discussion of inconsistent/missing methodology). One possible reason for the discrepancy could be related to the organs that were sampled (see Table for the Category 2 worker. The PER lists the limiting organ for the Category 2 worker as the liver. In the IMBA analysis, the liver did have an above-average percent increase (58%), although it was still well below the maximizing increase for the LLI (71%). However, if the increase for the liver is assumed to be bounding, the resulting threshold POC is still only about 39%. This value is still below the 41.49% stated in the PER.

Analysis of Cobble Cutters

The PER has very little to say on the addition of separate inhalation values for workers who were designated as Cobble Cutters. In Section 2.0 of the PER it states:

> *The intakes assigned to cobble cutters are higher than all others for the last two years of operation (1951 and 1952). If someone was exposed the entire four years, the non-cobble cutting exposure is bounding.* (Per-007, pg. 2)

In the PER's treatment of Category 3 workers (those assigned to the final 2 years of operation), it is not stated that it was assumed that a Cobble Cutter intake was used. Instead the PER states in Section 3.0:

> *Since designating the employee as a cobble cutter could increase the PC if employment was not for the entire four years, cases in which this may have an affect were evaluated as both a cobble cutter and a non-cobble cutter.* (PER-007, pg. 5)

While this would appear to take care of the issue, the fact remains that it is not clear whether the cobble cutter intakes, when higher than non-cobble cutters, were used in determining the range of POC values to address. If the higher intakes were not used, then this would result in a smaller and less claimant-favorable pool of claims to recalculate.

The second part of the statement asserts that maximum intake for workers who were present for all 4 years of operation is bounded by the non-cobble cutters. In order to verify this statement, SC&A performed a similar analysis as used in Section 2.7.4.2 to compare a Cobble Cutter worker, as defined in Revision 2 of the site profile, to the regular worker from Revision 0. The following intake parameters for the Cobble Cutter are shown in Table.

Table 2.5-8: Intake for Cobble Cutters over 4 Years

Time Period	Inhalation Rate for (dpm/day)		Ingestion Rate (dpm/day)
	0.5 um Particles	5 um Particles	
1/1/1949– 12/31/1949	4701.00	2572.00	2544.00
1/1/1950– 12/31/1950	4701.00	2572.00	2544.00
1/1/1951– 9/30/1951	5250.00	2470.00	1156.00
10/1/1951– 12/31/1952	5625.00	2632.00	385.00

The results of this analysis are shown in Table, along with the corresponding values associated for a Category 2 worker who was not a cobble cutter (found in Table 4 of this review).

Table 2.5-9: Results of Cobble Cutter Analysis

	Cobble Cutter	Non-Cobble Cutters
4-Year Total Dose Values		
Maximum Percent Difference	32%	71%
Average Percent Difference	- 21%	46%
Limiting Organ	Bb	Lower Large Intestine
Threshold POC	43.14%	36.92%
Total Dose Thru 2002 Values		
Maximum Percent Difference	32%	30%
Average Percent Difference	- 15%	24%
Limiting Organ	Bb	Lower Large Intestine
Threshold POC	43.10%	43.48%

It is clear from Table that the dose to Category 2 workers are adequately bounded by the non-cobble cutting dose, if the increase is assessed after 4 years as prescribed in the PER. However, if the increase is assessed through 2002, the cobble cutting dose becomes the bounding intake, although only by ~0.4%.

2.5.5 Conclusions

While SC&A agrees with the PER's conclusions concerning the effect of Revision 2 on external shallow dose (Category 1 workers), its independent review of the effect on internal dose did not agree in two of the three worker classes (Categories 2 and 3). In both cases where there was a discrepancy, the threshold POC calculated using IMBA was 5%–8% less than the PER value. When considering the recalculated POC values in Section 3.0 of the PER, it is clear that there is not a direct correlation between the original POC and a certain increase. For example, in Table 2 of the PER, an original POC of 42.49% is raised to 54.57% when recalculated, while a worker in the same category who had an original POC of 44.90% was recalculated at 21.65%.
Based on this trend, it is SC&A's recommendation that NIOSH revisit the issue to ensure that the pool of recalculated claims adequately encompasses those with the possibility of reaching or surpassing 50%. Also, the PER is rather arbitrary in how it presents its methods, assumptions, and conclusions, and so a more detailed approach would certainly benefit the PER. Since this document is not used in dose reconstruction, the added detail would not hinder the processing of claims, but rather further validate the completeness and precision of the program.

2.5.6 References

OCAS-PER-003. 2005. *Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases*, Rev. 0, Office of Compensation Analysis and Support, Cincinnati, Ohio. January 28, 2005.

OCAS-PER-007. 2006. *Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases*, Rev. 0, November 9, 2006. Office of Compensation Analysis and Support. Cincinnati, Ohio.

OCAS-PR-008. 2006. *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2, Office of Compensation Analysis and Support, Cincinnati, Ohio. December 6, 2006.

OCAS-TKBS-0003. 2006b. *Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation*, Rev. 00, Office of Compensation Analysis and Support, Cincinnati, Ohio.

ORAUT-TKBS-0001. 2003. *Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation, Lackawanna, New York: Period of Operation: 1949-1952*, Rev. 00, March 31, 2003. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-TKBS-0001. 2004. *Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation, Lackawanna, New York; Period of*

Operation: 1949-1952, Rev. 01, June 29, 2004. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

2.6 OCAS-PR-008: PREPARATION OF PROGRAM EVALUATION REPORTS AND PROGRAM EVALUATION PLANS

The review of OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Revision 2, dated December 6, 2006, was prepared by Stephen F. Marschke.

2.6.1 Purpose of the Procedure

The purpose of OCAS-PR-008 is as follows:

> *…to provide the process for evaluating the effect programmatic changes might have on previously completed dose reconstructions. This procedure also describes the general format and content of Program Evaluation Reports (PERs) and Program Evaluation Plans (PEPs) that are used to document the results of these evaluations.*

2.6.2 Review Protocol

The SC&A evaluation of OCAS-PR-008 is summarized in Table. This table presents a checklist containing objectives that SC&A developed to evaluate whether a procedure adequately supports the dose reconstruction process, as described in the introduction to this report. All instances in which the procedure was found to be deficient are explained in the subsequent text.

Table 2.6-1: OCAS-PR-008 Review Outline/Checklist

Document No.: OCAS-PR-008, Rev. 2	**Effective Date:** 12/06/2006
Document Title: Preparation of Program Evaluation Reports and Program Evaluation Plans	
Auditor: Stephen F. Marschke	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments

Table 2.6-1: OCAS-PR-008 Review Outline/Checklist

Document No.: OCAS-PR-008, Rev. 2	**Effective Date:** 12/06/2006
Document Title: Preparation of Program Evaluation Reports and Program Evaluation Plans	
Auditor: Stephen F. Marschke	

No.	Description of Objective	Rating 1–5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	

Table 2.6-1: OCAS-PR-008 Review Outline/Checklist

Document No.: OCAS-PR-008, Rev. 2	**Effective Date:** 12/06/2006
Document Title: Preparation of Program Evaluation Reports and Program Evaluation Plans	
Auditor: Stephen F. Marschke	

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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.6.3 Review Comments

Review Objective 1.1

Section 4.3.3 states, "The guidelines used to conduct the evaluation should also be used to conduct the POC evaluation." There are two concerns with this statement: (1) "the Evaluation" should be changed to "the Issue Evaluation (Section 4.2)," to be absolutely sure as to what is being referred to, and (2) there is no mention of 'guidelines' in Section 4.2, so it is unclear as to what should be used.

Also, in two locations, Section 5.4 instructs the OCAS to conduct a PEP or PER "as described in Section 5.0, above." Although Section 5 is entitled Procedure, it really documents responsibilities, not how to conduct a PEP or PER. Section 4 entitled General provides the instructions as to what is required to be included in a PEP or PER.

Review Objective 1.5

Section 5.2.2 states, "Depending on the scope of the PER, determine if a PEP is required." Likewise, each section pertaining to the PEP begins with the phrase, "As needed." Since no information is provided as to how to determine whether or not a PEP is needed, it appears to be left to the subjective judgment of the OCAS Team Leader.

2.6.4 References

OCAS-PR-008. 2006. *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2, Office of Compensation Analysis and Support, Cincinnati, Ohio. December 6, 2006.

2.7 OCAS-TIB-0013: SPECIAL EXTERNAL DOSE RECONSTRUCTION CONSIDERATIONS FOR MALLINCKRODT WORKERS

The review of OCAS-TIB-0013, Rev. 0, dated October 26, 2005, was prepared by Robert Barton, with Richard Olsher and Robert Anigstein.

2.7.1 Purpose of the Technical Information Bulletin

The stated purpose of this TIB is as follows:

> *…to provide guidance on the application of geometry-based dose correction factors to external dosimetry badge data for Mallinckrodt workers in particular job classifications. The factors are to be used for the periods of time where the individual's work history places him/her in that job.*

2.7.2 Review Protocol

The SC&A evaluation of OCAS-TIB-0013, *Special External Dose Reconstruction Considerations for Mallinckrodt Workers*, is summarized in the Table. This table presents a checklist containing objectives that SC&A developed to evaluate whether a procedure adequately supports the dose reconstruction process, as described in the introduction to this report. All instances in which the procedure was found to be deficient are explained in the subsequent text.

Table 2.7-1: OCAS-TIB-0013 Review Outline/Checklist

Document No.: OCAS-TIB-0013, Rev. 0	**Effective Date:** 10/26/2005
Document Title: Special External Dose Reconstruction Considerations for Mallinckrodt Workers	
Auditor: Robert Barton, Richard Olsher, and Robert Anigstein	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	

Table 2.7-1: OCAS-TIB-0013 Review Outline/Checklist

Document No.: OCAS-TIB-0013, Rev. 0	**Effective Date:** 10/26/2005
Document Title: Special External Dose Reconstruction Considerations for Mallinckrodt Workers	
Auditor: Robert Barton, Richard Olsher, and Robert Anigstein	

No.	Description of Objective	Rating 1–5*	Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	1	See Review Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	N/A	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	2	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	

Table 2.7-1: OCAS-TIB-0013 Review Outline/Checklist

Document No.: OCAS-TIB-0013, Rev. 0	**Effective Date:** 10/26/2005
Document Title: Special External Dose Reconstruction Considerations for Mallinckrodt Workers	
Auditor: Robert Barton, Richard Olsher, and Robert Anigstein	

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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	1	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.7.3 General Comments

The purpose of OCAS-TIB-0013 is to assess the possible underestimation of doses to organs in the lower torso based on the geometry of a film badge located on the lapel of a worker's coat. A correction factor for the measured dose was developed for three example scenarios; (1) ingot machining, (2) pitchblende cleanup, and (3) denitration pot work. The three scenarios were chosen in order to represent three different geometries where the location of the film badge could result in a significant underestimate of the dose to particular organs if correction factors are not applied to account for geometry of exposure. The document concludes that the worst of these cases (the correction factor related to ingot machining) should be the value applied to develop a dose for organs in the lower torso.

SC&A performed its own analysis of the problem using the probabilistic computer codes MCNP5 and MCNPX (Monte Carlo N-Particle Transport code - LANL 2004). These codes were utilized to calculate the different flux values at assumed geometrical distances from the given sources (cylindrical slab for pitchblende, shielded vertical cylinder for denitration pot activities, and unshielded horizontal cylinder for ingot work). The results of the analysis show that the geometrical correction factor for the lower torso, as developed in the TIB document, is much lower than the factor derived by SC&A. Hence it does not represent a claimant-favorable approach.

2.7.4 Review Comments

Review Objective 1.1

The writing style is generally clear, but the paragraphs are not numbered sequentially (e.g., Section 4.0 precedes Section 3.3).

Review Objective 1.2

The attempt to validate the model, using data from ring dosimeters, should precede the conclusions in Section 3.2, since these conclusions presuppose the validity of the model.

Review Objective 1.3

The TIB is not clear as to the methodology and parameters assumed in the NIOSH point-kernel shielding computer code, Attila, calculation. Important parameters such as average worker geometry, in particular worker height and assumed dosimeter position, were not indicated in the description. Also, the source geometry, photon spectra, and assumed expected composition/activity were not included in the TIB description of its methodology. Although the geometric parameters can be inferred from OCAS-TIB-0013, Figures 2, 3, and 4, which show the three dimensional CAD geometry used in the Attila input, the translation to physical values is subjective at best, and results in significant inaccuracy. More exact input parameters were obtained via private communication with the TIB's author (Macievic 2006).

Review Objective 2.2

The procedure understates the maximum correction factor to be applied to the badge readings, as is discussed further under Review Objective 7.3. Thus, the procedure does not provide adequate guidance for defining the claimant-favorable assumptions.

Review Objective 5.2

The TIB assumes an apparent geometry where the badge is fitted in the middle of the chest (as seen in Figures 2 and 3 of the document). If the badge were worn off-center on the chest or at another location such as the collar (typically around 10 cm from the center), the use of the stated correction factors on the measured exposure would result in the underestimation of the corrected exposure. Also, the analysis assumes a worker height of ~178 centimeters (approximately 5'10). Although this would be in the interest of claimants shorter than this height, it would also introduce an underestimation for workers taller than the assumed height. Some discussion as to how this assumed worker height was obtained, as well as verification that it creates a plausible upper bound for the claimant, would benefit the analysis. For example, the ICRP Publication 89 lists 176 cm as the reference height of the adult male (ICRP 2002), while for U.S. males between 18 and 74 the mean and 90th percentile heights are 175.5 and 187.0 cm, respectively (DHHS 1987).

Review Objective 7.3

In order to verify the analysis presented in OCAS-TIB-0013, SC&A used the MCNP (Monte Carlo N-Particle) computer program to model the same scenarios modeled by NIOSH using the Attila program. The first SC&A MCNP analysis attempted to reproduce the Attila results using MCNP5, and the photon spectra and exposure geometry furnished by Macievic (2006). However, as described below, upon detailed review of the NIOSH model, concerns were identified regarding the photon spectra and exposure geometry. Therefore, a second MCNP analysis was performed using MCNPX, and photon spectra and exposure geometry developed by SC&A. Both MCNP analyses are discussed below, including comparing their results to NIOSH Attila results.

MCNP5 Comparison with Attila Results

The stated purpose of this TIB is to develop a geometry correction factor for dosimeters worn on the lapel in relation to three distinct source geometries that would result in significant under-estimation of the exposure recorded by the film badge. The TIB comes to the conclusion that a correction factor of 2.1 should be used to correct the badge readings for the organs in the lower torso. To verify this, a MCNP5 run was performed under the same geometrical configurations and source terms identified by the Attila analysis. More specifically, the problem was considered for gamma dose only (as specified on page 3 of the TIB), using the source spectrum and geometrical values provided by OCAS (Macievic 2006). The doses were obtained by tallying the photon flux, using point detectors for the ingot and pitchblende scenarios, and a ring detector to take advantage of the rotational geometry of the denitration pot scenario. The tallies were then modified by a dose function to obtain the Hp(10,0°) or the personal dose equivalent at a depth of 10 cm for an angle of incidence of 0 degrees (ICRP 1996).

The results of the MCNP5 calculation show that the maximum correction factor for the lower torso is approximately 7.6 for the ingot worker scenario. The results of the MCNP5 calculations and the corresponding factors developed by Attila are shown in Table.

Table 2.7-2: Mallinckrodt Worker: Attila and MCNP5 Developed Badge Correction Factors

Location	Scenario					
	Uranium Ingot		Pitchblende		Denitration Pot	
	Attila	MCNP5	Attila	MCNP5	Attila	MCNP5
Lapel Badge	1	1	1	1	1	1
Lower Torso	2.125	7.609	2.11	2.17	0.03333	0.0607
Hands	3.65	4.009	1.2047	--	1.6667	--

As seen in Table, the correction factors are in reasonably close agreement for the lower torso in the case of the pitchblende cleanup scenario; however, the ingot scenario is underestimated by a factor of 3, and the denitration pot scenario is underestimated by a factor of 2. In all cases sampled, the correction factors developed by MCNP were larger than the Attila model. This might be explained if the Attila model was performing a volume averaging technique over various locations on the lower torso; however, this is not clearly defined and would not represent a maximum dose received.

MCNPX Analysis with SC&A Revised Assumptions

Source Spectrum. It is not currently known where the source spectrum utilized by OCAS was obtained (no reference listed in the TIB). The spectrum provided to SC&A (Macievic 2006, Attachment 2.7.A), which details the parameters used in the Attila code, had some significant errors relating to branching ratios and specific activities of the various isotopes listed. For example, the specific activities for Th-234 and Pa-234m assume an in-growth of uranium progeny of approximately 100 days after purification. This is a reasonable assumption given the nature of the work being performed. However, the value listed for "gammas/sec" implies that Pa-234m and Pa-234 have the same specific activity. This is incorrect, given that Pa-234m decays via gamma emission to Pa-234 in only 0.16% of the disintegrations, while the other 99.84% are a transition from Pa-234m to U-234 via a beta emission. Therefore, the gamma contribution from Pa-234 is overestimated by more than a factor of 600.

When considering the U-235 chain and its short-lived progeny, the activity concentration with respect to U-238 is correct (shown as 1.5×10^{-8} Ci/g); however, this is incorrectly translated to the "gammas/sec" value. When the incorrectly stated "gammas/sec" value is converted to its associated activity concentration, the value of 1.1×10^{-10} Ci/g is obtained. Therefore, the contribution from U-235 and its progeny are underestimated by about a factor of 140.

The most current source of nuclear decay data is the Evaluated Nuclear Structure Data File (ENSDF), which is updated and maintained by the National Nuclear Data Center at the Brookhaven National Laboratory. A convenient compendium of these data is found in "WWW Table of Radioactive Isotopes" (TORI) (Firestone et al. 1999). This Web-based data set, which is also accessible via http://ie.lbl.gov/toi/nucSearch.asp, provides direct links to the ENSDF that enable the user to access data more recent than those in the TORI tables. The nuclear decay data used by SC&A in the MCNPX analysis were obtained from these sources.

β-Bremsstrahlung. Macievic appears to ignore the β-bremsstrahlung contribution to the photon spectra of uranium. A separate MCNPX run was made by SC&A to analyze the bremsstrahlung spectra. As observed in Table, below, these x-rays contribute about 50% of the total dose in the MCNPX analysis.

Exposure Geometry. The treatment found in the TIB does not account for the fact that film badges have a significant angular dependence. This factor is important because in each of the three scenarios, photons coming directly from the source (which is at or below the waist) would impinge on the badge at an oblique angle. While photons that are normally incident on the front face of the badge will be read with close to 100% efficiency, a 45° angle of incidence to the front face of the badge can result in efficiencies between 46%–91% for energies of 0.11–1.2 MeV respectively (Hine and Brownell 1956). This would result in a significant underestimation of the dose if the exposure readings for the film badges were taken at face value.

The SC&A MCNPX analysis accounted for angular dependence. The exposure geometry was based on information furnished by Macievic, shown in Attachment 2.7.A, **Error! Reference source not found.**. The ingot was modeled as a cylinder of solid uranium metal, 50.8 cm (1.66 ft) long and 33.02 cm (1.08 ft) in diameter, with a density of 18.95 g/cm^3. The dosimeter was modeled as a hollow rectangular solid, 1 cm × 1 cm × 1 mm thick. Two dosimeter locations

were modeled. One was at the same elevation as the cylindrical ingot, 19.7 cm (~0.65 ft) from the center of the ingot along a line perpendicular to its axis. The center of the second dosimeter was at an elevation of 58.2 cm (1.91 ft) above the center of the cylinder, again displaced 19.7 cm in the x direction, and 10 cm in the y direction. The y direction displacement is to account for the fact that a dosimeter worn on the lapel would be off-center by as much as 10 cm. The x axis is assumed to be perpendicular to the frontal plane of the body (i.e., the anterioposterior direction), while the y axis is perpendicular to the sagittal plane.

MCNPX Analysis. Since the largest correction factor was previously shown to be from the "ingot machining" scenario (see Table), that was the only scenario analyzed with MCNPX Version 26C (Hendricks 2006). MCNPX was used because it enables the accumulation of particles over a specified surface (such as a 3-dimensional rectangular envelope of a personal dosimeter), binned by energy and by azimuthal angle. The analysis employed 19 photon energy bins spanning the range of 0–2.25 MeV, which encompassed the entire γ-ray spectrum of natural uranium and virtually all of the bremsstrahlung spectrum. These bins were selected so that the midpoint of each bin was approximately equal to one of the energies for which fluence-to-air kerma conversion coefficients are listed by ICRP (1996, Table A.1). We also used six angular bins, spanning the range of 0º–90º in 15º increments.

Separate MCNPX runs were required for the γ-ray and bremsstrahlung spectra. The output consisted of the incident flux at each of the two badge locations (tabulated by energy and angle), and normalized per source particle from the ingot cylinder. The next step was to convert the flux tallies into a dose quantity for each dosimeter location. First, correction factors of fluence-to-$H_p(10)$ were developed by multiplying the fluence-to-air kerma conversion factors (ICRP 1996, Table A.1) by the air kerma-to-$H_p(10, 0°)$ factors (ICRP 1996, Table A.24), to create energy-dependent fluence-to-$H_p(10, 0°)$ factors. When necessary, linear interpolation was used to adjust the ICRP factors to the MCNPX energies. Finally, to account for the angular dependence, the fluence-to-$H_p(10, 0°)$ factors were further multiplied by the appropriate angular factors. These angular factors were determined by linear interpolation by energy and angle of the angular factors also listed in ICRP 1996, Table A.24. This created the desired fluence-to-$H_p(10)$ conversion factors from which the doses were calculated.

Table shows the results of the MCNPX calculation. The $H_p(10, \alpha)$ dose rates are calculated for the bremsstrahlung and gamma components at both dosimeter locations. The dose rates are given as both a dose per source particle (as given by MCNPX), as well as a converted dose per disintegration. The contribution from bremsstrahlung x-rays, as well as the gamma components are then summed at each badge location to give a total dose from photons.

Table 2.7-3: Results of the MCNPX Calculation and Analysis for Lower Torso and Lapel Dosimeter Locations

Badge Location:		Lower torso		Lapel		Ratio (lapel/torso)
Exposure Source	**n[a]**	**pSv/p[b]**	**pSv/dis[c]**	**pSv/p**	**pSv/dis**	
γ rays	0.518	1.12E-06	5.82E-07	1.11E-07	5.77E-08	—
Bremsstrahlung	1.85	3.04E-07	5.62E-07	2.97E-08	5.48E-08	—
Total			1.14E-06		1.12E-07	**10.2**

[a] Number of source particles per disintegration of U-238
[b] Dose in picosieverts per source particle
[c] Dose in picosieverts per disintegration of U-238

As shown in Table , the contribution from bremsstrahlung is comparable to that from gamma radiation. While this does not have a significant affect on the dose ratio sought, it calls into question the methodology employed by the TIB, which does not address this additional source of exposure. More important, the table demonstrates that the dose ratio between the lower torso and the lapel is approximately 10.2. This represents an increase by a factor of almost 5 over the conclusion of the TIB, which lists a maximum conversion factor of 2.1 from the lapel to the lower torso.

Additional Comments

Direct β Dose. OCAS-TIB-0013 states that the same ratio of doses to the badge worn on the lapel to those to the lower torso would apply to β radiation. This is an unproved assertion that needs to be substantiated. Electron dose has an angular dependence that is different than that for photon radiation (see ICRP 1996, Tables A.45–A.47).

Neutron Dose. Neutron doses are not mentioned in OCAS-TIB-0013. There would be some neutron dose from the uranium ingot scenario, and substantially more from the denitration pot due to the (α,n) reaction in UO_3, especially since the sides of the steel pot would not be nearly as effective in shielding the lower torso from neutrons as from photons.

Measured Dose Comparison. Another issue is found in the attempted validation of the method by comparison of the calculated geometric correction factors developed by the Attila model to a correction factor obtained by comparison of ring dosimeters worn by selected workers in 1949 (Section 4.0 of the TIB). Though the TIB states that most of the data from this monitoring period are currently not available, it uses the specific data from five cases that were available. The first two sources, labeled subjects "1" and "2," reflect beta doses received during the trial period. Since the Attila model was based purely on photon exposures, comparison of these beta exposures to the calculated photon exposures is questionable.

The comparison of experimental to calculated values is visually shown on a probability plot. This plot depicts the five different measured doses versus the three calculated ratios for the "hand to lapel" scenario. This chart is misleading in its conclusions, as the actual work performed by the study subjects is not specified, so a comparison to the three different source geometries used in the calculation is not possible.

At best, the TIB comparison of "measured to calculated ratios" shows that the Attila-generated values are in the same general range as the measured values. Since this range is relatively large (1.67–3.17), the conclusion that these specific cases validate the Attila based methodology is not well supported.

2.7.5 Conclusion

OCAS-TIB-0013 does not represent a scientifically valid or a claimant-favorable approach to developing a correction factor for organs in the lower torso. SC&A's analysis of the problem using MCNPX concluded that the TIB underestimates the dose conversion factor by a factor of almost five. This would not be explained by differences in parameters used in the models, since the SC&A analysis, using MCNP5 (which used all of the geometric and source parameters

specified by OCAS), produced conversion factors that were approximately three times higher than the TIB values.

Therefore, in both cases the TIB has significantly underestimated the conversion factor and does not represent a sufficiently claimant-favorable approach to the dose reconstruction process.

Attachment 2.7.A: Source Problem Information Provided by OCAS

Note: Attachment A has been reformatted from the five pages originally provided by Macievic (2006) to three; however, all of the original parameters remain unchanged.

Human figure made of water

Diameter of ingot: 1.08 Ft

Length of ingot: 1.66 Ft

Width of body from finger tip of left hand to finger tip of right hand: 1.56 Ft

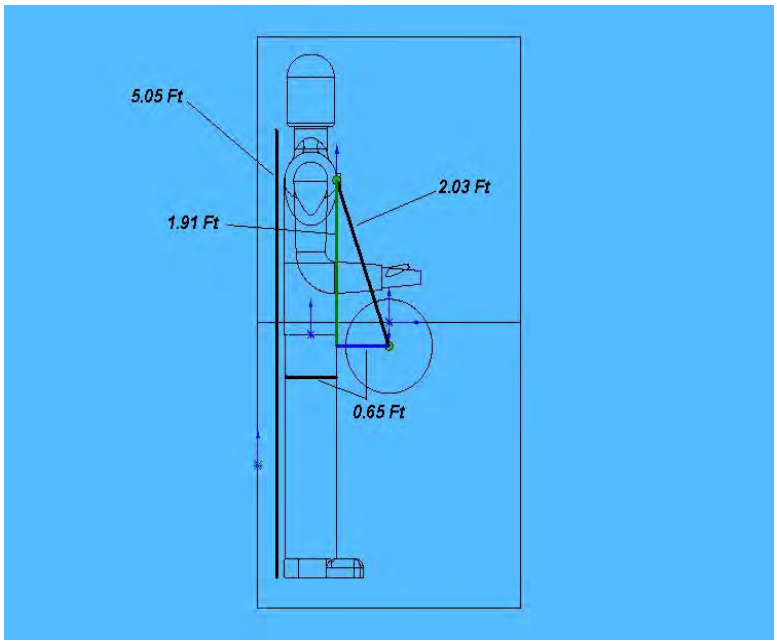

Figure 2.7-1: Diagram of Human Figure with Ingot

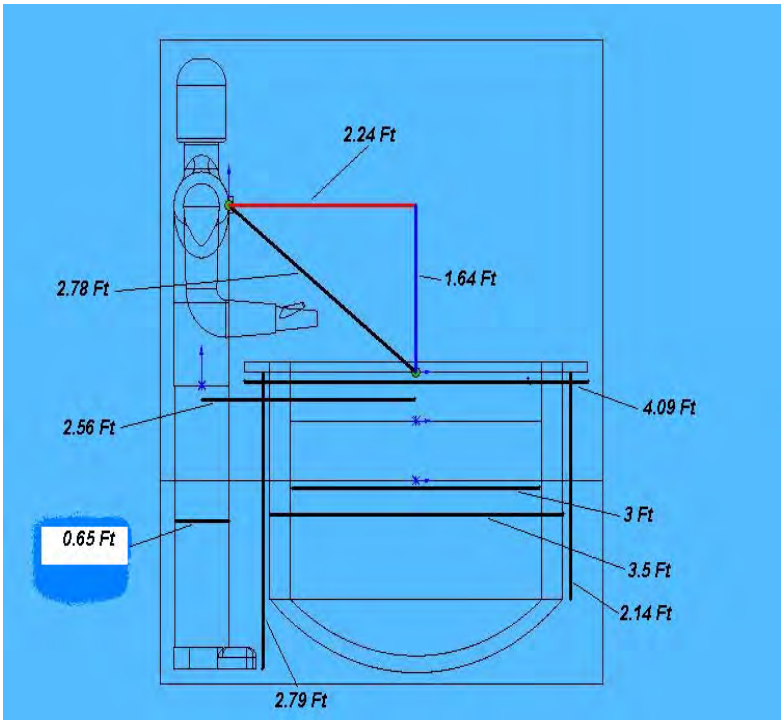

Figure 2.7-2: Denitration Pot (Pot made of steel) Dimensions with Same Human Figure from Ingot

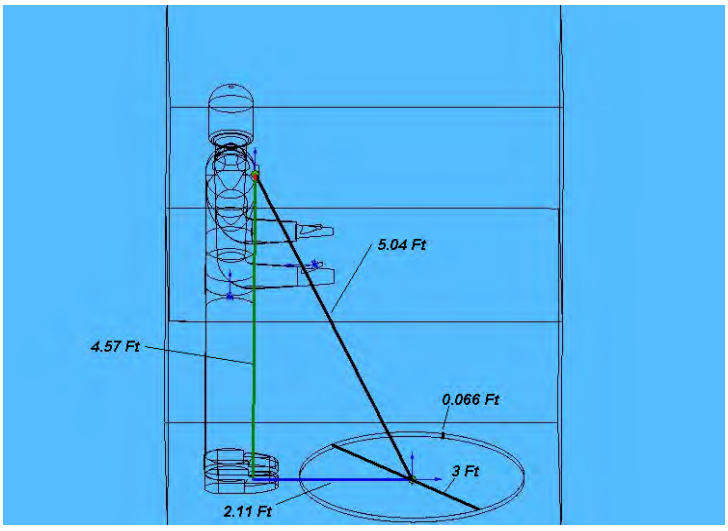

Figure 2.7-3: Pitchblend Dimensions with Human Figure Same as Previous Two Cases

Source data

Item	Radius (cm)	Length (cm)	Weight (g)
Cylindrical Ingot	16.51	50.8	824360

U-238 Chain

Nuclide	Specific Activity (Ci/g)	Emissions (dis/sec)
U-238	3.2973E-07	1.0057E+10
Th-234	3.10811E-07	9480140000
Pa-234m	3.10811E-07	9480140000
U-234	3.2973E-07	1.0057E+10
Th230	8.13514E-13	24813.236
Ra-226	4.81081E-17	1.4673608

U-235 Chain

Nuclide		
U-235	0.000000015	457519800
Th-231	0.000000015	457519800

URANIUM-CYLINDRICAL INGOT PROBLEM

Natural Uranium

Uranium metal density 18.95 g/cm^3

Intensities refer to percentage of disintegrations of nuclide itself, not from parent series.

Nuclide	NOT USED Beta MeV	NOT USED fraction	Gamma MeV	fraction	gammas/sec
Th-234	0.076	0.027	0.0633	0.038	360245320
	0.095	0.062	0.0924	0.027	255963780
	0.096	0.186	0.0928	0.027	255963780
	0.1186	0.725	0.1128	0.0024	22752336
Pa-234m	2.28	0.986	0.766	0.00207	19623889.8
			1.001	0.0059	55932826
Pa-234	0.5834	0.04	0.132	0.197	1867587580
	0.6174	0.021	0.57	0.107	1014374980
	0.6807	0.023	0.883	0.118	1118656520
	0.6887	0.24	0.926	0.109	1033335260
	0.6926	0.11	0.946	0.12	1137616800
	0.6944	0.042	0.053	0.0012	11376168
	0.7107	0.16	0.121	0.0004	3792056
	0.7112	0.038			
	0.8104	0.077			
	0.8334	0.023			
	1.183	0.1			
U-234			0.053	0.0012	687.9119328
			0.121	0.0004	229.3039776

Th-230			0.0677	0.0037	0.005233111
			0.142	0.0007	0.000990048
			0.144	0.00045	0.00063646
Ra-226			0.186	0.0328	2.74338E-06
U-235			0.1438	0.105	345884.9688
			0.163	0.047	154824.7003
			0.1857	0.54	1778836.982
			0.205	0.047	154824.7003
Th-231	0.205	0.15	0.0256	0.148	487533.0989
	0.287	0.49	0.0842	0.065	214119.2664
	0.304	0.35			

DENITRATION POT PROBLEM

UO3 mixture
assume 3/4 of pot filled with UO_3
824360 grams of UO_3 per pot, most of weight is U, assume 1pot = 1cylindrical ingot
same gammas and energies as in ingot above

PITCHBLENDE RAFFINATE (AM7) PROBLEM

Nuclide	MeV	fraction	Ci	gammas/sec
Th-230	0.0677	0.0037	24.4	3340360000
Th-230	0.142	0.0007	24.4	631960000
Th-230	0.144	0.00045	24.4	406260000
Th-232	0.126	0.0004	0.001	14800
Ra-226	0.186	0.0328	0.158	191748800

2.7.6 References

Firestone, R.B., Ekstrom, L.P., and Chu, S.Y.F., "WWW Table of Radioactive Isotopes," American Physical Society, Division of Nuclear Physics Meeting, October 20-23, 1999.

Hendricks, J. S., et al. 2006. "MCNPX, Version 26C," LA-UR-06-7991. <http://mcnpx.lanl.gov/>

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ICRP (International Commission on Radiological Protection) 1996. *Conversion Coefficients for use in Radiological Protection against External Radiation*. ICRP Publication 74. *Annals of the ICRP*, *26* (3/4), Elsevier Science, Inc.: Tarrytown, New York.

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Macievic, G. V. Health Physicist, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health. < [glm7@cdc.gov]> "*RE: OCAS-TIB-0013 Information Request*," December 6, 2006, personal e-mail to Robert Barton, SC&A, Inc.

OCAS-TIB-0013. 2005. *Special External Dose Reconstruction Considerations for Mallinckrodt Workers*, Rev. 0. National Institute of Occupational Safety and Health, Office of Compensation Analysis and Support: Cincinnati, Ohio.

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2.8 OCAS-TIB-0014: ROCKY FLATS INTERNAL DOSIMETRY COWORKER EXTENSION

The review of OCAS-TIB-0014, *Rocky Flats Internal Dosimetry Coworker Extension*, Rev. 00, dated December 07, 2006, was prepared by Joyce Lipsztein, PhD.

2.8.1 Purpose of the Technical Information Bulletin

The stated purpose of this TIB is to provide monitored coworker information for calculating and assigning occupational internal doses to employees at RFETS for whom no or insufficient bioassay monitoring records exist. A TIB that analyzes Internal Dosimetry Coworker data at RFETS was previously completed (ORAUT-OTIB-0038). That document analyzed the data from the beginning of operations at the site to 1988. For that effort, data was obtained from the CEDR repository of data. In order to extend the analysis beyond 1988, data were obtained from the Rocky Flats site's HIS-20 database. The purpose of this TIB is to extend the previous TIB (ORAUT-OTIB-0038) utilizing the same methodology.

2.8.2 Review Protocol

SC&A's evaluation of OCAS-TIB-0014 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the TIB adequately supports the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 2.8-1: TIB-0014 Review Outline/Checklist

Document No.: OCAS-TIB-0014, Rev. 00	**Date:** 12/07/2006
Document Title: Rocky Flats Internal Dosimetry Coworker Extension	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	See Review Comments
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	3	
3.2.3	Missing dosimetry data	3	
3.2.4	Unmonitored periods of exposure	3	

Table 2.8-1: TIB-0014 Review Outline/Checklist

Document No.: OCAS-TIB-0014, Rev. 00	**Date:** 12/07/2006
Document Title: Rocky Flats Internal Dosimetry Coworker Extension	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	4	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	
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)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.8.3 General Comments

Urinalysis data **collected by Rocky Flats** for uranium and plutonium from 1989 to 2005 were extracted from the HIS-20 database. In-vivo Am-241 lung data were not addressed in this TIB. Bioassay data were analyzed by quarter or year, depending on the amount of data available during the periods. A lognormal distribution was assumed. After log transforming the data, the 50^{th} and 84^{th} percentiles were determined for each period.

NIOSH demonstrated the comparability of dose distributions between the broader contractor and decontamination and decommissioning (D&D) subcontractor population, by providing a comparison of termination bioassay results for plutonium and uranium. Results were provided for (1) top-tier contractors, (2) all subcontractors, and (3) D&D subcontractors *[Analysis of Termination Bioassay Results for Rocky Flats during the Shutdown and D&D Era (1990–2005)]* (NIOSH 2006). SC&A reviewed the analysis of termination bioassay results and generally concurs with the NIOSH assessment. SC&A accepted the concept of applying OCAS-TIB-0014 as an extension of ORAUT-OTIB-0038 for worker populations in the D&D era.

In TIB-0014, in the same way as in OTIB-0038, two sequential fitting approaches were used to interpret the urinalysis bioassay data. The first one grouped the bioassay monitoring data by quarter or year, depending on the amount of data available during the periods. A lognormal distribution was assumed as the best representation of all the RFP workers' bioassay results during a certain period of time. After log transforming the data, the mean (50^{th}), and mean plus one standard deviation (84^{th}) percentiles were determined for each period of time. The second approach consisted of the derivation of an inhalation intake function that would reproduce the 50^{th} and 84^{th} percentiles bioassay values that were calculated using the first approach. The IMBA Expert OCAS-Edition computer program was used to fit the bioassay results to a series of inhalation intakes. Data from 1989 through 2005 were fit as a series of chronic intakes, through inhalation, using a default breathing rate of 1.2 m^3/hr and a 5-µm activity median aerodynamic diameter (AMAD) particle size distribution. The IMBA fit was derived for a period of several consecutive years. Two intake periods were fit to the derived 50^{th} and 84^{th} percentile uranium excretion data. Two intake periods were fit to the data for Type M material and one was fit for Type S material to the derived 50^{th} and 84^{th} percentile plutonium excretion. The fit to Type S Pu is an minimized intake. If the POC is <50%, for the minimized Type S intake, it should be followed by a manual fit to the coworker bioassay data for the time frame of interest for the employee, using the assumption of Type S material.

2.8.4 Review Comments

Review Objectives 1.1 through 1.5

Our review has identified that the procedure is not complete in terms of required data. The document uses data whose source is not referenced.

TIB-0014 is consistent with all other TIBs, OTIBs, and procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. TIB-0014 is sufficiently prescriptive to minimize the need for subjective decisions.

Review Objective 3.2

TIB-0014 is meant to address site-specific data pertaining to in-vivo/in-vitro bioassay data, missing dosimetry data, and unmonitored periods of exposure. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 5.1, 5.2, and 5.3

TIB-0014 provides the methodology to determine the doses for employees at DOE sites that were not monitored for internal ionizing radiation exposure, or the records of such monitoring are incomplete or unavailable. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objective 6.1

Although it provides adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal), TIB-0014 does not adequately account for the uncertainty of dose estimates, as described in the Review Objective 7.3 comments.

Review Objective 7.3

The SC&A review of TIB-0014 revealed at least two areas of concerns with the validity of the scientific protocols that were employed. These concerns are presented below:

(1) The Use of the 50th Percentile to Calculate Intakes and Doses

SC&A finds that the use of a model based on the 50^{th} percentile of the excretion rates of the workers will misrepresent the higher exposures experienced by unmonitored subcontractors at RFP. SC&A is supportive of intake models based on a percentile that encompasses all exposures from D&D exposures.

As in its review of ORAUT-OTIB-0038, which OCAS-TIB-0014 extends to the D&D era, SC&A notes that the intake model for OCAS-TIB-0014 was derived using an IMBA fit for a period of several consecutive years. As a consequence, for some time periods, the dose will be calculated using an intake rate that corresponds to urinary excretion values smaller than the chosen percentile (50^{th}). SC&A considers the uncertainties in the adequacy of the bioassay program and in the completeness of radiation records associated with D&D activities at RFP to be large and that a coworker model based on the 50^{th} percentile of the bioassay records does not adequately address these uncertainties.

(2) In-Vivo Counting Results

SC&A also finds OCAS-TIB-0014 to be incomplete because it does not address in-vivo counting results. For respiratory organ dose calculations, OCAS-TIB-0014 recommends applying Type M Pu, followed by the minimizing Type S intake. If both actions do not yield a POC >50%, NIOSH recommends manually fitting the coworker bioassay data for the time frame of interest for the employee, using the assumption of Type S material. In ORAUT-OTIB-0038, this manual fit of the data includes Am lung data. The uncertainties associated with the calculation of doses to the lung from urine data are large. The correlation of Pu retention in the lungs with the excretion rate in urine is indirect and depends on the chemical and physical forms. Different matrix materials containing Pu may have specific dissolution behavior. Absorption parameters depend on the production temperature. The method of formation of the material and its history (temperature, specific surface area) can influence the fraction rapidly absorbed and the long-term

retention half-time. The different types of material encountered in D&D activities produce different urinary excretion patterns. As a consequence, there is an increased uncertainty in the association of the urinary excretion rate with lung retention or lung deposition.

2.8.5 Conclusions

SC&A examined TIB-0014, in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. SC&A accepts NIOSH's position that it is possible to derive a surrogate exposure model for the unmonitored worker based on the distribution of internal doses received by the monitored workers at RFP in the D&D era. However, the use of a model based on the 50th percentile of the excretion rates may misrepresent the higher exposures experienced by unmonitored workers.

TIB-0014 should contain information on Am lung data for calculating potential unmonitored worker doses to the lung.

2.8.6 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

NIOSH 2006. *Analysis of Termination Bioassay Results for Rocky Flats during the Shutdown and D&D Era (1990–2005)*, National Institute for Occupational Safety and Health, Response to SC&A Comments on December 18, 2006.

OCAS-TIB-0014. 2006. *Rocky Flats Internal Dosimetry Coworker Extension*, Rev. 00, National Institute for Occupational Safety and Health (NIOSH), Office of Compensation Analysis and Support, Cincinnati, Ohio. December 7, 2006.

ORAUT-OTIB-0038. 2006. *Technical Information Bulletin: Internal Dosimetry Coworker Data for Rocky Flats Environmental Technology Site*, Rev. 00, August 3, 2006. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

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3.0 OAK RIDGE ASSOCIATED UNIVERSITIES TEAM TECHNICAL INFORMATION BULLETINS (OTIB)

3.1 ORAUT-OTIB-0002: MAXIMUM INTERNAL DOSE ESTIMATES FOR CERTAIN DOE COMPLEX CLAIMS

The review of ORAUT-OTIB-0002, *Maximum Internal Dose Estimates for Certain DOE Complex Claims*, Rev. 02, dated February 7, 2007, was prepared by Joyce Lipsztein, PhD.

3.1.1 Purpose of the Technical Information Bulletin

The stated purpose of this TIB is, "to provide a method to facilitate timely processing of claims under the EEOICPA that involve cancer to an organ with little or no reported dose from internally deposited radionuclides that might be associated with work at DOE complex sites." OTIB-0002 is only to be used for "maximizing" cases (or where the dose is significantly overestimated); and cases that use OTIB-0002 for assessing internal dose can **not** be compensated. Thus, the assumptions used in the OTIB should represent the upper bound values.

3.1.2 Review Protocol

As part of the first set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated Revision 1 of *Maximum Internal Dose Estimates for Certain DOE Complex Claims* (January 10, 2004). Our findings were published in The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction, dated January 2005 (SCA-TR-Task3). Following the submission of this report and its findings, an expanded review and issues-resolution process was initiated. The process began by NIOSH providing written responses to each of SC&A's findings. Under the direction of a Board-appointed Workgroup, a series of meetings was held between representatives of NIOSH and SC&A auditors to discuss and resolve each finding. This process resulted in the preparation of an issues-tracking matrix, whereby the closeout status of each finding is tracked.

The resolution of many findings identified during our review of Revision 1 of OTIB-0002 required NIOSH to incorporate changes in a future revision of the document. Our evaluation of OTIB-0002, Revision 2, therefore, was designed to ensure that (1) the findings identified in Revision 1 were adequately resolved and (2) the document adequately supports the dose reconstruction process. Table provides a list of applicable OTIB-002, Revision 1 findings, and our evaluation to assess whether those findings were adequately addressed.

SC&A's evaluation of ORAUT-OTIB-0002 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.1-1: Evaluation of Findings Identified in the Review of ORAUT-OTIB-0002

Review Objective	ORAUT-OTIB-0002, Rev. 01 Finding Description	Resolution Ranking	Corrected in Rev. 02?	Comments
1.1/1.2/1.5	Guidance not written in a clear and logical manner (i.e., Section 3.1.1 provides reasons for using 10 and 20 times 10% MPBB as maximum intakes that are difficult to follow and understand). (OTIB-0002-01)	None Given	No	Our re-review identified that, in several sections, the writing style is not clear and unambiguous
1.3	Guidance only references data from documents that need to be known to understand the procedures described. (OTIB-0002-02)	Low	No	The document uses critical information and historical data without providing references.
4.1	Methods described for calculating maximum internal doses are difficult to understand and reproduce. (OTIB-0002-04)	Low	Partially	
5.1	Assumption that intakes are 10 to 20 times the 10% MPBB is not always justifiable in terms of new ICRP models. (OTIB-0002-05)	Low	No	This assumption remains unchanged.
5.2/5.3	Assumption that the intakes are 10 to 20 times the 10% MPBB is not claimant favorable for many nuclides. (OTIB-0002-06)	None Given	No	This assumption remains unchanged.
5.2/5.3	Assignment of solubility types based on criterion of choosing the solubility type that produces the larger doses to system organs is not correct for many nuclides. (OTIB-0002-07)	None Given	No	Following Table 4-1, the assignment of solubility types remains unchanged.
Technical Issue	Fractional retention values in Table 3.1.1-1 are incorrect. These fractions refer to stable elements and must be corrected with a decay factor for the specific radionuclide. (OTIB-0002-08)	None Given	No	The fractional retention values (now in Table 4-1) remain unchanged.
Technical Issue	It is arbitrary to use 3-4 days post intake to calculate the fractional retention in whole body for inhalation type F and 90 days for type M to account for rapid clearance from the lung. (OTIB-0002-09)	None Given	No	Table 4-1 still uses 3-4 days for type F and 60-90 days for type M.
Technical Issue	Section A.2.6, Organs of Interest, (p. 14) include the thyroid, however, Table 3.1.1-4 (p.8) does not identify thyroid. (OTIB-0002-10)	Low	Not Applicable	Section A.2.6 'Organs of Interest' has been deleted.
Technical Issue	Section 4.0, first sentence "The calculation of organ dose assumes that the covered employee had maximum intakes of all of the radionuclides listed in Table 3.1.1-1" should refer to Table 3.1.1-2. (OTIB-0002-11)	Low	Yes	This sentence has been corrected, and is now the first sentence of Section 5.

Table 3.1-2: ORAUT-OTIB-0002 Review Outline/Checklist

Document No.: ORAUT-OTIB-0002, Rev. 02	**Effective Date:** 02/07/2007
Document Title: Maximum Internal Dose Estimates for Certain DOE Complex Claims	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	2	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	3	See Review Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined	N/A	

Table 3.1-2: ORAUT-OTIB-0002 Review Outline/Checklist

Document No.: ORAUT-OTIB-0002, Rev. 02	**Effective Date:** 02/07/2007
Document Title: Maximum Internal Dose Estimates for Certain DOE Complex Claims	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
	in 42 CFR 82.2?		
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?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.1.3 General Comments

The method provided in OTIB-0002 to assign internal doses is based upon the following:

> *…the "largest reasonably possible value" of the source term that consisted of radionuclides that are or were typically the more significant radionuclides (by either preponderance or by internal dose significance) on a site. For this worst-case estimate of internal dose, it is assumed that on the first day of employment, the worker had an acute inhalation intake of each of the radionuclides in the source term.*
>
> *Additional assumptions to develop this method are:*
>
> - *All intakes are inhalations of standard 5 micrometer AMAD, except for I-131, which is assumed to be in vapor form (class SR-1).*

- *The most soluble form of the radionuclide specified in ICRP (1995) was used to maximize*

- *dose to systemic organs, except as noted below; dose to lung is not germane to this exercise.*

- *Because maximum permissible body burdens (MPBB) were the derived limits for so many years, the assumed implausible uptake was based on a percent of the radionuclide-specific MPBB for soluble chemical forms as defined in National Bureau of Standards (NBS) Handbook 68 [also referred to as National Committee on Radiation Protection (NCRP) Publication 22](NBS 1959). It was assumed that an intake resulting in 10% of a MPBB would not have likely occurred to an unmonitored worker or would have likely resulted in a readily noticeable bioassay result in a monitored worker, readily noticeable air sample, or other indicator of personnel contamination. In other words, an event that provided the possibility of an intake that would have resulted in a body burden exceeding 10% of the MPBB would not have gone unnoticed and there would be some sort of indication in the worker's records. This assumption applies to facilities with active radiation protection programs where bioassay or air monitoring programs were present and able to detect such intakes. The current ICRP methodology is used to calculate doses from these implausible intakes.*

- *For types F and M materials, the associated derived intakes (i.e., intake resulting in a 10% MPBB) were assumed to be 10 and 20 times 10% of the MPBB, respectively. The factors of 10 and 20 are based on the current ICRP models and approximate the differences between an intake and the activity that is present in the body after the initial clearance of the short-term compartments. These factors are used to relate body burden, the historical quantity of control that was based on ICRP Publication 2 (ICRP 1959) methods, to intake, the present quantity of control that is based on current ICRP methods. These factors were estimated from tables in the November 2002 issue of Health Physics that list the intake retention fraction for the whole body (without the extrathoracic (ET) region) as a function of time after acute intake for different elements and inhalation types (Potter 2002). Because initial deposition in the nonsystemic organs was not considered by ICRP (1959) to be part of the body burden, the selected retention fractions allowed some time for the rapid clearance components.* (OTIB-0002, pg. 4)

Those assumptions, which constitute the basis for the derivation of the methodology described in the TIB, were presented by NIOSH without a technical explanation.

NIOSH does not substantiate the assumption that "an intake that resulted in 10% of an MPBB would likely not have occurred to an unmonitored worker or would have likely resulted in a readily noticeable bioassay result in a monitored worker, readily noticeable air sample, or other

indicator of personnel contamination." OTIB-0002 methodology to calculate the maximum plausible dose is based on deriving intakes that would result in body burdens that are 10 to 20 times the 10% MPBB. SC&A finds that the basic assumption for deriving intakes and doses should be better explained by NIOSH.

SC&A considers that the technical approach used in this document needs some refinement. For example, the *time for the rapid clearance components,* was presented as 3 and 4 days for Type F nuclides and 60 and 90 days for Type M nuclides, without a clear indication of how they were derived. In addition, the multiplication factors 10 and 20 were not derived correctly for many nuclides, as described in Review Objective 7.3.

3.1.4 Review Comments

Review Objective 1.1

Our review has identified that, in several sections, the writing style is not clear and unambiguous. The following paragraphs exemplify some of the difficulties encountered in the analysis of the document.

(1) It is difficult to understand the meaning of an organ with "little dose" from internally deposited radionuclide. "The purpose of this TIB is to provide a method to facilitate timely processing of claims under the EEOICPA that **involve cancer to an organ with little or no reported dose from internally deposited radionuclides that might be associated with work at DOE complex sites."** [Emphasis added] The only way to evaluate the dose to an organ is to calculate the dose to the organ.

(2) Some of the assumptions that constitute the basis of the document are presented without a clear indication on how they were derived. For example, the fractional retentions in whole body are calculated at 3–4 days post intake for Type F, and 60 days and 90 days for Type M. NIOSH 's only explanation is "Because initial deposition in the nonsystemic organs was not considered by the ICRP (1959) to be part of the body burden, the selected retention fractions allowed some time for the rapid clearance components."

(3) In Table 4-2 of OTIB-0002, Th-230 is specified, with the following note: "thorium-230 can be used as a surrogate for Th-232." There is no further instruction on what to do with this information. Should the DR add to the list of radionuclides exposures to Th-232 in the same amount as Th-230?

Review Objective 1.3

The procedure is not complete in terms of required data. The sources of certain critical information are not referenced. The document references historical data without substantiating them with the sources. The following paragraphs, extracted from OTIB-0002, exemplify the need for more information from NIOSH:

- *For this worst-case estimate of internal dose, it is assumed that on the first day of employment the worker had an acute inhalation intake of each of the radionuclides in the source term in the amounts listed below.*

  Based on historical data, it is believed to be unlikely that such an intake could have occurred without being detected by workplace monitoring at the time. It is also believed that this is an overestimate of internal dose for an unmonitored worker or a worker with no bioassay results exceeding detection thresholds. [Emphasis added]

- NIOSH does not substantiate the assumption that

  . . . an intake that resulted in 10% of an MPBB would likely not have occurred to an unmonitored worker or would have likely resulted in a readily noticeable bioassay result in a monitored worker, readily noticeable air sample, or other indicator of personnel contamination. In other words, an event that provided the possibility of an intake that would have resulted in a body burden exceeding 10% of the MPBB would not have gone unnoticed and there would be some indication in the worker's records.

  This assumption may in fact be appropriate for the intended purpose of this OTIB. However, the document would benefit from additional discussion and validation of this assumption.

Review Objective 1.4

SC&A's review has identified that the procedure may not be consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. In particular, for sites where a coworker model was developed, it is difficult to evaluate which procedure (OTIB-0002 or coworker model) should be applied in cases of employees who were not included in a bioassay program.

Review Objective 1.5

SC&A's review has identified that the procedure is not sufficiently prescriptive to minimize the need for subjective decisions. The following paragraphs illustrate SC&A concerns:

- The decision on who to apply the method described in OTIB-0002, without prior calculation of the dose, is considered by SC&A subjective:

  *The purpose of this TIB is to provide a method to facilitate timely processing of claims under the EEOICPA that involve cancer to an organ with **little** or no reported dose from internally deposited radionuclides that might be associated with work at DOE complex sites.* (Emphasis added)

- The application of the procedures described in this TIB for workers whose initial hire date was before 1970, requires the need of subjective decisions:

The covered employee's initial start date was before 1970 (for the DOE Hanford Site, before 1953), provided the dose reconstruction report includes an evaluation or explanation that demonstrates the doses from Table 4-2 intakes overestimate the actual or potential doses received by the worker. The following are some examples of potential information to use in this evaluation.

1. *Employee job title*
2. *Bioassay monitoring results*
3. *Work location or other job conditions*
4. *Recorded external dose*
5. *Other site employees with similar jobs*

Review Objective 2.2

OTIB-0002 is meant to be efficient for claims with suspected cumulative low doses. Some subjective decisions are sometimes required in defining the target population to apply the procedure, as outlined in Review of Objective 1.5.

Review Objectives 5.1, 5.2, and 5.3

Objectives 5.1, 5.2, and 5.3 were designed to assess whether procedure decisions are claimant-favorable in instances of missing data, in instances of unknown parameters effecting dose estimates, and in instances where the claimant was not monitored.

- The Review Objective 1.3 already notes that NIOSH does not substantiate the assumption that "an intake that resulted in 10% of an MPBB would likely not have occurred to an unmonitored worker or would have likely resulted in a readily noticeable bioassay result in a monitored worker, readily noticeable air sample, or other indicator of personnel contamination. In other words, an event that provided the possibility of an intake that would have resulted in a body burden exceeding 10% of the MPBB would not have gone unnoticed and there would be some indication in the worker's records."

- In addition, the assumption that the intakes are 10 to 20 times the 10% MPBB is not always justifiable in terms of the new ICRP models, and for many nuclides, this is not a claimant-favorable approach, as exemplified under the Review Objective 7.3 comments.

Review Objective 7.3

The review of the scientific protocols that were employed revealed that the fractional retentions in Table 4-1 are incorrect. They are the fractional retention values exactly as they appear in the tables in the November 2002 issue of Health Physics. Those fractions refer to the stable element. Each value must be corrected with a decay factor for the specific radionuclide in question. Depending on the radionuclide's half-life, the correction that needs to be made is significant. For example:

- For Type M Nb-95, for example, the fractional retention in whole body is, at 60 days equal to 0.015 and at 90 days equal to 0.007. The corresponding factor to multiply the

intake are 67 (60 days) and 144 (90 days) and do not justify the multiplication factor of 20, suggested by NIOSH.

- For Co-58, Type M, the fractional retention in whole body is equal to 0.023 at 60 days and equal to 0.014 at 90 days. The corresponding factors to multiply the intake are 43 (60 days) and 71 (90 days), and not 20, as was used, as follows:

  The assumption of type S for Co-58 and Co-60 is used..... The fractional retention in the whole body is similar for type M and type S at 60 and 90 days, so the derived intake is estimated as 20 times the 10% MPBB.

3.1.5 Conclusions

SC&A examined OTIB-0002 in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. In its review, SC&A found areas of concern, as specified above, that must be resolved by NIOSH.

3.1.6 Workbook

To facilitate entry of organ doses into the IREP computer code, the Maximum Internal Dose Calculation Workbook 3.03 was developed. The Maximum Internal Dose Calculation Workbook 3.03 was discussed and described in OTIB-0002, Rev. 0, but not in Rev. 1. Because it is not discussed in OTIB-0002, Rev. 1, and because it has not been revised recently to reflect OTIB-0002, Revision 1 changes, it is unknown whether NIOSH intends to continue using the Maximum Internal Dose Calculation Workbook 3.03. Nonetheless, SC&A performed a review of the Maximum Internal Dose Calculation Workbook 3.03, and the results of that review have been included in the draft report, *Review of Nine General Dose Reconstruction Tools* (SCA-TR-TASK3, Supplement 2, April 2007).

3.1.7 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ICRP (International Commission on Radiological Protection) 1959. *Report of Committee II on Permissible Dose for Internal Radiation,* ICRP Publication 2, Oxford: Pergamon.

ICRP (International Commission on Radiological Protection) 1973. *Implications of Commission Recommendations that Doses be Kept As Low As Readily Achievable,* ICRP Publication 22. Oxford: Pergamon.

ORAUT-OTIB-0002. 2004. *Maximum Internal Dose Estimates for Certain DOE Complex Claims*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 10, 2004.

ORAUT-OTIB-0002. 2007. *Maximum Internal Dose Estimates for Certain DOE Complex Claims,* Rev. 02, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 7, 2007.

Potter, C. A. 2002. *Intake Retention Fractions Developed from Models Used in the Determination of Dose Coefficients Developed for ICRP Publication 68—Particulate Inhalation*, Health Physics, Volume 83, Number 5, pp. 594–789.

SC&A 2007. *Review of Nine General Dose Reconstruction Tools* (SCA-TR-TASK3, Supplement 2, S. Cohen and Associates, Vienna, Virginia. April 2007.

3.2 ORAUT-OTIB-0005: INTERNAL DOSIMETRY ORGAN, EXTERNAL DOSIMETRY ORGAN, AND IREP MODEL SELECTION BY ICD-9 CODE

The review of ORAUT-OTIB-0005, *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code,* Rev. 02 PC-1, dated February 10, 2006, was prepared by Joyce Lipsztein, PhD.

3.2.1 Purpose of the Technical Information Bulletin

The stated purpose of this TIB is "to provide guidance on selecting appropriate ICRP modeled organs/tissues to estimate the internal dose for specific ICD-9 codes, the appropriate organs/tissues to estimate external dose, and the appropriate model in the Interactive RadioEpidemiological Program (IREP). This TIB also provides information for selecting and assessing likely primary cancers for secondary cancers."

3.2.2 Review Protocol

As part of the first set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated Revision 1 of *IMBA Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code* (January 23, 2004). Our findings were published in *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, dated January 2005 (SCA-TR-Task3). Following the submission of this report and its findings, an expanded review and issues-resolution process was initiated. The process began by NIOSH providing written responses to each of SC&A's findings. Under the direction of a Board-appointed Workgroup, a series of meetings was held between representatives of NIOSH and SC&A auditors to discuss and resolve each finding. This process resulted in the preparation of an issues-tracking matrix, whereby the closeout status of each finding is tracked.

From SC&A's review of OTIB-0005, Revision 1, a single issue remained unresolved on the issues tracking matrix, that being for Review Objective 1.4:

> Document inconsistent with ICRP 66 regarding the assignment of the oral cavity as a nonmetabolic organ (in IMBA), instead of ET2 region. (Issue number: OTIB-0005-01)

After the first review, the ICRP issued a new model for the Human Alimentary Tract Model, ICRP Publication 100 (ICRP 2006). The oral cavity is no longer part of the ET2 region. It is now part of the HAT (Human Alimentary Tract). In the ICRP 100, the dose to the oral cavity is

compared to a typical non-source organ such as the muscle. NIOSH's treatment of the oral cavity is compatible with the new ICRP, and the comment is satisfactory resolved.

SC&A's evaluation of ORAUT-OTIB-0029 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.2-1: ORAUT-OTIB-0005 Review Outline/Checklist

Document No.: ORAUT-OTIB-0005, Rev. 02 PC-1	**Effective Date:** 02/10/2006
Document Title: Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

Table 3.2-1: ORAUT-OTIB-0005 Review Outline/Checklist

Document No.: ORAUT-OTIB-0005, Rev. 02 PC-1	**Effective Date:** 02/10/2006
Document Title: Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	5	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.2.3 General Comments

OTIB-0005 document is a basic document to be used in all dose reconstructions. As described in the document:

> *OTIB-0005 designates the appropriate internal dosimetry organ/tissue selection for the various ICD-9 coded cancers, the appropriate organ/tissue to estimate external dose, and the appropriate IREP model to use as well.* (OTIB-0005, pg. 4)

No dose reconstructions can be realized without using OTIB-0005.

3.2.4 Review Comments

Review Objectives 1.3 and 1.5

The procedure is written in a clear and unambiguous style. Data and discussions are presented in a logical sequence.

The procedure is not always complete in terms of require data and the DR will need, for some types of cancer, advice from the ORAU medical team, as exemplified in the following paragraph:

> *Due to the complexity of determining the appropriate organ/tissue for some ICD-9 code cancers, a medical review by an ORAU team physician is required to determine the organ/tissue to use in IMBA for those cancers.* (OTIB-0005, pg. 30)

The procedure is consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. The need for subjective decisions is minimized.

Review Objective 5.1

OTIB-0005 procedure decisions are claimant favorable in instances of missing data, as for example the approaches in cases of secondary cancers, and multiple secondary cancers with unknown primary cancer site or multiple primary and secondary cancers. The following paragraphs, extracted from OTIB-0005, exemplify this claimant –friendly approach:

> *When there are cancers of multiple organs or the cancer site is unknown, the remainder organ should be selected as the model to apply dose. However, if the organ location can be determined through the medical records or a medical review, then an organ in close physical proximity should be selected. The remainder selection provides a claimant favorable estimate of dose.* [OTIB-0005, pg. 30]

> *For secondary cancers with unknown primary cancers sites, the likely primary cancer sites are listed in Table 3-2. Since the likely primary cancer sites are listed only by ICD-9 code (three digit codes with no extensions), it is possible for a single likely primary cancer site to have multiple options for IMBA, external, and IREP organ model selection. In this case, each possible option must be assessed and the option that yields the largest probability of causation shall be submitted.* [OTIB-0005, pg. 31]

> *In some claims, multiple secondary cancers with unknown primary cancer location may be indicated. In such cases, unless the DOL specifically states differently, each likely primary cancer site from each secondary cancer is to be treated separately, with individual IREP probability of causation determinations and combined as separate primary cancers.* [OTIB-0005, pg. 31]

OTIB-0005 is also claimant favorable in cases of organs in close proximity to the thyroid:

> *For cancer sites where "Thyroid/Remainder" is listed for the external organ selection, there is no external dose model for the organ of interest and the organ is located in close proximity to the thyroid. The thyroid has higher organ dose conversion factors than the remainder selection, thereby maximizing the dose. If a more realistic dose assessment is required rather than a maximizing dose assessment, then the remainder organ should be selected to calculate dose.* [OTIB-0005, pg. 30]

Review of Objectives 7.1 and 7.3

OTIB-0005 procedures are detailed enough to be followed by the dose reconstructor. It employs scientifically valid medical protocols and ICRP model organs to help the calculation of the POC.

3.2.5 Conclusions

SC&A examined OTIB-0005 and concurs with its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. OTIB-0005 is an essential document for the assignment of the POC in dose reconstruction.

3.2.6 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ICRP (International Commission on Radiological Protection) 1995. *ICRP Publication 66: Human Respiratory Tract Model for Radiological Protection,* Annals of the ICRP Volume 24/1-3, 1995.

ICRP (International Commission on Radiological Protection) 2006. "Human Alimentary Tract Model for Radiological Protection," ICRP Publication 100.

ORAUT-OTIB-0005. 2004. *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code,* Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 23, 2004.

ORAUT-OTIB-0005. 2006. *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code*, Rev. 02 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 10, 2006.

ORAUT-OTIB-0029. 2005. *Internal Dosimetry Coworker Data for Y-12*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. April 5, 2005.

SC&A 2005. *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-Task3, S. Cohen and Associates, McLean, Virginia. January 2005.

3.3 ORAUT-OTIB-0006: DOSE RECONSTRUCTION FROM OCCUPATIONALLY RELATED DIAGNOSTIC X-RAY PROCEDURES

The review of ORAUT-OTIB-0006, *Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures*, Rev. 3, dated December 21, 2005, was prepared by Harry J. Pettengill, Ph.D. Input was also taken from a prior Rev. 2 review of the same OTIB by Hans Behling.

3.3.1 Purpose of the Technical Information Bulletin

Under EEOICPA, diagnostic x-rays, specifically chest x-rays, were required as a condition of employment and are included as part of the total occupational radiation exposure to the atomic worker. This document was published by ORAUT as an OTIB to be used for DOE and AWE sites relating to "… using a detailed methodology for dose reconstruction from diagnostic medical x-rays that were sustained by workers as a condition of employment, and provides the technical basis for dose reconstruction in the absence of specific dose measurements or records of technical factors." This OTIB further states that it "supplements and expands upon the guidance provided in…OCAS-IG-001."

3.3.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0006 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in this report.

Table 3.3-1: ORAUT-OTIB-0006 Review Outline/Checklist

Document No.: ORAUT-OTIB-0006, Rev. 3	**Effective Date:** 12/21/2005
Document Title: Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures	
Auditor: Harry J. Pettengill, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	

Table 3.3-1: ORAUT-OTIB-0006 Review Outline/Checklist

Document No.: ORAUT-OTIB-0006, Rev. 3	**Effective Date:** 12/21/2005
Document Title: Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures	
Auditor: Harry J. Pettengill, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	4	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	4	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.3.3 Review Comments

Review Objectives 1.0 and 7.0

For a procedure to support a dose reconstruction process that is expeditious and timely, the procedure should prioritize its content with the most important/relevant information presented first, followed by technical support data and data that are interesting but not essential.

In Section 1 (Introduction), the procedure attempts to define and clarify what constitutes occupational medical exposures. Unfortunately, early consideration by NIOSH was that it constituted those exposures necessitated as "a condition of employment only." To date, most dose reconstruction has limited medical dose to being from pre-employment, annual, and termination chest x-rays. Little or no consideration was given for other exams such as back x-rays (lumbar spine), which were also a condition of employment. Past reviews of earlier revisions of this procedure have pointed this out, and NIOSH agrees that, these exams and further required screening exams of high-risk workers, such as beryllium and asbestosis workers, should be included. This revision of the OTIB is helpful, but it should be further revised such

that dose reconstruction will include all potential work-related doses, especially screening exams.

Section 2.0 of this OTIB provides a lengthy and detailed technical explanation regarding various parameters (i.e., beam kilovoltage, current, filtration, collimation, exposure time, distance, and waveform) that affect the beam output and, **if known**, can be used to estimate the potential air dose to a patient for a given diagnostic x-ray. However (and not surprisingly), the OTIB acknowledges the **unlikely** availability of such data (i.e., kVp, mA, filtration, distance, and exposure time), but not until Section 3.0, page 15, of the TIB, which states the following:

> *X-ray output measurements are likely to be unavailable, particularly prior to about 1980 [when occupational x-rays probably ceased to be required for employment]. In the **absence of suitable measurement** data, medical diagnostic x-ray dose reconstruction can be accomplished using **technique factors** along with published output data that provide beam intensity per mAs as a function of kVp, filtration, and distance.* [Emphasis added.]

The unlikely availability of beam measurement data is restated several more times:

Section 3.1, page 16:

> *Although beam output measurements may typically be unavailable, diagnostic medical x-ray dose reconstruction using actual measurement data is the preferred method for determining the dose to the worker from this source, so much that **special effort** to determine if such measurements have been made is justifiable.* [Emphasis added.]

Section 3.1, page 16:

> *If the actual beam quality is unknown, as is likely the case, to ensure claimant favorability, a higher rather than lower HVL should be assumed*

Section 3.2, page 17:

> *When beam measurement data are unavailable, as is likely to be the case, **technique factors** can be used to obtain reasonable estimates of exposure. The basic data required for kVp, filtration, exposure in mAs, and distance. Beam output data are available from a number of publications, including NCRP Report No. 102 (NCRP, 1989). Table B.3 in this report (p 99) provides average air kerma rates for medical diagnostic x-ray equipment operating at various kVps with 2.5 mm Al filtration at distances from 30 to 182 cm from the source. Correction for different thickness of Al filtration can be made by reference to Table 3.1, p 13. Using these tables, a reasonable estimate of beam output and hence entrance kerma can be obtained. Once the entrance kerma has been determined, organ doses are determined in the manner described above for reconstruction using **measurement data**.* [Emphasis added.]

The difference between **measurement data** and **technique factors** for deriving dose estimates is trivial, since both techniques require knowledge about kVp, mA, filtration, distance, and exposure time that the procedure warns "are unlikely to be available." By far, the most probable method for estimating medical occupational exposures will involve the use of default values, which the procedure does not address until the very end.

In summary, this document reads more like an introductory reference text on medical x-rays than a procedure. It not only presents an excess of background information that is well-understood by a dose reconstructor, but is also of limited use since the required data are "unlikely to be available." In spite of the unlikely availability of data, the procedure, nevertheless, justifies the need for the dose reconstructor to make "…that special effort to determine if such measurements have been made…."

Reconstruction by means of default values as given in Section 3.3 of this procedure appears adequate and claimant favorable. As such, Section 3.3 should have been the principal component of this procedure. However, several other factors should be taken into consideration when using default values as presented in the procedure as shown in Table 3-4 (Default Dose Values by Procedure). These default values are derived from other historic studies and are not based upon actual measurements of x-ray machines used at DOE sites. Although the authors were careful to use minimum filtration, low kilovoltage, slow film, and no additional collimation, it still cannot describe the characteristics inherent to equipment in use at DOE sites during the early years. Typically, historic review has shown these parameters varied widely from site to site, and was more dependent on the type of equipment in use.

There is some ambiguity regarding the use of default values. Table 3.4 identifies a default value of 3.0 cGy entrance kerma for photofluorographic chest examination, and proceeds to apply this value to default organ dose values given in Table 4.0-1 of Section 4.0. Section 5.0 of the OTIB provides some historical dose data on behalf of photofluorography that include a 1959 study of Hanford by Rising and Soldat. In that study the upper bound entrance skin exposure in air (ESE) for photofluorographic chest examinations was 1.53 R with the following recommendation:

> *Thus, although the Hanford measured value is likely an upper limit and hence an overstatement of the actual exposure from photofluorography to the average patient, this 1.53 R ESE value should be used in the absence of data to ensure claimant favorability.*

Thus, the OTIB provides two default values for photofluorography, which differ by a factor of 2 [i.e., 3.0 cGy entrance kerma versus 1.53 R (ESE)]. This raises two questions: (1) is the 1.53 R default value uniquely applicable to Hanford, and (2) if so, is there a defensible explanation for a two-fold higher value for all other DOE/AWE sites? The absence of a defensible explanation clearly raises the question regarding consistency of the dose reconstruction process.
Also, a major consideration is the period of use of photofluorographic (PFG) equipment at DOE sites. The procedure prescribes that a dose reconstructor should assume that PFG was in use unless it is shown as not being available. Unfortunately, many dose reconstructors have used the absence of 6x9 inch film in a claimant's file as the basis to rule out PFG. Given that medical records and x-ray films are often separated, this could result in significant lost dose.

It would be more prudent for the procedure to state that dose reconstructors should use 1 PFG per year (1.53 R) prior to 1960, as a base and add other x-rays found in the files.

3.3.4 References

NCRP (National Council on Radiation Protection and Measurements) 1989. *Medical X-ray, Electron Beam, and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance, and Use)*, Report No. 102, NCRP, Bethesda, Maryland.

OCAS-IG-001. *External Dose Reconstruction Implementation Guideline*, Rev. 2, Office of Compensation Analysis and Support. August 25, 2006.

ORAUT-OTIB-0006. 2003. *Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures*, Rev. 2, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 29, 2003.

ORAUT-OTIB-0006. 2005. *Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures*, Rev. 3, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 21, 2005.

3.4 ORAUT-OTIB-0013: INDIVIDUAL DOSE ADJUSTMENT PROCEDURE FOR Y-12 DOSE RECONSTRUCTION

The review of ORAUT-OTIB-0013, Rev. 00, dated September 9, 2004, was prepared by Ron Buchanan, PhD, CHP, and Harry Chmelynski, PhD.

3.4.1 Purpose of the Technical Information Bulletin

There is not a specific section that states the purpose of OTIB-0013 (ORAUT 2004a). However, from the introduction and the remainder of the text, it can be determined that this document describes a scaling procedure that can be applied to coworker data to estimate doses during periods when workers were not monitored prior to 1961, if these unmonitored workers had at least five quarters of monitoring data during the period from 1961 through 1965. These estimates are used to supplement the measured doses, ultimately for use in external dose reconstruction. The scaling factors are estimated using the ***maximum likelihood*** statistical method, as described in Frome and Watkins 2004. A similar procedure for estimating the scaling factors based on a Bayesian statistical approach is discussed in OTIB-0015. Both methods are reported to yield very similar results. For large samples, the Bayesian and maximum likelihood estimates of the scaling factors should converge.

3.4.2 Review Protocol

SC&A's evaluation of OTIB-0013 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in this report.

Table 3.4-1: ORAUT-OTIB-0013 Review Outline/Checklist

Document No.: ORAUT-OTIB-0013, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Individual Dose Adjustment Procedure for Y-12 Dose Reconstruction	
Auditor: Ron Buchanan, PhD, CHP and Harry Chmelynski, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	3	See Review Comments
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	2	See Review Comments

Table 3.4-1: ORAUT-OTIB-0013 Review Outline/Checklist

Document No.: ORAUT-OTIB-0013, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Individual Dose Adjustment Procedure for Y-12 Dose Reconstruction	
Auditor: Ron Buchanan, PhD, CHP and Harry Chmelynski, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	5	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.4.3 Review Comments

Review Objective 1.1

Generally, OTIB-0013 is written in a style that is clear and unambiguous. However, there are areas where the data are not clearly defined or there are conflicts in the years stated. These are:

- **Recorded-dose data points in Figure 1 unclear:** OTIB-0013 on page 5 states that the solid green dots in Figure 1 are for when the recorded dose was known for the period 1961 through 1965 for the individual in the example; it then goes on to calculate the unknown doses, with error bars, for each quarter for the period 1956 through 1960.

However, the figure on page 6 shows solid green dots for all quarters for all years; 1956–1965. It is not clear from the text why there are the solid green dots representing measured doses in Figure 1 for the period 1956 through 1960, if it was necessary to calculate unmonitored doses because of lack of monitoring during that period.

- **Conflict concerning the time period the DR is to apply this OTIB -** It is not clear from the OTIB for what time period these dose adjustment factors are to be applied because of the following statements:

  – OTIB-0013: On page 3, Section 3.0, it states, "…unmonitored quarters from 1951 through 1960."

  – OTIB-0013: On page 4, Section 4.0, it states, "…unmonitored between January 1951 and December 1960."

  – OTIB-0013: In the heading of Table 1, it states, "…doses 1951 to 1965." **However, Table 1 lists data for 1947, 3rd quarter through 1965, 4th quarter.**

  – OTIB-0013 provides information and data for PROC-0042, which uses the term "…prior to 1961" on page 3 of PROC-0042.

  – PROC-0042: Table 5.1 lists data for the period 1947–1965.

  – Workbook: *Y-12_Workbook CB_1951–1960 and CF After 1960 1.14.:* List data for 1951 through 1961 in its Lookup Parameter spreadsheet.

For consistency in dose reconstruction, this OTIB needs to define the specific period that the dose reconstructor (DR) is to apply this data and scaling procedure.

Review Objective 3.2.1

The following two items were identified concerning the use of personal dosimeter and dosimetry data:

- **No real coworker data for 1947 to 1956 -** Periods when most of the recorded dosimetry data were not available, or not usable to derive a dose distribution, were not specifically mentioned in this OTIB to inform the DR what data was, and was not, used to obtain the coworker dose distribution data. It is not stated in this document that the dose data for the years 1947–1956 (3rd quarter) in Table 1, p. 8, are not actually from badged workers' dose records. In fact, these values are *inferred* doses from regressions analysis of 147 badged workers at Y-12 for the period of 1956–1965. Document RPRT-0032 must be analyzed to understand the development of this data. Even if this is an acceptable method to use in view of the lack of actual, reliable, recorded dose data for 1947–1956, it should be clearly stated in the procedure that this is the case and not presented as actual dose of record.

- **Incorrect LOD value -** On page 4 of the OTIB it assumes an LOD = 30 mrem for use in calculating Y^o to be used when the worker's recorded dose = 0. However, ORAUT-

TKBS-0014-6, page 12, Table 6.3.1-2 lists the *laboratory* MDL (or LOD) to be 40 mrem for 1948–1980. Additionally, the MDL values for dosimeters at Y-12 are listed in Table 3 of Watkins, et al. 2004, which is reproduced below as Table.

Table 3.4-2: Minimum Detection Level (MDL) and Assigned MDL Doses* for Film Used to Measure Beta and Gamma Radiation Exposures at the Y-12 Plant

Period of time**	MDL	Assigned MDL
January 1948 to January 1950	30	30
January 1950 to January 1952	30	0
January 1952 to September 1952	50	50
September 1952 to January 1953	43	43
January 1953 to July 1954	50	50
July 1954 to July 1956	30	30
July 1956 to July 1961	30	15
July 1961 to October 1980	30	Not Applicable

* Doses in mrem.

** Dates are approximate because the changes did not occur for all employees at the same time

Source: Watkins et al. 2004, Table 3

Considering these larger documented values for LODs, the laboratory minimum LOD of 40 mrem should at least be used in this analysis.

Review Objective 3.2.4

The purpose of OTIB-0013 is to provide estimates of scaling factors for each worker based on the relationship of the available data in the 1961–1965 period relative to coworker data in the same quarters. If a Y-12 worker was employed for at least five quarters from 1961 to 1965, this document proposes that the individual's monitoring data can be used to "adjust" the coworker dose distributions to provide estimates for unmonitored periods from 1951 through 1960. However, as described below, a very important assumption of the constant scaling factor is not supported in the OTIB.

Unsupported assumption of constant scaling factor. The method for applying the estimated scaling factors is based on the assumption that the individual's potential for exposure during the 1950s is similar to that from 1961 to 1965, and that the individual's doses differ from the coworker population dose by a constant factor both in the later years when data are available for comparison, and in the earlier unmonitored years. No evidence is presented to support these important assumptions. It is likely that the appropriate scaling factor may change over time for many individuals, especially those who change job assignments during the 15-year time frame covered by the analysis, but also for other workers due to changes in working methods and activities. No evidence is presented that five quarters of data provide sufficient information to estimate the scaling factors with sufficient precision. Moreover, under the proposed procedure the most uncertain scaling factors, estimated for the individuals with only five quarters of data, are then applied to the largest number of unmonitored quarters, compounding the effects of uncertainty.

The scaling procedure also assumes that suitable lognormal distributions for the coworker population in the time periods prior to 1961 are available from other sources. The parameters μ and σ for the lognormal distributions reported in OTIB-0013, Table 1, are plotted in the lower two curves in Figure. Also shown in Figure are the trend line linear regressions for each parameter. The three upper curves in the figure show the median, mean, and 95th percentile of the lognormal distributions. A noticeable dip in the median, mean and 95th percentile occurs in 1961, when more-widespread monitoring was adopted. Prior to this, only workers thought to have higher potential for exposure were being monitored. After 1961, the dose distributions have remained at lower levels. Note that the dip in 1961 occurred mainly due to the reduction in the parameter μ, while σ actually increased by a small amount. These effects are what would be expected if workers at the lower end of the distribution begin to be tested while the previously monitored, mostly higher, doses remain somewhat the same before and after 1961. These changes would be expected to increase the variance and decrease the median.

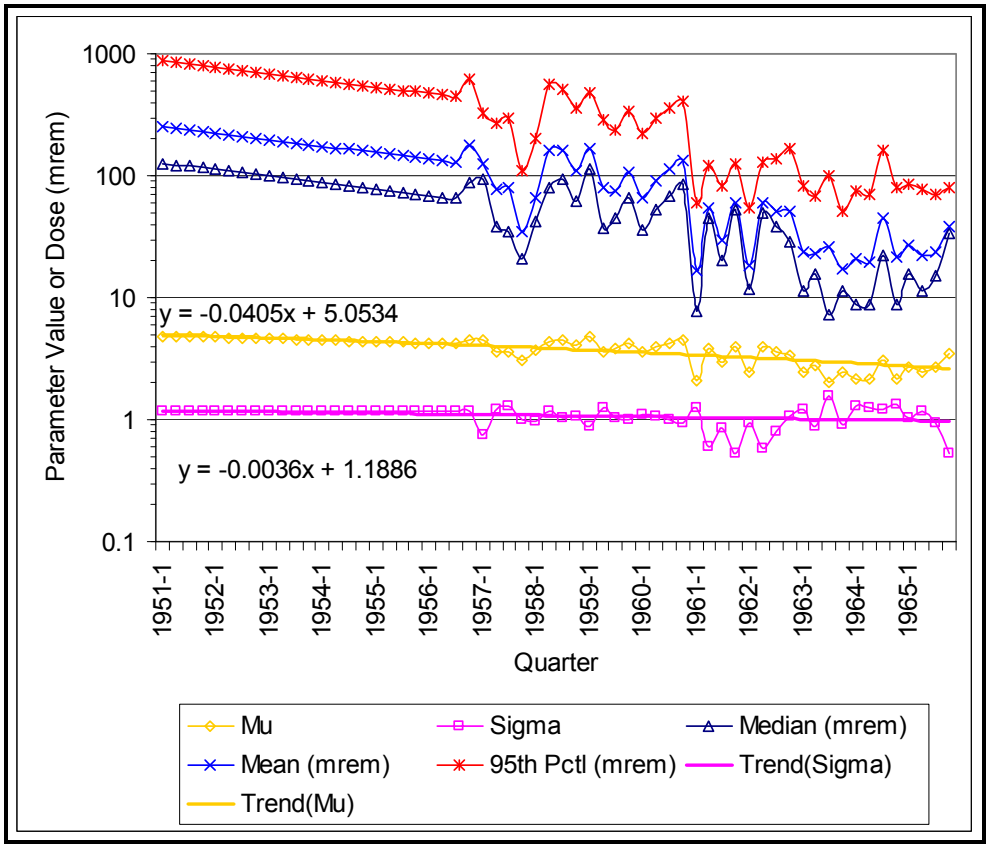


Figure 3.4-1: Estimated Coworker Lognormal Distribution Parameters Mu and Sigma with Trendlines, and Mean, Median, and 95th Percentile of the Dose Distribution, by Quarter

Note that a similar dip occurred in 1958, but dose levels quickly recovered. This suggests that the variability in measured dose levels was greater prior to 1961 than after, because a smaller number of workers were being monitored and the quarterly doses to these workers were more variable. The parameter values for the coworker lognormal distributions in the early years appear to be based on simple backward extrapolation of coworker distributions in later years. No

evidence is presented that this backward extrapolation is claimant favorable. Indeed, given the increased variability in the 1957 to 1961 time interval compared to post-1961, it is unlikely that the parameter values in the years before 1957 would be as uniform as indicated in Figure.

The derivation of coworker lognormal distributions for the early years is not a topic addressed in this document, only the derivation of worker-specific scaling factors. Despite the mathematically correct use of maximum likelihood methods for estimating the scaling factors, the constancy of the scaling factors over time and the application of such factors to possibly inappropriate distributions in the early years are not adequately addressed.

The product of the procedure is a set of scaling factors which are used to adjust the coworker distributions and assign a unique distribution to each worker in the unmonitored quarters.

Review Objective 7.3

Discontinuity at low and zero doses. The example provided on page 4 and completed on page 5 was very informative and helped to clarify the procedure. However, analyzing the example data in OTIB-0013, Table 2, and the y_t^o function which replaces y_t (the ln of recorded dose, d) when the recorded dose is zero as described on page 4 for use in determining the maximum likelihood estimate, φ,. indicates a discontinuity in the dose assignment function in the 0–10 mrem range. For example, if two identical workers were to receive the doses as listed in OTIB-0013, Table 2, with worker *A* receiving three zeros as listed in the "d" Column of the table and worker *B* receiving three 7-mrem doses instead of three zero-mrem doses, then according to the present dose assignment (using the y_t^o function if d = 0) for the 1st quarter of 1957, worker *A* would be assigned 151.4 mrem and worker *B* would be assigned 126.7 mrem; 16% less dose. A sample calculation shows that, in fact, worker *A* could receive ten zero doses and worker *B* could receive ten 7-mrem doses and worker *B* would receive a dose assignment 16% less than worker *A*, while, according to the records, worker *B* received 70 mrem more dose than worker *A* during the period 1961–1965. This could result in inequality in dose assignments for each year prior to 1961 that this method is used, i.e., a worker is penalized for having low doses recorded as opposed to zero readings. It should be noted that this problem diminishes as the recorded doses approach a significant fraction of the LOD value (however, increasing of the LOD as recommended in Section 3.2.1 of this report would extend the range of the problem). It should also be noted that PROC-0042 instructs the dose reconstructor to not use the scaling procedure if the scaling factor goes negative, which according to this analysis is caused by a large number of zeros or very low doses recorded. However, dose assignment inequality could still occur and this discontinuity in dose assignment methodology should be corrected.

3.4.4 Workbooks

The following workbook makes use of the correction factors derived in this OTIB and implemented in PROC-0042:

Y-12_Workbook CB_1951–1960 and CF After 1960 1.14.

Incorrect use of Scaling Factor terminology in Workbook, etc. There is a misuse of terminology that could result in incorrect dose assignment if the dose reconstructor is not

familiar with the intent of both OTIB-0013 and PROC-0042. This stems from using the term "scaling factor" interchangeably for φ and for e^{φ}. OTIB-0013 defines and uses the term "scaling factor" appropriately; however, the workbook and PROC-0042 do not. On page 4, OTIB-0013 defines the scaling factor: "The estimate of the scaling factor φ …", and on page 7 and 14, PROC-0042 defines the scaling factor: "The scaling factor, φ,…" However as pointed out in SC&A's recent review of PROC-0042, the term is incorrectly used when referring to e^{φ}. This occurs again in the workbook in the Lookup Parameters spreadsheet, Column CU, line 3 and lines 5–6. By the definitions quoted above, Phi in Column CS is actually the scaling factor φ; whereas Column CU, lines 5–7 are e^{φ}. Additionally, Column CU, line 3, should read "If scaling factor is >= 0 then we can use modeled data, else we must stop." Or, it could be changed to read "If $e^{(\text{scaling factor})}$ is >= 1 then we can use modeled data, else we must stop." and be correct; if modeled data refers to the data in Table 1 and the procedures in OTIB-0013 and PROC-0042. Also, Column CU, lines 5–6 should be changed to read "$e^{(\text{scaling factor})}$.

3.4.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-PROC-0042. 2004. *Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant Prior to 1961*, Rev. 00, September 9, 2004. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

ORAUT-OTIB-0013. 2004a. *Dose Adjustment Procedure for Y-12 Dose Reconstruction*, Rev. 00, September 9, 2004. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

ORAUT-OTIB-0015. 2004b. *Technical Information Bulletin: Bayesian Methods for Estimation of Unmonitored Y-12 External Penetrating Doses with a Time-dependent Lognormal Model*, Rev. 00, September 9, 2004. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

ORAUT-RPRT-0032. 2005. *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 1 – Gamma Radiation*, Rev. 00, April 13, 2005. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

ORAUT-TKBS-0014-6. 2003. *Technical Basis Document for the Y-12 National Security Complex – Occupational External Dosimet*ry, Rev. 00, November 19, 2003. Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee.

Watkins, J.P., G.D. Kerr, E.L. Frome, W.G. Tankersley, and C.M. West. 2004. *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee, Part 1 – Gamma Radiation*, ORAU Technical Report # 2004-0888.

3.5 ORAUT-OTIB-0015: BAYESIAN METHODS FOR ESTIMATION OF UNMONITORED Y-12 EXTERNAL PENETRATING DOSES WITH A TIME-DEPENDENT LOGNORMAL MODEL

The review of ORAUT-OTIB-0015, Rev. 00, dated September 9, 2004, was prepared by Ron Buchanan, PhD, CHP, and Harry Chmelynski, PhD.

3.5.1 Purpose of the Technical Information Bulletin

There is not a specific section that states the purpose of this OTIB. However, it does state in the introduction that this OTIB describes the Bayesian procedure in general, discusses Bayesian regression and prediction analysis of external penetrating dose data for Y-12 with a time–dependent lognormal model, and estimates a scale factor for imputation of unmonitored does for an individual.

3.5.2 Review Protocol

SC&A's evaluation of OTIB-0015 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.5-1: ORAUT-OTIB-0015 Review Outline/Checklist

Document No.: ORAUT-OTIB-0015, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Bayesian Methods for Estimation of Unmonitored Y-12 External Penetrating Doses with a Time-Dependent Lognormal Model	
Auditor: Ron Buchanan, PhD, CHP and Harry Chmelynski, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	N/A	

Table 3.5-1: ORAUT-OTIB-0015 Review Outline/Checklist

Document No.: ORAUT-OTIB-0015, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Bayesian Methods for Estimation of Unmonitored Y-12 External Penetrating Doses with a Time-Dependent Lognormal Model	
Auditor: Ron Buchanan, PhD, CHP and Harry Chmelynski, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	4	See Review Comments
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	4	See Review Comments
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?	1	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	

Table 3.5-1: ORAUT-OTIB-0015 Review Outline/Checklist

Document No.: ORAUT-OTIB-0015, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Bayesian Methods for Estimation of Unmonitored Y-12 External Penetrating Doses with a Time-Dependent Lognormal Model	
Auditor: Ron Buchanan, PhD, CHP and Harry Chmelynski, PhD	

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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	5	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	2	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	2	See Review Comments
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.5.3 Review Comments

Review Objective 1.1

Generally, OTIB-0015 is written in a style that is clear and unambiguous. However, one area that is lacking in detail is Section 2.1 on page 4 where the variables used in the equations are not defined, i.e., beta. The reader is required to refer to associated references, i.e., ORNL/TM-2004/146 (Frome and Watkins 2004), OTIB-0013, and/or PROC-0042 to analyze the equations.

Review Objective 3.2.1

Personal dosimeter and dosimetry data were adequately addressed, except in the following area:

- **Incorrect LOD value -** The OTIB was generally claimant favorable in the use of recorded or missing dosimetry data affecting dose estimates. However, on page 4 of the OTIB it assumes an LOD = 30 mrem for use in calculating scaling factor. However, ORAUT-TKBS-0014-6, page 12, Table 6.3.1-2 lists the *laboratory* LOD to be 40 mrem for 1948–1980. Additionally, the MDL values for dosimeters at Y-12 according to ORAU Technical Report 2004-0888 (Watkins et al. 2004) page 11, are reproduced below as Table.

Table 3.5-2: Minimum Detection Level (MDL) and Assigned MDL Doses* for Film Used to Measure Beta and Gamma Radiation Exposures at the Y-12 Plant

Period of time**	MDL	Assigned MDL
January 1948 to January 1950	30	30
January 1950 to January 1952	30	0
January 1952 to September 1952	50	50
September 1952 to January 1953	43	43
January 1953 to July 1954	50	50
July 1954 to July 1956	30	30
July 1956 to July 1961	30	15
July 1961 to October 1980	30	Not Applicable

* Doses in mrem.

** Dates are approximate because the changes did not occur for all employees at the same time

Source: Watkins et al. 2004, Table 3

Considering these larger documented values for LODs, the laboratory minimum LOD of 40 mrem should at least be used in this analysis.

Review Objective 3.2.4

The OTIB makes use of 40 quarters of coworker data for 1956 to 1965 in the last equation on page 4 and in the text in the latter part of page 4. However, according to ORAU Technical Report 2004-0888 (Watkins et al. 2004), the only data that are reliable for that period is the 4th quarter of 1956 through the 4th quarter of 1965, which is 37 quarters, not 40 quarters of data as used in OTIB-0015.

Review Objective 4.1

Prescriptive approach is included in the discussion of Review Objective 7.2.

Review Objective 7.1

The level of detail is included in the discussion of Review Objective 7.2.

Review Objective 7.2

The flow of material for the estimation of unmonitored external penetrating doses at Y-12 is:

- General statistical theory and formal development in TM-2004/146 (Frome and Watkins 2004) to
- Specific theory and formulation in OTIB-0015, to
- Y-12 application developed in ORAU Technical Report 2004-0888 (Watkins et al. 2004) and then to methodology specific to Y-12 in OTIB-0013, and finally to
- Dose reconstruction (DR) procedures and instructions in PROC-0042.

For a document to be useful to a DR it must contain some form of instructions, equations, data tables, correction factors, etc.; or some necessary information related to such items. However, OTIB-0015 contains no such items. It does not contain any prescriptive information, but it does contain levels of detail far more than is reasonable, needed, or desired, for DR. OTIB-0015 is not a technical instruction document as much as it is a specific statistical theory document and is not necessary for use, or as a reference, by dose reconstructors for correct DRs. The document in itself is well written and mostly correct (except as noted above), but the DR should not be burdened with reading and understanding this specific-theory document.

3.5.4 Workbooks

There are no workbooks involved with this OTIB. The workbook *Y-12_Workbook CB_1951–1960 and CF After 1960 1.14* eventually makes use of the results of the specific theory and formulation developed in this OTIB.

3.5.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

Frome, E., and Watkins, J. 2004. *Statistical Analysis of Data with Non-detectable Values*, ORNL/TM-2004/146, Oak Ridge National Laboratory: Oak Ridge, Tennessee.

ORAUT-OTIB-0013. 2004a. *Dose Adjustment Procedure for Y-12 Dose Reconstruction*, Rev. 00, September 9, 2004. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-OTIB-0015. 2004b. *Technical Information Bulletin: Bayesian Methods for Estimation of Unmonitored Y-12 External Penetrating Doses with a Time-dependent Lognormal Model*, Rev. 00, September 9, 2004. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-PROC-0042. 2004. *Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant Prior to 1961*, Rev. 00, September 9, 2004. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-TKBS-0014-6. 2003. *Technical Basis Document for the Y-12 National Security Complex – Occupational External Dosimet*ry, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 19, 2003.

Watkins, J., Kerr, G., Frome, E., Tankersley, W., and West, C. 2004. *Historical Evaluation of Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee, (Part 1 – Gamma Radiation)*, ORAU Technical Report 2004-0888, Oak Ridge Associated Universities: Oak Ridge, Tennessee.

3.6 ORAUT-OTIB-0021: EXTERNAL COWORKER DOSIMETRY DATA FOR THE X-10 SITE

The review of ORAUT-OTIB-0021, *External Coworker Dosimetry Data for the X-10 Site*, Rev. 01, dated November 7, 2006, was prepared by Ron Buchanan, PhD, CHP.

3.6.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0021 (ORAUT 2006) is to provide information to allow dose reconstructors to assign doses to workers at the X-10 site who have no or limited monitoring data, based on site coworker data. The data in this TIB are to be used in conjunction with ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Dose Assignment*. This document provides site coworker data and information that may be used only for cases not requiring best estimate calculations. Such cases include clearly non-compensable cases for which a higher external dose can be assigned than was likely to have been actually received, or clearly compensable cases for which a lower external dose can be assigned than was likely to have been actually received.

3.6.2 Review Protocol

SC&A's evaluation of OTIB-0021 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.6-1: ORAUT-OTIB-0021 Review Outline/Checklist

Document No.: ORAUT-OTIB-0021, Rev. 01	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Data for the X-10 Site	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	

Table 3.6-1: ORAUT-OTIB-0021 Review Outline/Checklist

Document No.: ORAUT-OTIB-0021, Rev. 01	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Data for the X-10 Site	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1–5*	Comments
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permitunforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as requiredunder the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	4	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	

Table 3.6-1: ORAUT-OTIB-0021 Review Outline/Checklist

Document No.: ORAUT-OTIB-0021, Rev. 01	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Data for the X-10 Site	
Auditor: Ron Buchanan, PhD, CHP	

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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.6.3 Review Comments

Review Objective 1.1

Generally, the OTIB was written in a fairly clear and unambiguous manner. However, some wording and errors contained in the text creates confusion and requires several rereads, and/or assumptions to be made, to clarify the issues. The following are the areas identified:

- Page 6, Section 4.0, Item # 1, states, "Revision 1 of this document provides site coworker data and information that may be used only for cases not requiring best estimate calculations." However, the last sentence states, "Revision 1 of this document will provide dose distributions and additional information based on the data presented herein to permit the processing of cases requiring a best estimate analysis." There may be an error in the last sentence of the paragraph; perhaps it should read "**Future revisions** of this document…"

- Page 6, Section 4.0, Items #3 and #4 contains identical text. Therefore, Item #4 needs to be deleted.

- Page 7, Section 6.0; the wording and intended significance of latter part of the first paragraph is unclear. It reads as follows:

> *Starting in 1961, the CEDR data are identified by quarter. Since the site implemented a quarterly badge exchange cycle for essentially all workers*

> *starting in the third quarter of 1956, these CEDR data are directly correlated to the X-10 site monitoring results.*

It is not obvious how it is correlated, and to what, and the significance of this correlation.

It goes on to state:

> *Prior to 1961, the CEDR data for X-10 typically include from one to three monitoring results each year for an individual. This is as indication that the result represents annual summaries of the quarterly or weekly (which was the typical exchange frequency prior to the third quarter of 1956) dosimetry data.*

If the exchange frequency was 4 (i.e., quarterly) to 50 (i.e., weekly) times per year then it is not clear how one to three entries each year would indicate an annual summary of this many monitoring periods.

At the end of the paragraph it states:

> *The fact that two or three results are associated with some individuals is an indication that dosimetry results from Oak Ridge sites other than X-10 (e.g., K-25 and Y-12) were included. It does not appear possible based on either the CEDR or CER data to separate the doses associated with the individual Oak Ridge sites prior to 1961; thus, these data should be used with caution by the dose reconstructors.*

It is not clear if this is the same one to three results referred to in the previous sentence or not, or how these results would indicate that the dosimetry results were from other Oak Ridge sites.

- Page 10, last sentence of the first paragraph, states the following:

> *Additionally, assigning beta dose as gamma dose in IREP has no negative effect because the radiation effectiveness factors are the same for >15 keV electrons and >250 keV photons, and are higher for both <30 keV photons and 30–250 keV photons.*

The meaning of the last part of this statement is unclear in its present form. After consulting reference OTIB-0060, February 6, 2007, it is assumed to mean the following:

> *Additionally, assigning beta dose as gamma dose in IREP has no negative effect because the radiation effectiveness factors (REF) are the same for >15 keV electrons and >250 keV photons, and the REFs are higher for <30 keV photons and 30–250 keV photons than they are for beta particles.*

Review Objective 1.2

The OTIB was written in a manner that presented the data in a logical sequence. However, Section 8.0, page 11, of this OTIB does not provide any details concerning the data contained in Table 3, but instead makes a reference to OTIB-0052 (ORAUT 2006). OTIB-0052, page 32, Section 8.2, explains that the total dose is equal to 1.4 x recorded dose, plus the coworker missed dose. However, an analysis of the data in Table 3 of OTIB-0021 shows that it is more complex than this simple statement. The data entries in Table 3 depend how the data in Table 2 were derived, i.e., if the non-zero coworkers' dose were greater than the coworkers' dose, including zeros plus ½ LOD from Table 1 or the other way around (this can be different for the different percentiles within a given year). This comparison is made in Section 7.0, page 9, Step #3 of OTIB-0021, but not incorporated into Section 8.0 to assist the DR in understanding the contents of Table 3 for Construction Trade Workers (CTW). Some of the entries in Table 3 were spot checked by SC&A and verified as derived from one of the two prescribed methods. However, not all entries in Table 3 reflect values derived from either of the two methods. For example, the entry in Table 2 for 1950 for the 99th percentile is 3.113 rem; therefore [1.40 × 3.113 = **4.358**] or [(3.113 - 0.780 missed dose) × 1.40 + 0.780 = **4.046**] should appear in Table 3 at the 99th percentile for 1950, but the entry in Table 3 is ***4.172*** rem, neither of these derived numbers. For 1950, the entry in Table 3 for the 95th percentile is 2.246 (i.e., 1.40 × 1.604 = 2.246) and the entry in Table 3 for the 50th percentile is 0.780 rem (i.e., (0.780 - 0.780) × 1.40 + 0.780 = 0.780 rem), which appears to be correctly derived by one of the two methods. The 99th percentile value for 1955 is another example where the entry in Table 3 does not appear to be derived from Table 2 by use of either of the two stated methods.

This could cause confusion or incorrect dose assignment for CTWs if the DR expected, or automatically assigned, doses to an unmonitored CTW that were simply 1.4 × the data entries in Table 2.

Review Objective 1.3

Most of the data needed to follow the prescribed steps were contained in this OTIB. However, the footnote of Table 1, page 8, informs the DR that the LOD values for low-energy beta are not reliable. It then goes on to state that the X-10 TBD should be reviewed to *identify* such potential exposure scenarios. However, it does not inform the DR how to handle these low-energy beta exposures once they are identified.

Review Objective 5.2

Section 7.0, page 9, Item #1, describes the database from which the coworker dose data were obtained. It explains how the partial-year doses were extrapolated. However, the last sentence makes the statement, "Prior to 1961, reported doses were not extrapolated since the reported values apparently represented doses received during the entire year." The assumption that the annual recorded doses prior to 1961 represented an entire year of monitoring is not supported. In fact, there would have been the normal partial years of monitoring/employment that would make the average annual recorded dose somewhat less than the dose that would have been received in a full 12-month period. The recorded doses prior to 1961 would need to be adjusted by an

average monitoring period factor, such as 12/11 if the average employment/monitoring period was 11 months, etc.

3.6.4 Workbooks

The external coworker dose data for the X-10 site contained in the DR tool entitled *Complex Wide CoWorker Data 1.10* was compared to the data in Table 2 of this OTIB. The values of the data were the same in both documents.

3.6.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0020. 2004. *Use of Coworker Dosimetry Data for External Dose Assignment*, Rev. 00, December 29, 2004. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-OTIB-0021. 2006. *Technical Information Bulletin: External Coworker Dosimetry Data for the X-10 Site*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 7, 2006.

ORAUT-OTIB-0052. 2006. *Technical Information Bulletin: Parameters to Consider When Processing Claims for Construction Trade Workers*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. August 31, 2006.

ORAUT-OTIB-0060. 2007. *Technical Information Bulletin: Internal Dose Reconstruction*, Rev. 00, Oak Ridge Associated Universities Team (ORAUT): Oak Ridge, Tennessee. February 6, 2007.

3.7 ORAUT-OTIB-0026: EXTERNAL COWORKER DOSIMETRY DATA FOR THE K-25 SITE

The review of ORAUT-OTIB-0026, *External Coworker Dosimetry Data for the K-25 Site*, Rev. 00 PC-2, dated November 15, 2006, was prepared by Harry J. Pettengill, PhD, and supported by Joe Zlotnicki, PhD.

3.7.1 Purpose of the Technical Information Bulletin

The purpose of this OTIB is to provide information to allow ORAUT dose reconstructors to assign doses to workers at the Oak Ridge Gaseous Diffusion Plant (K-25) who have no or limited monitoring data, based on site coworker data. The data in this OTIB are to be used in conjunction with ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Dose Assignment*.

3.7.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0026 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the OTIB adequately supports the dose reconstruction process, as described in this report.

Table 3.7-1: ORAUT-OTIB-0026 Review Outline/Checklist

Document No.: ORAUT-OTIB-0026, Rev. 00 PC-2	**Effective Date:** 11/15/2006
Document Title: External Coworker Dosimetry Data for the K-25 Site	
Auditor: Harry J. Pettengill, PhD and Joe Zlotnicki, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
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?	4	See Review Comments
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

Table 3.7-1: ORAUT-OTIB-0026 Review Outline/Checklist

Document No.: ORAUT-OTIB-0026, Rev. 00 PC-2	**Effective Date:** 11/15/2006
Document Title: External Coworker Dosimetry Data for the K-25 Site	
Auditor: Harry J. Pettengill, PhD and Joe Zlotnicki, PhD	

No.	Description of Objective	Rating 1–5*	Comments
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	4	See Review Comments
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	4	See Review Comments
3.2.4	Unmonitored periods of exposure	4	See Review Comments
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?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	4	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	4	See Review Comments
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.7.3 Review Comments

Review Objectives 1.2, 1.3, 1.5, and 2.1

A concern arises in the guidance provided to dose reconstructors (DR) in Section 7, item 5. (OTIB-0026, page 8). The use of professional judgment is recommended. The DR is required to determine whether a worker was in one of the following three categories:

> *…unlikely to have been exposed…*, or
> *…Exposed to intermittent low levels of radiation…*, or
> *…routinely exposed…*

Based on the DR's judgment, a choice is made to use the on-site ambient dose, the 50th percentile, or 95th percentile as a best estimate of the workers' dose. This is contrary to the requirement for dose calculations to follow a prescriptive approach. This concern is discussed in detail in the SC&A report, *The Review of NIOSH/ORAU Procedures and Methods Used for Dose Reconstruction, Supplement 1* (SC&A 2006). The OTIB should develop a more detailed prescriptive approach to this issue that enables the DR to categorize the worker without the routine need for personal judgment.

Review Objectives 3.2.1 through 3.2.4

Until approximately 1980, few of the dosimeters issued at the K-25 site were processed. Thus the coworker data that is developed in OTIB-0026 is significant and will play a role in the dose determination for many workers.

The doses that are assigned in the database are based on a composite of limited measurements and an assignment of the LOD/2 entered in place of missing or null results as required in OTIB-0020. As discussed in the external dosimetry section of the site profile review report, it is not entirely clear when and how dosimeters were pulled for processing. Thus the entire database for coworkers is based to a great extent on an unknown group of (presumably) higher exposure individuals, coupled with a large component attributable to the LOD/2.

Review Objectives 4.1 and 7.1 thru 7.3

There is a concern with the development of the shallow dose table (Table 2, OTIB-0026): The process of deriving the data for the table resulted in zero values for the non-penetrating component of dose for 19 of the 41 years the table addresses. The OTIB describes the issue as:

> *…With the methodology described above, null values for non-penetrating dose can occur because of the subtraction of the reported penetrating doses from the reported shallow doses and the favorable to claimant method described above to establish coworker doses based on the addition of potential missed doses. However, a "zero" value in Table 2 for non-penetrating dose will not result in a dose of zero being assigned to an organ such as the skin. For example, the 50th percentile dose to the skin in 1948 would be assigned entirely as 0.780 rem of photons. This approach does not result in an underestimation of probability of*

> *causation (which is determined by the Department of Labor) because assigning beta dose as gamma dose in IREP has no negative effect, since the radiation effectiveness factors are the same for >15 keV electrons and >250 keV photons, and are higher for 30–250 keV photons.* [OTIB-0026, pg. 10]

This issue is dismissed as unimportant, as it is stated that IREP will automatically assign the penetrating dose to the non-penetrating input. This may well be technically appropriate at the present time. However, surely this assumption would collapse were NIOSH to modify IREP in the future and change this particular programming rule. Consideration should be given to modifying the table to ensure that a modification of IREP does not inadvertently cause the system to fail with regard to non-penetrating dose calculations. In this reviewer's opinion, the reliance on the current design of a software program as a method of ensuring the accuracy of input data from a very different component of the overall dose reconstruction system is a weak quality link.

3.7.4 Conclusions

There are two areas where the OTIB will provide a significantly claimant-favorable approach. First, as discussed in the final paragraph of section 7.0 of the TIB, the annual doses show a marked decline once actual dosimetry results are used in place of estimates. Although doses might be expected to decline slightly when dosimeter processing is first ramped up due to increased worker and management awareness, the reduction by factors ranging by 5 to 10 signify that the estimates were crafted conservatively.

The second area where a conservative approach has been taken is in the use of the system wide modifying factor for construction workers as laid out in OTIB-0052 and incorporated in the November 2006 version of OTIB-0026. This OTIB reviewed a number of sites and a system wide adjustment factor of 1.4 was adopted for construction workers. This is claimant favorable for K-25, which was a selected site for the review. The data shows that the construction worker doses were bounded by the total worker dose for every year of K-25 operation except one. Thus for all other years, the coworker dose assigned for construction trades will automatically be increased by a factor of 1.4, despite the fact that the data shows that this is not required for K-25.

3.7.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0020. 2005. *Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 7, 2005.

ORAUT-OTIB-0026. 2006. *Technical Information Bulletin: External Coworker Dosimetry Data for the K-25 Site*, Rev. 00 PC-02, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 15, 2006.

ORAUT-OTIB-0052. 2007. *Parameters to Consider When Processing Claims for Construction Trade Workers*, Rev. 00 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 16, 2007.

SC&A 2006. *Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-TASK3 Supplement 1, Rev. 0, Draft Report, June 8, 2006. S. Cohen and Associates, McLean, Virginia.

3.8 ORAUT-OTIB-0027: SUPPLEMENTARY EXTERNAL DOSE INFORMATION FOR ROCKY FLATS PLANT

The review of ORAUT-OTIB-0027, *Supplementary External Dose Information for Rocky Flats Plant*, Rev. 00, dated May 19, 2005, was prepared by Ron Buchanan, PhD, CHP.

3.8.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0027 is to supplement the information given in ORAUT-TKBS-0011-6, *Technical Basis Document for the Rocky Flats Plant - Y-12 - Occupation External Dosimetry*, Rev. 00, and ORAUT-TKBS-0011-4, *Technical Basis Document for the Rocky Flats Plant – Y-12 - Occupation Environmental Dosimetry*, Rev. 01. This OTIB provides additional information for calculating dose from low-energy photons and electrons, and dosimetry uncertainty factors.

3.8.2 Review Protocol

SC&A's evaluation of OTIB-0027 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.8-1: ORAUT-OTIB-0027 Review Outline/Checklist

Document No.: ORAUT-OTIB-0027, Rev. 00	**Effective Date:** 05/19/2005
Document Title: Supplementary External Dose Information for Rocky Flats Plant	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	

Table 3.8-1: ORAUT-OTIB-0027 Review Outline/Checklist

Document No.: ORAUT-OTIB-0027, Rev. 00	**Effective Date:** 05/19/2005
Document Title: Supplementary External Dose Information for Rocky Flats Plant	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1–5*	Comments
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	1	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.8.3 Review Comments

Review Objective 1.1

The procedure was written in a fairly clear and unambiguous manner. However, some of the errors contained in the text create confusion and require several rereads to clarify the issues. The following are the errors identified:

- Page 5, Section 1.0 – *Occupational External Dosimetry (Rev. 01)* should read *Occupational Environmental Dose (Rev. 01)*.

- Page 5, Section 2.0 – First paragraph, 5th line, is it correct to assume that the word "they" refers to the gloves; as opposed to material, windows, etc., pulled outside for storage?

- Page 5, Pre-1960 – First paragraph, 5th line, should read "as a sum of each of the two windows (OW + CD)"; not "as the sum of each of the three windows (OW + CD + BR)," because BR was not present in this era of dosimeters.

- Page 5, Pre-1960 – First paragraph, next to the last line, should read "contribution was," not "contribution is was."

- The change from film to TLDs most likely did not take place all at once, but the OTIB contains inconsistencies in the year that film was discontinued and TLDs started. The text on page 6 states around 1970, however, Table 4-1 on page 7 lists 1969 for photons and 1968 for electrons. The change-over date for photons and electrons should be the same, and agree with the text.

- Page 8, Table 4-2 lists the period for Panasonic TLD for photons as *1983–1998*. Most likely this should read *1983–2003* to agree with the rest of the data in the table.

The procedure goes into some details concerning the past and then the presently recommended methods to be used for calculating non-penetrating and penetrating doses from recorded doses for each of the three time periods. It would be useful, and may help to prevent misunder-standing, if a summary table of presently recommended methods was provided for quick reference at the end of Section 2.0.

Review Objective 1.5

In general, the procedure is prescriptive and eliminates the need for subjective decisions or data interpretation on the part of the DR. However, several statements are made that could leave the DR without a clear course of action. Twice on page 6 it is stated that "Alternatively, if original component data is available in the dosimetry record, Pen and Skin doses can be calculated using CD, BR and OW results and the equations above." This is a true statement, but it is most likely unrealistic for a DR to perform these very time-consuming and possibly error-prone data manipulations.

Review Objective 5.2

The procedure is generally claimant favorable, but a situation could arise that leaves the DR without definite directions when there is an unknown parameter that could affect dose estimates. Twice on page 6 and once on page 7, the statement is made, "Using these equations and available knowledge of source material (e.g., plutonium, enriched or depleted uranium) spectra,…" where knowledge of source material is referring to the data in Table 2-1. However, the DR is not provided with what is the most claimant-favorable default source material to use if the worker's source material is unknown.

Review Objective 6.1

Pages 7 and 8 of the OTIB provide uncertainty factors for photon, neutron, and electron doses for different time periods at RFP. However, there is no mention of the appropriate probability distributions to use in the IREP Input, which would be a "constant" for measured doses.

3.8.4 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-TKBS-0011-4. 2004b. *Technical Basis Document for the Rocky Flats Plant - Y-12 - Occupation Environmental Dosimetry*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. June 29, 2004.

ORAUT-TKBS-0011-6. 2004a. *Technical Basis Document for the Rocky Flats Plant - Y-12 - Occupation External Dosimetry*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 20, 2004.

ORAUT-OTIB-0027. 2005. *Supplementary External Dose Information for Rocky Flats Plant*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 19, 2005.

3.9 ORAUT-OTIB-0029: INTERNAL DOSIMETRY COWORKER DATA FOR Y-12

The review of ORAUT-OTIB-0029, *Internal Dosimetry Coworker Data for Y-12*, Rev. 00, dated April 5, 2005, was prepared by Joyce Lipsztein, PhD.

3.9.1 Purpose of the Technical Information Bulletin

The stated purpose of OTIB-0029 is to provide detailed calculations and an assignment of intakes to energy employees who, for a variety of reasons, were not monitored for internal exposure or whose records of such monitoring are incomplete or unavailable, based on coworker data from the Y-12 Site.

3.9.2 Review Protocol

SC&A's evaluation of OTIB-0029 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.9-1: ORAUT-OTIB-0029 Review Outline/Checklist

Document No.: ORAUT-OTIB-0029, Rev. 00	**Effective Date:** 04/05/2005
Document Title: Internal Dosimetry Coworker Data for Y-12	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	3	See Review Comments
3.2.3	Missing dosimetry data	2	
3.2.4	Unmonitored periods of exposure	2	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	

Table 3.9-1: ORAUT-OTIB-0029 Review Outline/Checklist

Document No.: ORAUT-OTIB-0029, Rev. 00	**Effective Date:** 04/05/2005
Document Title: Internal Dosimetry Coworker Data for Y-12	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	
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)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.9.3 General Comments

OTIB-0029 states the following:

> *Bioassay results were obtained from the Oak Ridge Institute for Science and Education (ORISE) Center for Epidemiologic Research (CER) Dosimetry Database, which contains uranium urinalysis records from the Y-12 site for 1950 to 1988. The database results are in units of disintegrations per minute (dpm)/day, although original urinalysis results were reported in terms of either mass or activity concentrations, depending on the measurement method. The assumptions used to convert mass results to activity concentrations for inclusion in the database are not known, nor are the assumptions used to normalize spot sample results to 24 hours.* (OTIB-0029, pg. 3)

In OTIB-0029, two sequential fitting approaches were used to interpret the urinalysis bioassay data. The first one grouped the bioassay monitoring data by quarter or year, depending on the amount of data available during the periods. A lognormal distribution was assumed as the best

representation of all RFP workers' bioassay results during a certain period of time. After log transforming the data, the 50th and 84th percentiles were determined for each period of time. The second approach consisted of the derivation of an inhalation intake function that would reproduce the 50th and 84th percentiles bioassay values that were calculated using the first approach.

As explained in OTIB-0029:

> *The IMBA Expert OCAS-Edition computer program was used to fit the bioassay results to a series of inhalation intakes. … Data from January 1952 through December 1988 were fit as a series of chronic intakes.*
>
> *The initial intake assumptions were based on periods that coincided with major operations on the site. The years 1947 to 1951 had very specific operations and were therefore modeled as one intake period. However, the bioassay data had some distinct patterns, so the intake dates were adjusted to obtain a better approximation of the data. There appeared to be low-level chronic intakes of uranium throughout long periods, with briefer, larger intakes superimposed on them. To model this pattern, three long-term chronic exposures were assumed to cover 1947 through 1988. Five shorter chronic exposures were modeled on top of the early period to account for the intermittent rises in the urine results.* [OTIB-0029, pg. 4]

Exposures to Type M or Type S uranium compounds were assumed, for the derivation of intakes using the IMBA fit to the urinalysis data. Intakes were assumed to be via inhalation using a default breathing rate of 1.2m^3/h and a 5-µm AMAD particle size distribution.

Contributions from contaminants in recycled uranium, including plutonium, Np-237, and Tc-99, must be added to the uranium dose, according to information contained in ORAUT-TKBS-0014-5, about intake values relative to the uranium intake amounts.

3.9.4 Review Comments

Review Objectives 1.1 through 1.4

Our review has identified that the document references and uses data from documents that need to be known, in order to understand the procedures described.

The OTIB is consistent with all other OTIBs and procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. OTIB-0029 is sufficiently prescriptive to minimize the need for subjective decisions.

Review Objectives 3.2.2, 3.2.3, and 3.2.4

OTIB-0029 is meant to address site-specific data pertaining to in-vitro bioassay data, missing dosimetry data, and unmonitored periods of exposure. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 5.1, 5.2, and 5.3

OTIB-0029 is meant to assign doses for employees at DOE sites that were not monitored for internal ionizing radiation exposure or the records of such monitoring are incomplete or unavailable. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objective 6.1

Although it provides adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal), OTIB-0029 does not adequately account for the uncertainty of doses estimates, as described in the Review Objective 7.3 comments.

Review Objective 7.3

The SC&A review of OTIB-0029 revealed at least six areas of concerns with the validity of the scientific protocols that were employed. These concerns are presented below:

(1) Database

The ORISE CER database of uranium urinalysis records for the Y-12 site for 1950–1988 was used, without questioning the accuracy of these records. The records were used despite the problems pointed out on page 3 of ORAUT-OTIB-0029:

> *The database results are in units of disintegrations per minute (dpm)/day, although original urinalysis results were reported in terms of either mass or activity concentrations, depending on the measurement method. The assumptions used to convert mass results to activity concentrations for inclusion in the database are not known, nor are the assumptions used to normalize spot sample results to 24 hours.*

(2) Choice of the Lognormal Distribution and the 50th Percentile Intake Rates

Bioassay results were obtained from the ORISE Center for Epidemiologic Research (CER) Dosimetry Database, which contains uranium urinalysis records from the Y-12 site for 1950 to 1988 (ORAUT-OTIB-0029, page 3). The urine records from the database were analyzed by month and were fit into a lognormal distribution. The 50th and 84th percentiles were calculated for each month.

The intake rates were calculated using the IMBA Expert OCAS-Edition computer program. Intakes were assumed to be chronic exposures via inhalation. The monthly bioassay results were used to obtain a series of inhalation intakes. *Doses to be assigned to individuals are calculated from the 50th-percentile intake rates.*

There is no explanation on the choice of the 50th percentile. Monthly urinary results from Y-12 workers, from 1952 to 1988, were characterized by NIOSH as being typical of a lognormal distribution. As expected with data that can be modeled by a lognormal distribution, the urine activity results must be positively skewed, for each month, during 26 years. SC&A does not

agree with the choice of the 50th percentile to characterize the non monitored worker's intake from coworker data as a claimant-favorable approach. A more appropriate claimant-favorable assumption is to use the upper percentiles activity urine results to calculate intake rates and doses.

The last 10 years of the Table A-1 (page 11 of 21), for example, are characterized by 50th percentile values below the detection limits for natural uranium (11dpm/d), showing that the majority of the data were below detection limits. The high value of the geometric standard deviation, on the other hand, is a hint to the fact that the positive values probably are much higher than the detection limits. The intake rates as derived for March 1, 1978–September 30, 1984, and from October 1, 1984–December 31, 1988, are very small, and lead to equivalent doses to body tissues and organs that are also insignificant. This is clearly a non claimant-favorable approach, since many of the workers presented high urine activity concentrations, as a consequence of high intakes of uranium. As the high results are consistently measured, every month (each month results are characterized by the positively skewed lognormal distribution), one can conclude that contamination was happening regularly at Y-12. Even for Type S uranium, whose excretion rate decreases very slowly, the conclusion stays the same. The contribution of 1-month chronic exposure to the activity of a urine sample collected at the end of the following month does not justify the results on Table A-1. The uranium activity of Type S compounds in urine samples taken 1-month post exposure are expected to be 5 to 10 times lower than post-weekend samples taken during the month of chronic exposure. Thus the existence of a lognormal distribution every month, with the parameters described in Table A-1, leads to the conclusion of regular, monthly exposures at Y-12. SC&A considers that the claimant-favorable approach to workers that were not monitored is to consider them exposed to the higher level of contamination that was characteristic of Y-12.

(3) Post-weekend sampling:

ORAUT-OTIB-0029 assumes that, "Because of the nature of work at Y-12, a chronic exposure pattern best approximates the true exposure conditions for most workers with a potential for intakes."

A chronic constant intake was assumed by NIOSH. Results were interpreted without considering that samples were taken *Monday morning before entering the working area. That is, routine samples were submitted after a minimum of 48-hr absence from the work area* (ORAUT-TKBS-0014-5). At Y-12 *the primary urine collection method was a spot sample submitted Monday morning before entering the work area……* (ORAUT-TKBS-0014-5)

Intakes were back calculated from urine results, by fitting bioassay results for different periods. NIOSH did not consider the 48-hour absence from work and, as a result, the intake rates derived on ORAUT-OTIB-0029 are lower than if they were calculated using the same data, but considering Monday morning excretion samples.

The interpretation of bioassay results for chronic exposures of workers should take into consideration the day of the week on which samples are taken. In this way the short-term components associated with lung clearance will be accounted for, since the early clearance component(s) of excretion may introduce a significant difference before and after an interruption

in exposure, e.g., the weekend. For uranium exposures, the 48-hour waiting period prior to submitting urine samples is particularly relevant.

NIOSH did not use the fact that urine samples were collected on a Monday morning, after a minimum of 48-hours absence from the work area. The model used by NIOSH was a chronic constant daily intake of uranium. SC&A has compared intake rates of uranium obtained from urine samples collected (1) during continuous intake (as was assumed by NIOSH) and (2) on a Monday, 2 days after continuous intake paused due to the weekend. SC&A has concluded that the approach taken by NIOSH is not claimant favorable. For example, after 1 year of exposure, the same amount of uranium excreted in urine will generate daily intake rates, using the NIOSH intake model, that are as follows:

- For Type F compounds, 4.3 times lower than if samples were assumed to be taken after the weekend
- For Type M compounds, 2.2 times lower than if samples were assumed to be taken after the weekend
- For Type S compounds, 2 times lower than if samples were assumed to be taken after the weekend

It is not clear how many working days per year were used by NIOSH, and there is no hint on what was the working schedule of the Y-12 personnel. Even if one assumes that NIOSH conservatively considered 7 days a week exposure, instead of 5 or 6 days a week exposure, the NIOSH model still will underestimate the annual exposure by:

- For Type F compounds, 3 times for workers on 5 days per week schedule and 3.7 for workers on 6 days per week schedule
- For Type M compounds, 1.6 times for workers on 5 days per week schedule and 1.9 for workers on 6 days per week schedule
- For Type S compounds, 1.5 times for workers on 5 days per week schedule and 1.7 for workers on 6 days per week schedule

SC&A has included Type F compounds in the comparison, because workers at Y-12 were exposed to soluble forms of uranium, classified as absorption Type F by the ICRP. In ORAUT-TKBS-0014-5, the following is reported:

> *The uranium compounds with which Y-12 has worked ranges from highly soluble to very insoluble. …. Exposures to soluble compounds were monitored from the closing days of World War II by clinical tests of renal function and by fluorimetric tests for uranium in urine.*

SC&A recommends that the intake rates should be recalculated using the fact that urine samples were collected after a minimum of 48-hours absence from the work area.

(4) Material Types:

Uranium urine results were fit using Type M and Type S material. Exposures to Type F material was not considered, although in document ORAUT-TKBS-0014-5 it is specifically reported that workers were exposed to uranium compounds of different solubility, including soluble material. For example on item 5.2 of ORAUT-TKBS-0014-5, it is reported that:

> *The uranium compounds with which Y-12 has worked ranges from highly soluble to very insoluble. …. Exposures to soluble compounds were monitored from the closing days of World War II by clinical tests of renal function and by fluorimetric tests for uranium in urine.*

The interpretation of results from urinary excretion of uranium Type F materials, after 48-hours absence from work, produce intake rates that result in doses that can be, depending on the time of exposure, for many organs (most of the systemic organs) higher than if Type M or S were used.

Figure, below, is used to illustrate these findings. It was calculated for a worker exposed for 1 year to chronic constant daily intakes. The 1-year committed equivalent doses to the different organs, per Bq U-234 excreted after the weekend at the end of the working year, is shown. Thus, assumptions for the values on Figure are:

> Years of Exposure to U-234: 1 year
> Post-weekend urine sample collected on the last month of the 1st year
> Equivalent Doses calculated for the 1st year after the beginning of work

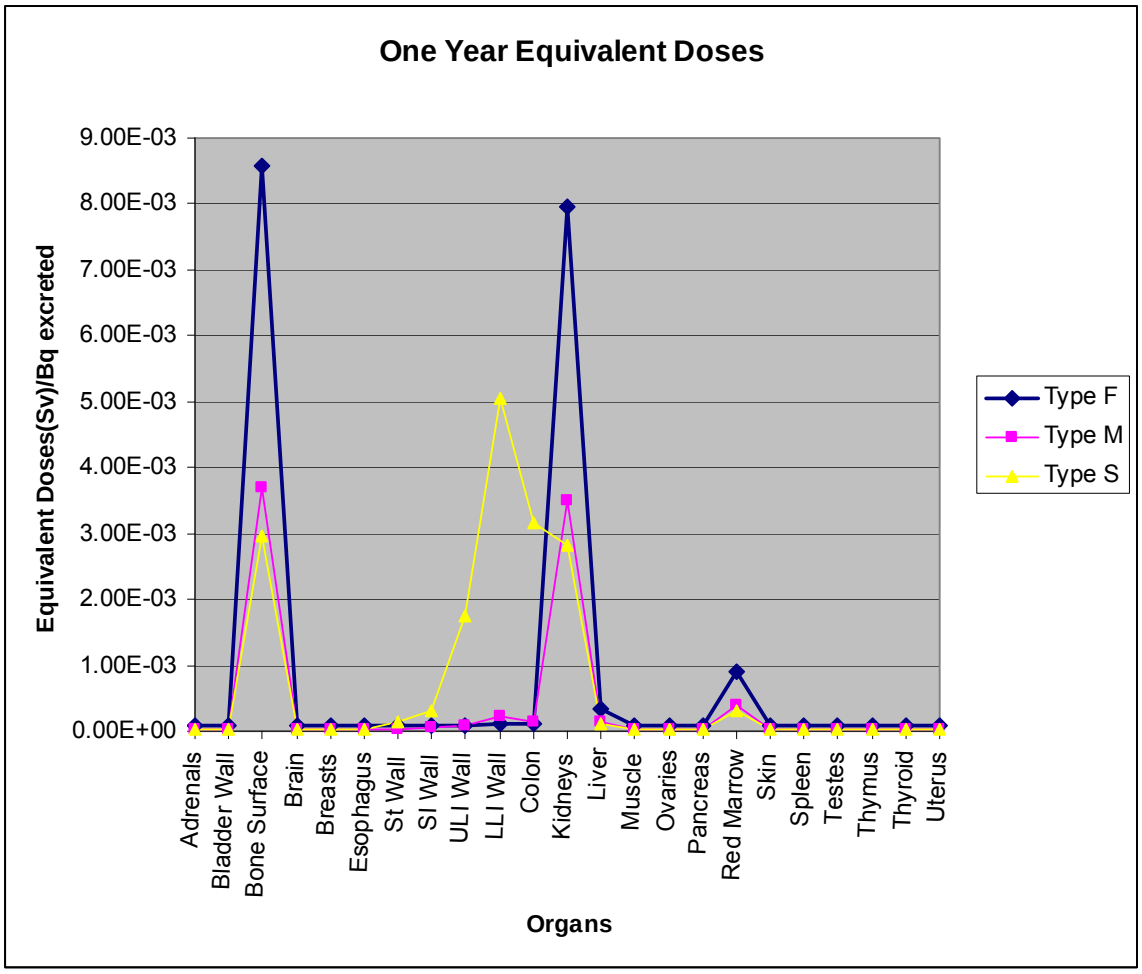


Figure 3.9-1: 1-Year Doses, Excluding the Respiratory Tract

SC&A finds that the assumption that doses should be assigned based on exposures to uranium compounds of solubility Types M and S, without considering Type F compounds, not claimant favorable for many cancer sites. This assumption does not follow instructions given in 42 CFR 82. The 42 CFR 82, specifically states that:

> *…, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process.*

3.9.5 Conclusions

SC&A examined OTIB-0029, the coworker model for internal dose assessment for Y-12, in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. SC&A accepts NIOSH's position that it is possible to derive a surrogate exposure model for the unmonitored worker based on the distribution of internal doses received by the monitored workers at Y-12. However, the use of a

model based on the 50th percentile of the excretion rates of the workers, may misrepresent the higher exposures experienced by unmonitored workers at Y-12.

OTIB-0029 proposed intakes for uranium should be redone taking into consideration that samples at Y-12 were collected after the weekend. Assigned intakes should include Type F uranium compounds.

3.9.6 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-TKBS-0014-5. 2006. *Technical Basis Bulletin: Y-12 National Security Complex – Occupational Internal Dose*, Rev. 02 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 10, 2006.

ORAUT-OTIB-0029. 2005. *Internal Dosimetry Coworker Data for Y-12*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. April 5, 2005.

3.10 ORAUT-OTIB-0030: EXTERNAL COWORKER DOSIMETRY DATA FOR THE HANFORD SITE

The review of ORAUT-OTIB-0030, *External Coworker Dosimetry Data for the Hanford Site*, Rev. 00, dated November 7, 2006, was prepared by Ron Buchanan, PhD, CHP.

3.10.1 Purpose of the Technical Information Bulletin

The purpose of this OTIB is to provide information to allow ORAUT dose reconstructors to assign doses to workers at the Hanford Site who have no or limited monitoring data, based on site coworker data. The data in this OTIB are to be used in conjunction with ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Dose Assignment*.

3.10.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0030 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.10-1: ORAUT-OTIB-0030 Review Outline/Checklist

Document No.: ORAUT-OTIB-0030, Rev. 00	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Data for the Hanford Site	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	

Table 3.10-1: ORAUT-OTIB-0030 Review Outline/Checklist

Document No.: ORAUT-OTIB-0030, Rev. 00	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Data for the Hanford Site	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1–5*	Comments
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.10.3 Review Comments

Review Objective 1.2

OTIB-0030 was written in a manner that presented the information in a logical sequence. However, Section 8.0, page 8, of this OTIB does not provide any details concerning the data contained in Table 3, except to make a reference to OTIB-0052. OTIB-0052, page 32, Section 8.2, explains that the total dose to be assigned to Construction Trade Workers (CTWs) is equal to 1.4 × recorded dose, plus the coworker missed dose. However, an analysis of the data in Table 3 of OTIB-0030 shows that it is more complex than this simple statement. The data entries in Table 3 depend how the data in Table 2 were derived, i.e., if the non-zero coworkers' dose were greater than the coworkers' dose including zeros plus ½ LOD from Table 1, or if it was the other way around (this can be different for the different percentiles within a given year). This comparison is made in Section 7.0, page 7, Step #4 of OTIB-0030, but not incorporated into Section 8.0 to assist the DR in understanding the contents of Table 3 for CTWs. Some of the entries in Table 3 were spot checked by SC&A and verified as derived from one of the two prescribed methods. However, not all entries in Table 3 reflect values derived from either of the

two methods. For example, the entry in Table 2 for 1956 for the 95th percentile is 2.306 rem; therefore either [1.40 × 2.306 = **3.228**] or [(2.306 – 0.650 missed dose) × 1.40 + 0.650 = **2.968**] should appear in Table 3 at the 95th percentile for 1956, but the entry in Table 3 is ***3.076*** rem, neither of two derived numbers. For 1956, the entry in Table 3 for the 99th percentile is 4.421 [i.e., (3.344 – 0.650) × 1.40 + 0.650 = 4.421] and the entry in Table 3 for the 50th percentile is 0.695 rem [i.e., (0.682 – 0.650) × 1.40 + 0.650 = 0.695 rem] which appears to be correctly derived by one of the two methods. The 99th and 50th percentile values for 1959 are another example where the entry in Table 3 does not appear to be derived from Table 2 by use of either of the two stated methods.

This could cause confusion or incorrect dose assignment to CTWs, if the DR expected or automatically assigned doses to an unmonitored CTW that were simply 1.4 x the data entries in Table 2.

Review Objective 1.3

The OTIB generally provided the data needed and/or the appropriate references. However, on page 8, last part of the first paragraph, it is stated that "…and non-penetrating doses are assigned as electrons >15 keV with corrections applied to account for clothing attenuation or other applicable considerations…" The OTIB does not provide the DR with data, or reference to specific OTIBs or procedures from which information can be obtained, with which to make these corrections for clothing or other applicable considerations. Additionally, no explanation or examples are provided on what might constitute *other applicable considerations*.

This situation could lead to each DR having to expend resources to locate the necessary information, and could also result in inconsistency among the different DRs.

3.10.4 Workbook

The external coworker dose data for the Hanford site contained in the DR tool entitled *Complex Wide CoWorker Data 1.10* was compared to the data in Table 2 of this OTIB. The values of the data were the same in both documents.

3.10.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0020. 2004. *Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 29. 2004.

ORAUT-OTIB-0030. 2006. *Technical Information Bulletin: External Coworker Dosimetry Data for the Hanford Site*, Rev. 00 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 7, 2006.

ORAUT-OTIB-0052. 2006. *Technical Information Bulletin: Parameters to Consider When Processing Claims for Construction Trade Workers*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. August 31, 2006.

3.11 ORAUT-OTIB-0032: EXTERNAL COWORKER DOSIMETRY DATA FOR THE SAVANNAH RIVER SITE

The review of ORAUT-OTIB-0032, *External Coworker Dosimetry Data for the Savannah River Site*, Rev. 00 PC-1, dated November 7, 2006, was prepared by Doug Farver, CHP, CSP.

3.11.1 Purpose of the Technical Information Bulletin

The purpose of ORAUT-OTIB-0032 is to provide information to allow ORAUT dose reconstructors to assign doses to Savannah River Site (SRS) workers who have no or limited monitoring data, based on site coworker data. The data are to be used in conjunction with ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Dose Assignment*.

3.11.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0032 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in this report.

Table 3.11-1: ORAUT-OTIB-0032 Review Outline/Checklist

Document No.: ORAUT-OTIB-0032, Rev. 00 PC-1	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Coworker Data for the Savannah River Site	
Auditor: Doug Farver, CHP, CSP	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	Refers to ORAUT-OTIB-0020 and ORAUT-OTIB-0052
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments

Table 3.11-1: ORAUT-OTIB-0032 Review Outline/Checklist

Document No.: ORAUT-OTIB-0032, Rev. 00 PC-1	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Coworker Data for the Savannah River Site	
Auditor: Doug Farver, CHP, CSP	

No.	Description of Objective	Rating 1–5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	4	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	4	

Table 3.11-1: ORAUT-OTIB-0032 Review Outline/Checklist

Document No.: ORAUT-OTIB-0032, Rev. 00 PC-1	**Effective Date:** 11/07/2006
Document Title: External Coworker Dosimetry Coworker Data for the Savannah River Site	
Auditor: Doug Farver, CHP, CSP	

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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.11.3 General Comments

OTIB-0032 presents the external dosimetry coworker data to be used by the dose reconstructors and a brief discussion on how the data were calculated. The coworker dosimetry data is based both on worker dosimeter results and doses potentially missed due to limitations of the dosimeter design and/or processing. The document does not provide a detailed technical justification for the calculational methods, nor does it give any specific guidance on how or when the coworker data are to be used.

3.11.4 Review Comments

Review Objectives 1.1, 1.3 and 1.5

The document lacks clarity and repeatedly refers to material and methods described in ancillary documents, such as ORAUT-OTIB-0020 and ORAUT-OTIB-0052.

Specific examples include the following:

From Section 2.0:

> *The ORAU Team is conducting a series of coworker data studies to permit dose reconstructors to complete certain cases for which external and/or internal monitoring data are unavailable or incomplete. Cases not having complete monitoring data may fall into one of several categories, including:*

- *The worker was unmonitored and, even by today's standards, did not need to be monitored (e.g., a non-radiological worker).*
- *The worker was unmonitored, but by today's standards would have been monitored.*
- *The worker may have been monitored but the data are not available to the dose reconstructor.*
- *Partial information is available, but it is insufficient to facilitate a dose reconstruction.*

As described in ORAUT-OTIB-0020,1 some cases not having complete monitoring data can be processed based on assumptions and methodologies that do not involve coworker data. For example, many cases falling in the first category above can be processed by assigning ambient external and internal doses based on information in the relevant site Technical Basis Documents (TBDs).

From Section 3.0:

As described in ORAUT-OTIB-0020,1 the general approach to developing coworker data for cases without external monitoring data involves two phases. The first (Phase I) permits cases to be processed when a "best and final" estimate of dose is not required for claim determination. The second (Phase II) facilitates the assignment of "best and final estimates" of dose, when necessary. This initial revision of this TIB provides coworker external dosimetry summary statistics applicable to Phase I dose reconstructions; coworker dose distributions applicable to Phase II dose reconstructions will be made available in a subsequent revision.

From Section 7.0:

The results are presented in Table 2 below. These percentile doses should be used for selected SRS workers with no or limited monitoring data, using the methodologies outlined in Section 7.0 of ORAUT-OTIB-0020.

Also, from Section 7.0:

Doses to organs impacted only by penetrating radiation (e.g., organs other than the skin, breast, and testes) are calculated based only on the "Gamma" columns in Table 2 combined with the appropriate organ dose conversion factors (DCFs). Doses to the skin, breast, and testes (and any other cancer location potentially impacted by non-penetrating radiation) are determined based on both the "Gamma" and "Non-penetrating" columns; gamma doses are assigned as photons with an energy range consistent with information in the external dosimetry TBD for the SRS, and non-penetrating doses are assigned as electrons

> *>15 keV with corrections applied to account for clothing attenuation or other applicable considerations (or as <30 keV photons, if appropriate).*

From Section 8.0:

> *Table 3 contains penetrating dose values that have been adjusted using the guidance given in Section 8.0 of ORAUT-OTIB-0052, "Parameters to Consider When Processing Claims for Construction Trade Workers." This guidance is applicable for construction trade workers who meet the criteria given in Section 3.0 of ORAUT-OTIB-0052.*

These statements require the dose reconstructor to use professional judgment to determine which Table 2 values to use based on the organ of interest. A separate table listing those organs whose doses are calculated with only the "Gamma" data and those calculated with both the "Gamma" and "Non-penetrating" data would eliminate any potential judgment errors.

Review Objectives 5.1, 5.2 and 5.3

The document does not give specific guidance on how to use the coworker external dosimetry data, so it is unclear if the document is favorable or unfavorable to the claimant. Tables 2 and 3 of the document contain 50th, 95th, and 99th percentile doses and Table 1 contains the maximum annual missed doses (based on n×LOD, where n is the exchange frequency). Typically, NIOSH calculates a missed dose using 50% of the maximum annual missed dose (n×LOD/2). So, for years 1966–1970, the missed annual penetrating and non-penetrating doses would be 0.240 rem and 0.300 rem respectively. Comparing these values with the Table 2 values for years 1966–1970 shows:

- All the Table 2 values for gamma (penetrating) are greater than the missed doses.
- All of the 95th and 99th percentile non-penetrating doses are greater than the missed doses.
- All but one of the 50th percentile non-penetrating doses is less than the missed doses.

As another example, consider the non-penetrating doses for 1951–1957. From Table 1, the maximum annual missed dose is 2.600 rem and half of that is 1.300 rem. Comparing these values to the Table 2 doses shows:

- All the 50th percentile doses are less than the missed doses.
- 67% (4 of 6) of the 95th percentile doses are less than the missed doses.
- 1 of 6 of 99th percentile doses is less than the missed dose.

Clearly, a coworker dose that is less than 50% of the maximum annual missed dose cannot be considered claimant favorable. So, depending on which percentile the dose reconstructor chooses, the dose or doses may or may not be claimant favorable.

3.11.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0020. 2004. *Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 29. 2004.

ORAUT-OTIB-0032. 2006. *External Coworker Dosimetry Data for the Savannah River Site*, Rev. 00 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 7, 2006.

ORAUT-OTIB-0052. 2006. *Technical Information Bulletin: Parameters to Consider When Processing Claims for Construction Trade Workers*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. August 31, 2006.

3.12 ORAUT-OTIB-0034: INTERNAL DOSIMETRY COWORKER DATA FOR X-10

The review of ORAUT-OTIB-0034, *Internal Dosimetry Coworker Data for X-10*, Rev. 00, dated December 13, 2005, was prepared by Robert W. Bistline, PhD.

3.12.1 Purpose of the Technical Information Bulletin

The stated purpose of this TIB is to provide the details of the calculation and assignment of intakes based on coworker data from Oak Ridge National Laboratory (ORNL) (X-10) for the purpose of estimating unmonitored exposures or where records of monitoring are incomplete or unavailable, whether for discrete periods or for the entire period of employment.

3.12.2 Review Protocol

SC&A's evaluation of OTIB-0034 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in this report.

Table 3.12-1: ORAUT-OTIB-0034 Review Outline/Checklist

Document No.: ORAUT-OTIB-0034, Rev. 00	**Effective Date:** 12/13/2005
Document Title: Internal Dosimetry Coworker Data for X-10	
Auditor: Robert W. Bistline, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	3	See Review Comments
3.2.3	Missing dosimetry data	3	
3.2.4	Unmonitored periods of exposure	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?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	

Table 3.12-1: ORAUT-OTIB-0034 Review Outline/Checklist

Document No.: ORAUT-OTIB-0034, Rev. 00	**Effective Date:** 12/13/2005
Document Title: Internal Dosimetry Coworker Data for X-10	
Auditor: Robert W. Bistline, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.12.3 General Comments

For ORNL workers that may have had occupational internal dose from intakes of radionuclides, but were not monitored for those intakes or were inadequately monitored, the OTIB provides a basis to calculate estimated intake rates for strontium, uranium, plutonium, and americium based upon analysis of coworker bioassay data described in ORAUT-OTIB-0019, *Analysis of Coworker Bioassay Data for Internal Dose Assignment*, Rev. 00, May 30, 2005. The SC&A review of OTIB-0019 (SCA-TR-TASK3 Supplement 1) showed that there are some weaknesses with its methodology, and that its results are not always claimant favorable.

OTIB-0034, Section 2.0 Overview states the following:

> *Bioassay results for ORNL were obtained from the Oak Ridge Institute for Science and Education (ORISE) Center for Epidemiologic Research (CER) Dosimetry Database, which contains urinalysis records from the ORNL site for the period 1951 to 1988. The database results are in units of disintegrations per minute (dpm)/24 hours. Because of the varied operations at the different ORNL*

> *facilities over time with the potential for exposure from numerous different radionuclides, the database contains urinalysis data for numerous radionuclides. These data are stored using Electronic Data Processing (EDP) codes. Data were stored under 64 different EDP codes and included measurements for five radioisotopes of uranium, four radioisotopes of plutonium, seven other transuranics radionuclides, numerous fission and activation products, and gross alpha and gross beta measurements. Except for follow-up for accidental exposures, they were collected on an annual sampling basis; therefore, the analysis that follows considers chronic exposures to estimate annual intakes. A statistical analysis of these data was performed in accordance with ORAU* [ORAUT-OTIB-0019]. *The resultant values were input to the Integrated Modules for Bioassay Analysis (IMBA) Expert OCAS-Edition computer program, and a fit to the data for each of the four radionuclides was performed to obtain intake rates for assigning dose distributions.* (OTIB-0034, p. 6)

OTIB-0034, Section 4.1 Assumptions

In OTIB-0034 a lognormal distribution for the annual data for each of the four radionuclides was assumed and the 50^{th} and 84^{th} percentiles were calculated. All the results were assumed to be representative of a full day (24 hrs) of urinary excretion. Each result used in the intake calculation was assumed to be normally distributed and all results weighted equally.

> *A chronic exposure was assumed; while this is unlikely for ORNL workers, it will approximate a series of acute intakes with unknown intake dates. Intakes were assumed to be via inhalation using a default breathing rate of 1.2 m^3/hr and a 5 μm activity median aerodynamic diameter (AMAD) particle size distribution.* (OTIB-0034, p. 7)

OTIB-0034, Section 4.2 Bioassay Fitting:

> *The IMBA Expert OCAS/Edition computer program was used to fit the bioassay results to a series of inhalation intakes. Data for each radionuclide were fit as a series of chronic intakes.*
>
> *Because the Type S strontium, uranium, and plutonium isotopes and Type M plutonium and americium isotopes present at ORNL have very long half-lives and because the material is retained in the body for long periods, excretion results are not independent. An intake in the early 1950s could contribute to urinary excretion in the 1980s or later.* (OTIB-0034, p.7)

OTIB-0034, Section 4.3.5 Additional Radionuclides:

> *It is recognized that hundreds of different radionuclides were present at ORNL at some point during its operations. However, bioassay data for additional radionuclides beyond ^{90}Sr, ^{238}U, ^{239}Pu, and ^{241}Am were deemed to be of little use for coworker estimations, largely because there were too few measurements to be statistically reliable for intake estimation. Three additional radionuclides, both*

> *important to internal Dosimetry and present in the reported air monitoring data were considered. These are ^{106}Ru, ^{137}Cs, and ^{144}Ce.*

Thus, this coworker approach is only useful for the four radionuclides noted, although hundreds of different radionuclides were recognized to have been present at ORNL at various points in time and in various locations that cannot always be identified or associated with specific individual workers.

3.12.4 Review Comments

Review Objective 1.3

The procedure is not complete in terms of required data. The document references and uses data and procedures from documents that need to be known in order to understand the described procedures in OTIB-0034.

The OTIB-0034 is consistent with all other OTIBs and procedures that are part of the hierarchy of procedures by NIOSH for dose reconstruction. It is also sufficiently prescriptive to minimize the need for subjective decisions.

Review Objectives 3.2.2 through 3.2.4

OTIB-0034 is meant to address site-specific data pertaining to in-vivo/in-vitro bioassay data, missing dosimetry data and unmonitored periods of exposure. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

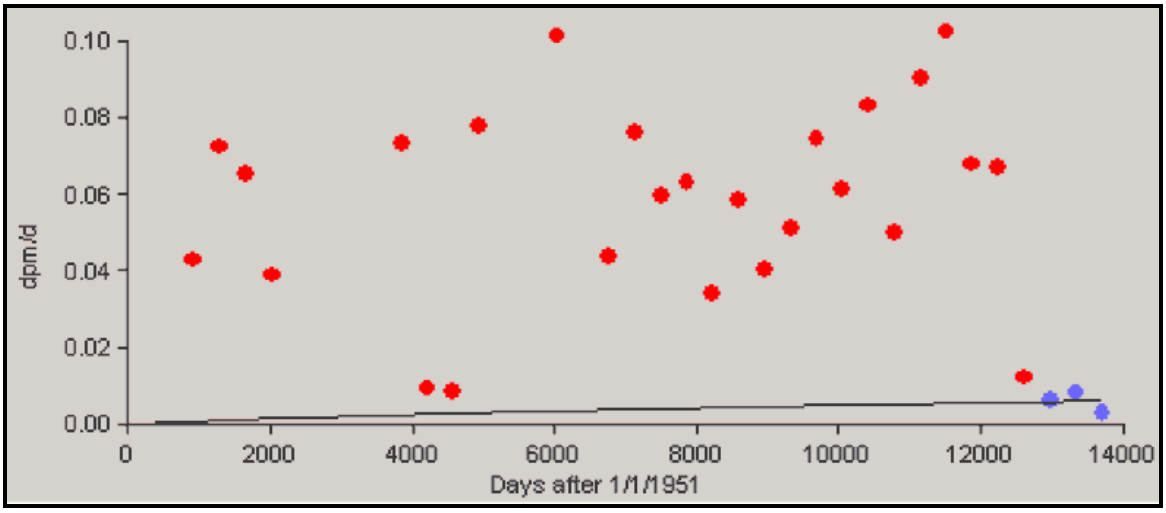
Review Objective 4.1

The procedure is consistent with other site coworker approaches, thus the default assumption is applied to assume only chronic intakes for the various radioisotopes and solubility Types (F, M, or S) of these radioisotopes. The procedure points out that "a chronic exposure pattern was assumed; while this is unlikely for workers at ORNL, it will approximate a series of acute intakes with unknown intake dates." This may not be claimant favorable in many cases at ORNL (X-10) considering the fact that ORAUT-TKBS-0012-5, notes that numerous buildings exist on the site where exact dates of operations of these facilities are not known, and, the site depended on area health physicists to determine if in-vitro bioassay monitoring and in-vivo monitoring should be done. Thus, identification of the workers to apply coworker models is difficult, if not impossible. The following is noted in Section 4.2 of the ORAUT-OTIB-0034:

> *To avoid potential underestimation of intakes for people who worked at ORNL for relatively short periods, each intake was fit independently, using only the bioassay results from the single intake period. This will result in an overestimate of intakes, particularly for assumed Type S exposures extending through multiple assumed intake periods.*

Review Objectives 5.1 through 5.3 and 7.3

Because of the varied operations at the different ORNL facilities over time with the potential for exposure from numerous different radionuclides, the ORNL database contains urinalysis data for numerous radionuclides that are stored using Electronic Data Processing (EDP) codes. The data are under 64 different EDP codes and include five radioisotopes of uranium, four radioisotopes of plutonium, seven other transuranic radionuclides, numerous fission and activation products, and gross alpha and gross beta measurements. However, the majority of the EDP codes contain fewer than 100 data entries; therefore, only a few codes contained enough entries to allow statistical evaluation for dose reconstruction—these included strontium, uranium, plutonium, and americium. The data from only these four radionuclides could be used to estimate annual intakes, assuming chronic exposures, with the values input to the IMBA Expert OCAS-Edition computer program to fit the 50th and 84th percentile bioassay results to series of inhalation intakes for the F, M, and S solubility types. SC&A agrees that the use of the 50th percentile in most cases will be client favorable. However, for plutonium Type S, the chronic intake for the entire set of years was fitted to the bioassay data for the last 3 years (1986 through 1988) and all the previous years of much higher values were ignored (see Figure A-23 on page 28 of 29 in ORAUT-OTIB-0034 shown in Figure).



Source: ORAUT-OTIB-0034, Figure A-23

Figure 3.12-1: Assumed Pu-239 Intake, 1951 to 1988, 50th Percentile Composite Results, Type S

The issue addressed under Review Comment 4.1 above also addresses a concern of not being claimant favorable in instances of missing data and where claimants were not monitored.

Figure shows the model intake rate fit for Type S material based on a chronic intake for the entire set of years fitted to the bioassay data for the last 3 years (1986 through 1988). It appears that the authors have selectively chosen the 50th percentile bioassay results for only the last 3 years and ignored all the previous data that are greatly elevated over these values to derive the inhalation intake model for the Type S Pu-239. This does not provide a claimant-favorable

model for reconstructing doses, as can be observed by the red dots in Figure (i.e., OTIB-0034, Figure A-23).

NIOSH use of the 50th percentile and the IMBA fit intake rate derived for the various time periods (such as the two time periods shown in Figures A-24 and A-25 for Am-241), the assumed and predicted intakes fit versus the values in the first approximately 5 years are much less and from about 3,800 days to 7,200 days the model fit is much higher. This is not to criticize the model but would indicate that the percentile used for deriving the intake should be greater. This would in turn be much more claimant favorable. On the positive side, it should be noted that the predicted fits for the strontium and uranium models, shown in earlier figures in OTIB-0034, are claimant favorable.

3.12.5 Conclusions

SC&A has examined OTIB-0034, the Internal Dosimetry Coworker Data for X-10 (ORNL) document, in terms of its technical approach, scientific validity, conceptual approach, and the degree of conservatism. SC&A accepts NIOSH's position that it is possible to derive a surrogate exposure model for the unmonitored workers based on the distribution of internal doses received by the monitored workers for at least four of the many radionuclides to which ORNL workers were exposed. Two of these may not be claimant favorable as modeled in this document and the many other radionuclides had insufficient bioassay monitoring results taken to allow statistical evaluation for the purposes of using coworker data for dose reconstructions.

3.12.6 References

ORAUT-TKBS-0012-5. 2006. *Technical Basis Document for Oak Ridge National Laboratory – Occupational Internal Dose, Rev. 00 PC-1*, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 30, 2006.

ORAUT-OTIB-0019. 2005. *Technical Information Bulletin: Analysis of Coworker Bioassay Data for Internal Dose Assignment*, Rev. 00, October 7, 2005. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-OTIB-0034, *Internal Dosimetry Coworker Data for X-10*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 13, 2005.

SCA-TR-TASK3 Supplement 1, Rev. 0, Draft, June 2006, *The Review of NIOSH/ORAU Procedures and Methods Used for Dose Reconstruction*, Supplement 1, S. Cohen and Associates, McLean, Virginia. June 8, 2006.

3.13 ORAUT-OTIB-0035: INTERNAL DOSIMETRY COWORKER DATA FOR K-25

The review of ORAUT-OTIB-0035, *Internal Dosimetry Coworker Data for K-25*, Rev. 00 PC-1, dated July 21, 2006, was prepared by Harry J. Pettengill, PhD, and supported by Bill James, PhD.

3.13.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0035 is to provide information for the application of K-25 coworker data in estimating unmonitored internal exposures. Some employees were not monitored for internal ionizing radiation exposure during the course of their employment, or the records are incomplete or unavailable. In such cases, data from monitored coworkers are used to estimate a claimant's possible exposure.

3.13.2 Review Protocol

SC&A's evaluation of OTIB-0035 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in this report.

Table 3.13-1: ORAUT-OTIB-0035 Review Outline/Checklist

Document No.: ORAUT-OTIB-0035, Rev. 00 PC-1	**Effective Date:** 07/21/2006
Document Title: Internal Dosimetry Coworker Data for K-25	
Auditor: Harry Pettengill, PhD and Bill James, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	

Table 3.13-1: ORAUT-OTIB-0035 Review Outline/Checklist

Document No.: ORAUT-OTIB-0035, Rev. 00 PC-1	**Effective Date:** 07/21/2006
Document Title: Internal Dosimetry Coworker Data for K-25	
Auditor: Harry Pettengill, PhD and Bill James, PhD	

No.	Description of Objective	Rating 1–5*	Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	4	See Review Comments
3.2.3	Missing dosimetry data	4	
3.2.4	Unmonitored periods of exposure	4	
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?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	4	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	

Table 3.13-1: ORAUT-OTIB-0035 Review Outline/Checklist

Document No.: ORAUT-OTIB-0035, Rev. 00 PC-1	**Effective Date:** 07/21/2006
Document Title: Internal Dosimetry Coworker Data for K-25	
Auditor: Harry Pettengill, PhD and Bill James, PhD	

No.	Description of Objective	Rating 1–5*	Comments
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	4	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.13.3 General Comments

For K-25 workers that may have had occupational internal dose from intakes of radionuclides, but were not monitored for those intakes or were inadequately monitored, the OTIB provides a basis to calculate estimated intake rates for uranium and Tc-99 based upon analysis of coworker bioassay data as described in OTIB-0035. This approach follows the processes previously described in *Analysis of Coworker Bioassay Data for Internal Dose Assignment* (ORAUT-OTIB-0019) and *Coworker Data Exposure Profile Development* (ORAUT-PLAN-0014). Although the approach described in the OTIB is generally consistent for unmonitored or inadequately monitored worker assessments, there are potential weaknesses, inaccuracies, and assumptions made that could result in dose calculations that are not always claimant favorable.

3.13.4 Review Comments

Review Objectives 1.2, 1.3, and 5.2

In response to a prior SC&A question on internal dose coworker data related to the site profile report it was stated that an individual who was never monitored is assumed to not have the potential to have received larger intakes than the majority of those who were monitored, and that one should assume that the coworker distribution is representative of their intakes—the median dose is therefore assigned as a lognormal distribution and the associated GSD is assigned to account for possible larger intakes and uncertainty associated with the distribution. The use of the median bioassay data values from 1948 to 1988 for uranium intake rates and 1978 to 1988 data for Tc-99 intake rates may not be reasonable or necessarily claimant favorable. Because there was undoubtedly some variation of intake rates around the median values, it does not appear to be claimant favorable to assume that a claimant's intake was a median intake as opposed to a higher value, such as 84th percentile value (+1 standard deviation). Therefore, this section of the OTIB warrants revision to be claimant favorable.

Review Objectives 3.2.2 through 3.2.4

The OTIB assumes using intakes modeled from 1948–1988 to estimate the intakes of workers prior to 1948, and states that if the workers "had larger intakes in the earlier years their bioassay results would have reflected this in the years that samples were collected." However, the procedure does not caution that relatively large acute intakes of uranium in chemical forms that have fast (Class F) absorption rates (such as UF_6, which was the most prevalent form at the site) may not be detectable several months or years after initial intakes and, therefore, may not be reflected with any sensitivity in samples taken several years after the intake. If any workers had relatively large intakes of Class F chemical forms of uranium in the early years (e.g., 1945 or 1946), it is very possible that bioassay in 1948 did not detect or reflect the intake(s). In an instance like this, only air sample or surface contamination data taken at the time of the intake would be relatively useful for identifying the intake, and this caution should be added to this procedure in a future revision.

Review Objectives 4.1 and 7.1

The procedure does not adequately model all intake scenarios; thus, the default assumption applied across the complex has been to assume only chronic intakes. The procedure points out that a chronic intake assumption can be used to approximate small acute intakes. There is no doubt that chronic, acute, or a series of either types or combinations of these types of intakes could have occurred at this site. The important issue is that the procedure should have a stronger basis for using any intake assumption that is not as claimant favorable as any realistic potential intake scenario that could be assumed and defend its use.

3.13.5 Conclusions

There were also a few strengths noted in the internal dosimetry coworker OTIB. The assumption of U-234 contributing 100% of the uranium isotope activity in the intake was clearly claimant favorable, due to having a higher dose factor for this isotope than for U-235 and U-238. Directing dose reconstructors to add the other radionuclides (plutonium, neptunium, etc.) in the default isotopic distribution identified in the K-25 Site Description TBD (ORAUT-TKBS-0009-2) to all uranium intakes after the start of processing recycled uranium is also important and claimant favorable. The guidance to run dose calculations with each uranium absorption rate (F, M, S) to determine which absorption rate gives the largest dose to the organ and probability of causation is also appropriate. The document is also consistent with other site coworker internal dosimetry approaches being applied.

3.13.6 References

ORAUT-PLAN-0014. 2004. *Coworker Data Exposure Profile Development*, Rev.00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 24, 2004.

ORAUT-OTIB-0019. 2005. *Technical Information Bulletin: Analysis of Coworker Bioassay Data for Internal Dose Assignment*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 7, 2005.

ORAUT-OTIB-0035. 2006. *Technical Information Bulletin: Internal Dosimetry Coworker Data for the K-25 Site*, Rev. 00 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. July 21, 2006.

ORAUT-TKBS-0009-2. 2004, *Technical Basis Document for the K-25 Site – Site Description*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 12, 2004.

3.14 ORAUT-OTIB-0037: INTERNAL DOSIMETRY COWORKER DATA FOR PADUCAH GASEOUS DIFFUSION PLANT

The review of ORAUT-OTIB-0037, *Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant*, Rev. 00, dated September 20, 2005, was prepared by Joyce Lipsztein, PhD.

3.14.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0037 is to provide the details of the calculation and assignment of intakes based on coworker data from the Paducah (Kentucky) Gaseous Diffusion Plant (PGDP) for the purpose of estimating unmonitored exposures or where records of monitoring are incomplete or unavailable.

3.14.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0037 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.14-1: ORAUT-OTIB-0037 Review Outline/Checklist

Document No.: ORAUT-OTIB-0037, Rev. 00	**Effective Date:** 09/20/2005
Document Title: Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	

Table 3.14-1: ORAUT-OTIB-0037 Review Outline/Checklist

Document No.: ORAUT-OTIB-0037, Rev. 00	**Effective Date:** 09/20/2005
Document Title: Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	See Review Comments
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	3	
3.2.3	Missing dosimetry data	3	
3.2.4	Unmonitored periods of exposure	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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	
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)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of	N/A	

Table 3.14-1: ORAUT-OTIB-0037 Review Outline/Checklist

Document No.: ORAUT-OTIB-0037, Rev. 00	**Effective Date:** 09/20/2005
Document Title: Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1–5*	Comments
	random sampling in developing a final distribution?		
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.14.3 General Comments

In OTIB-0037,

> *Uranium urine bioassay results from 1952 through 1988 were obtained from the PGDP Dosimetry Section. The data were copied from working files that are the basis for the PGDP annual dose reports and dose histories. Some of the bioassay data were taken from handwritten logs and then added to the electronic data base. PGDP urinalysis data were extracted from two separate Microsoft® Access files provided by the PGDP Dosimetry Section. File "PGDP_Historical_Urine" was the source of urinalysis data from 1977 through 1988. File "Historical_Urinalysis_Data_(unverified)" was the source of urinalysis data from October 1952 to mid-1977. There were no units associated with urinalysis results in this file. Comparison to results with identified units in file "PGDP_Historical_Urine" and with information presented in Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose* [ORAUT-TKBS-0019-5] *determined the results in this file were in units of milligrams per liter. Because both of the above files included PGDP uranium urinalysis data from 1977, the data were evaluated to identify and eliminate duplicate entries.*

In OTIB-0037, two sequential fitting approaches were used to interpret the urinalysis bioassay data. The first one grouped the bioassay monitoring data by quarter, from the final quarter of 1952 through 1988. The effective bioassay date was set equal to the midpoint of the analysis period.

A lognormal distribution was assumed as the best representation of the workers' bioassay results. After log transforming the data, the 50th and 84th percentiles were determined for each quarter.

The second approach consisted of the derivation of an inhalation intake function that would reproduce the 50th and 84th percentile bioassay values that were calculated using the first approach. The IMBA Expert OCAS-Edition computer program was used to fit the bioassay results to a series of inhalation intakes. Data from 1952 through 1988 were fit as a series of chronic intakes, through inhalation, using a default breathing rate of 1.2 m^3/hr and a 5-µm AMAD particle size distribution.

> *The total uranium results are in units of µg/L; therefore the results were multiplied by 1.4 in order to normalize them to the Reference Man excretion rate of 1400 mL per day. Bioassay results were converted from mass to activity before fitting assuming 0.0389 Bq/µg, characteristic of low-enrichment (2 percent) uranium. Low-enrichment uranium feed is the default value in* [ORAUT-TKBS-0019-5] *when the specific location where a claimant worked is not available. PGDP received uranium and began enrichment operations during June 1952 and first withdrew enriched uranium during November 1952. The November 1952 period is consistent with uranium urinalysis data; however, the first intake period was conservatively assumed to begin on June 1, 1952.*

The IMBA fit was derived for a period of several consecutive years. Two intake periods were fit to the derived 50th- and 84th-percentile uranium excretion data. Intakes due to Type F, Type M and Type S uranium were considered. Doses to be assigned to individuals are calculated from the 50th-percentile intake rates.

> *Because the uranium streams at PGDP could have contained recycled uranium, the dose from the added constituents, including plutonium, 237Np, and 99Tc, must be included. See* [ORAUT-TKBS-0019-5] *for information about intake values in relation to the uranium intake amounts.*

3.14.4 Review Comments

Review Objectives 1.1 through 1.4

Our review has identified that the procedure is not complete in terms of required data. The sources of some critical information are not referenced.

The OTIB is consistent with all other OTIBs and procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. OTIB-0037 is sufficiently prescriptive to minimize the need for subjective decisions.

Review Objective 3.2

OTIB-0037 is meant to address site-specific data pertaining to in-vivo/in-vitro bioassay data, missing dosimetry data, and unmonitored periods of exposure. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 5.1, 5.2, and 5.3

OTIB-0037 is meant to assign doses for employees at DOE sites that were not monitored for internal ionizing radiation exposure or the records of such monitoring are incomplete or unavailable. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objective 6.1

OTIB-0037 provides reasonable guidance for selecting the types of probability distributions (i.e., normal, lognormal), as described in the Review Objective 7.3 comments.

Review Objective 7.3

The SC&A review of OTIB-0037 revealed at least two areas of concerns with the validity of the scientific protocols that were employed. These concerns are presented below:

(1) The Lognormal Distribution:

In OTIB-0037, the bioassay monitoring data were analyzed by quarter, from the final quarter of 1952 through 1988. A lognormal distribution was assumed as the best representation of the workers bioassay results during a certain period of time. After log transforming the data, the 50th and 84th percentiles were determined for each period of time.

(1.1) The Representation of the Unmonitored Worker

The following is noted in TKBS-0019-5:

> *From the start of Plant operations in 1952, samples of urine from workers involved in enrichment operations were analyzed for uranium. Over time, other workers were included in the monitoring program.*

There is no clear definition of who was included in the early monitoring programs, when and which other workers were included in the program over time. In OTIB-0037, monitored and unmonitored workers are not compared by job types, radionuclide exposure lists, or contaminant air concentrations. It is possible that some workers who were not monitored received high doses and that some practices were only monitored after having been implemented for some time. Thus, it is important to know how to place the unmonitored worker in the distribution.

(1.2) The Misrepresentation of the High Urinalysis Results

The fitting of the data to a lognormal distribution was statistically acceptable, but many times did not represent well the data at the high-end of the results. There are significant discrepancies between the high "real" results and the ones generated by the curve. The analysis of the PGDP U values for 1954, by quarters, illustrates these discrepancies:

- **1st Quarter:** The 99th percentile as calculated by the lognormal equation is 48.93 µg/L and the 99th value (the result that occupies the rank 99, when results are placed in

ascending values order) is 300 µg/L. There are 78 values that are higher than the 95th value (100 µg/L). The 50th percentile (GM) is 10.6 µg/L.

- **2nd Quarter:** The 99th percentile as calculated by the lognormal equation is 68.3 µg/L and the 99th value is 600. There are 55 values that are higher than the 95th value (60 µg/L). The 50th percentile (GM) is 8.6 µg/L.

- **3rd Quarter:** The 99th percentile as calculated by the lognormal equation is 58.44 µg/L and the 99th value is 150 µg/L. The 50th percentile (GM) is 7 µg/L. In this quarter the difference between the 95th percentile and the 50th percentiles value is small, but the lognormal representation of results shows problems in the representation of the positive values, as can be illustrated by Figure, extracted from NIOSH data files, for 1954.

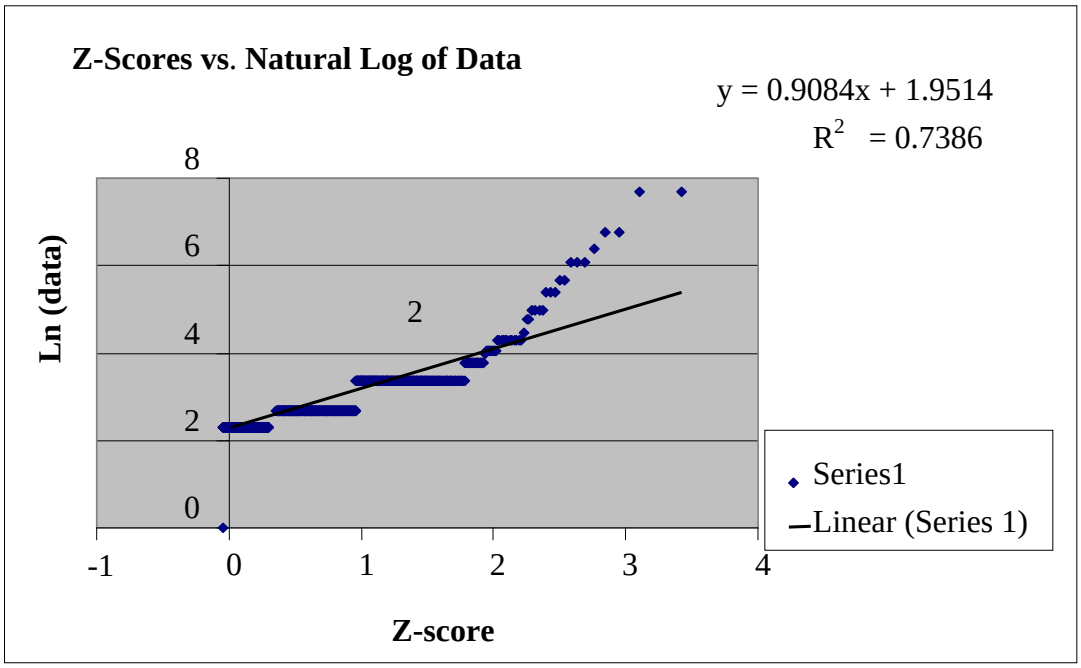


Figure 3.14-1: Lognormal Representation of 1954 Third Quarter Results

- **4th Quarter:** The 99th percentile as calculated by the equation is 82.9 µg/L and the 99th value is 300 µg/L. The R^2 for the equation is 0.7467, with larger discrepancies on the high-end of the curve, as shown in Figure, extracted from NIOSH PGDP U 1954 file. The 50th percentile as calculated by the lognormal equation is 6.05 µg/L.

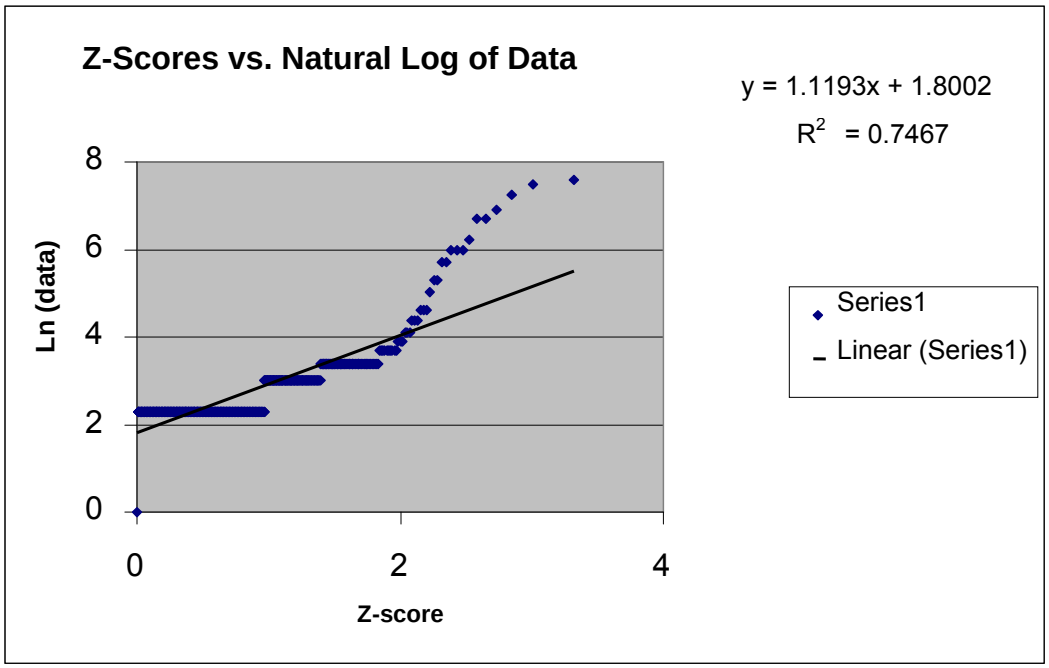


Figure 3.14-2: Lognormal Representation of 1954 Fourth Quarter Results

The misrepresentation of the higher results by the lognormal curves persists until the 1980s, when the problem practically disappears.

(2) The Intake Model

The IMBA Expert OCAS-Edition computer program was used to fit the 50th and 84th percentile bioassay results to a series of inhalation intakes. Data from 1952 through 1988 were fit as a series of chronic intakes, through inhalation, using a default breathing rate of 1.2 m^3/hr and a 5-µm AMAD particle size distribution. The IMBA fit intake rate was derived for two time periods (June 1, 1952–March 31, 1980, and April 1, 1980–December 31, 1988). The intake rates theoretically reproduce excretion rates. Figure, below (reproduced from Figure A-1, page 12, OTIB-0037), compares the theoretical fit for Type F materials to the individual 50th-percentile excretion rates. As can be observed, there are large discrepancies between the predicted bioassay results using the derived intake rates for the period (solid line) and the GM (50th percentile) results for the different periods (blue dots).

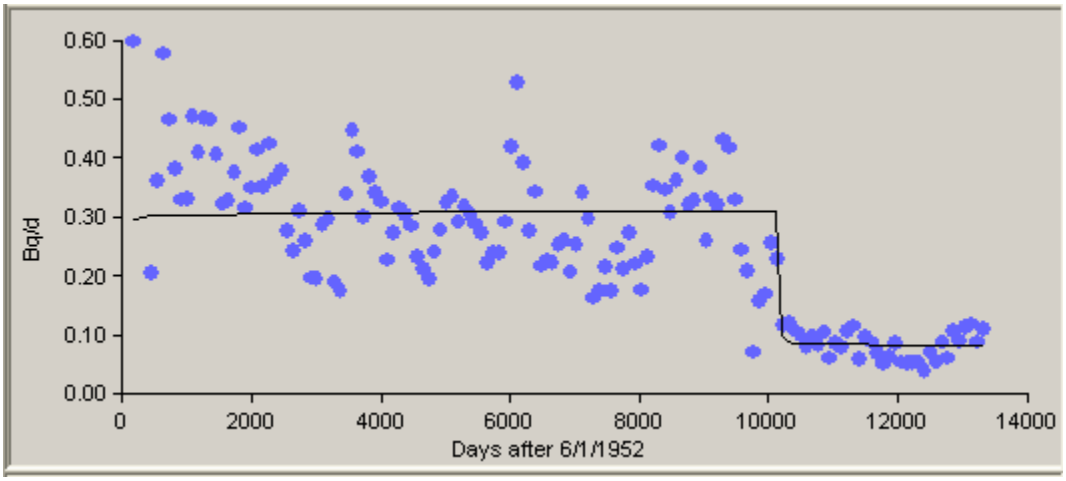


Figure 3.14-3: Type F Material Theoretical Fit Versus 50th Percentile Excretion Rates

As illustrated by Figure, the model intake rates do not reproduce exactly the 50th percentile of each period of time analyzed. In some time periods, the dose will be calculated using an intake rate that corresponds to urinary excretion values smaller than the 50th percentile of the excretion rates of the workers for that time period. This is particularly true in the earlier periods of time.

Thus, when NIOSH uses the 50th percentile dose distribution, it should not be understood as the 50th percentile of the workers' intake rates. They correspond to a model intake rate that will fit the chosen percentiles, with some periods of time when the urine excretion rates will be underestimated and some periods of time when they will be overestimated. This observation is not critical of the model intake rate, but instead is an argument in favor of raising the percentile, from which the intake should be derived.

(3) Doses from Recycled Uranium Contaminants

In the lack of bioassay data, SC&A concurs with NIOSH that doses must be based on information about intake values in relation to the uranium intake amounts.

3.14.5 Conclusions

SC&A examined OTIB-0037, the *Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant* document, in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. SC&A accepts NIOSH's position that it is possible to derive a surrogate exposure model for the unmonitored worker based on the distribution of internal doses received by the monitored workers. However, the use of a model based on the 50th percentile of the excretion rates of the workers, may misrepresent the higher exposures experienced by unmonitored workers.

3.14.6 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0037. 2005. *Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant*, Rev. 00, Oak Ridge Associated Universities, Cincinnati, Ohio. September 20, 2005.

ORAUT-TKBS-0019-5. 2007. *Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose*, Daniel S. Mantooth and Clark B. Barton, Revision 01 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 31, 2007.

3.15 ORAUT-OTIB-0038: INTERNAL DOSIMETRY COWORKER DATA FOR ROCKY FLATS ENVIRONMENTAL TECHNOLOGY SITE

The review of ORAUT-OTIB-0038, *Internal Dosimetry Coworker Data for Rocky Flats Environmental Technology Site*, Rev. 00, dated August 3, 2006, was prepared by Joyce Lipsztein, PhD.

3.15.1 Purpose of the Technical Information Bulletin

The stated purpose of this TIB is to provide monitored coworker information for calculating and assigning occupational internal doses to employees at Rocky Flats Environmental Technology Site (RFETS) for whom no or insufficient bioassay monitoring records exist.

3.15.2 Review Protocol

SC&A's evaluation of OTIB-0038 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the OTIB adequately supports the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.15-1: ORAUT-OTIB-0038 Review Outline/Checklist

Document No.: ORAUT-OTIB-0038, Rev. 00	**Date:** 08/03/2006
Document Title: Internal Dosimetry Coworker Data for Rocky Flats Environmental Technology Site	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	2	See Review Comments
3.2.3	Missing dosimetry data	2	
3.2.4	Unmonitored periods of exposure	2	

Table 3.15-1: ORAUT-OTIB-0038 Review Outline/Checklist

Document No.: ORAUT-OTIB-0038, Rev. 00	**Date:** 08/03/2006
Document Title: Internal Dosimetry Coworker Data for Rocky Flats Environmental Technology Site	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1-5*	Comments
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	2	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	1	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	1	
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)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	2	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.15.3 General Comments

Bioassay results, used in OTIB-0038, were obtained through the CEDR, which contains approximately 300,000 bioassay records from Rocky Flats Environmental Technology Site (RFETS) and includes measurements for uranium, plutonium, and americium for the years 1952 through 1988.

All of the uranium and plutonium urinalysis results were recorded either as positive numbers or zeros. In general, a zero entry meant the result was less than some reporting level; however, after April 6, 1970, actual results were reported. A large fraction of the uranium and plutonium urinalysis data was entered as zeros (zeros were reported in 176,900 records, a little over half of the results for all measurements). Where a reporting level was specified in the site TBD and where zeros were inserted for the actual values (below the reporting level) in the original data, a linear distribution between zero and the reporting level was substituted for the zeros. The linear distribution had the form, c/n, 2c/n, 3c/n, …, nc/n, where n is the number of zero values less than the reporting level, c.

NIOSH justified the linear distribution by stating that this linear distribution (alone) fits a lognormal transformation by better than 80% and typically significantly improves the goodness of fit for the entire data set. Furthermore NIOSH complements the justification by stating that the linear distribution has an average equal to half of the reporting value, consistent with the general dose reconstruction practice of assigning half of the lower limit of detection for missed dose calculations.

The reporting levels used were (1) for enriched uranium, 8.8 dpm/24 hr through 1963, and 20–28 dpm/24 hr after 1963; (2) for depleted uranium, 5.8 dpm/24 hr through April 1964, 20–28 dpm for May 1964–1979, and actual measured values thereafter; (3) and for plutonium, 0.88 dmp/24 hr through 1961, 0.2 dpm/24 hr for 1962–April 1970, and actual measured values after April 1970. The reporting level for gross alpha through 1963 was 8.8 dpm/24 hr (assigned as enriched uranium) and 0.9 dpm/24 hr thereafter (assigned as plutonium).

In-vivo Am-241 lung data from 1965 to 1988 were extracted from a Microsoft® Access table named RFFACW02_RFWB. There were just fewer than 80,000 Am-241 records in the lung database. From 1965 through 1971, all results (about 4,000) were reported as zero, with no explanation of what those values might have meant. Therefore, no analyses were performed on those data. After 1971, positive values began to appear, but there still were no exclusion instructions for when 0 values were reported. Therefore, 0 results were treated as zeros because no better information was available. Calculations of the lung plutonium values recorded with the Am-241 lung data were determined by using the Am-241 data and an assumed concentration of 100 ppm (by weight) of Am-241 in the plutonium.

In OTIB-0038, two sequential fitting approaches were used to interpret the urinalysis bioassay data. The first one grouped the bioassay monitoring data by quarter or year, depending on the amount of data available during the periods. A lognormal distribution was assumed as the best representation of all the RFP workers' bioassay results during a certain period of time. After log transforming the data, the 50^{th} and 84^{th} percentiles were determined for each period of time. The second approach consisted of the derivation of an inhalation intake function that would reproduce the 50^{th} and 84^{th} percentile bioassay values that were calculated using the first approach. The IMBA Expert OCAS-Edition computer program was used to fit the bioassay results to a series of inhalation intakes. Data from 1952 through 1988 were fit as a series of chronic intakes, through inhalation, using a default breathing rate of 1.2 m^3/hr and a 5-µm AMAD particle size distribution. The IMBA fit was derived for a period of several consecutive years. Five intake periods were fit to the derived 50^{th}- and 84^{th}-percentile uranium excretion data. Four intake periods were fit to the data for Type M material and one was fit for Type S

material to the derived 50th- and 84th-percentile plutonium excretion and americium lung burden data.

3.15.4 Review Comments

Review Objectives 1.1 through 1.4

Our review has identified that the procedure is not complete in terms of required data. The sources of some critical information are not referenced.

The OTIB is consistent with all other OTIBs and procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. OTIB-0038 is sufficiently prescriptive to minimize the need for subjective decisions. The basis to derive OTIB-0038 is difficult to understand.

Review Objective 3.2.2, 3.2.3, and 3.2.4

OTIB-0038 is meant to address site-specific data pertaining to in-vivo/in-vitro bioassay data, missing dosimetry data, and unmonitored periods of exposure. The technical review of methods used in this OTIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 5.1, 5.2, and 5.3

OTIB-0038 is meant to assign doses for employees at DOE sites that were not monitored for internal ionizing radiation exposure or the records of such monitoring are incomplete or unavailable. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 6.1 and 6.2

Although it provides adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal), OTIB-0038 does not adequately account for the uncertainty of dose estimates, as described in the Review Objective 7.3 comments.

Review Objective 7.3

The SC&A review of OTIB-0038 revealed at least five areas of concerns with the validity of the scientific protocols that were employed. These concerns are presented below:

(1) Interpretation of Zero Monitoring Results, Low Value Monitoring Results, and Reporting Levels

(1.1) The Linear Distribution:

SC&A finds that the linear distribution provided for use in OTIB-0038 as a substitution for low internal dose value results does not have a clear scientific basis for this application. NIOSH justified the use of the linear distribution by stating that this linear distribution (alone) fits a lognormal transformation by better than 80% and typically significantly improves the goodness

of fit for the entire data set. In addition, NIOSH states that the linear distribution has an average equal to half of the reporting value, consistent with the general dose reconstruction practice of assigning half of the lower limit of detection for missed dose calculations. SC&A believes that the basis for the use of the linear distribution is not clear. The reporting level is not a lower limit of detection. The reporting level is a non parametric value, unrelated to the real capacity of distinguishing between real measurement results and background or noise counts. Half the reporting level is not a scientifically statistically meaningful value and cannot be used to justify a procedure.

SC&A notes that such a linear distribution was not used for plutonium. For Pu, NIOSH has used the exact values as they were reported in the dose files and have substituted the zeros by the reporting level of 0.88. While the OTIB ranks the 0.88 values, it does not use those values to fit the lognormal distribution. SC&A believes there is no clear scientific rationale to accept that the registered values lower than 0.88 are real measurements and that the zeros are equal to 0.88.

In OTIB-0038 the intake is derived based on the 50th percentile of a lognormal fit to the bioassay results in a certain period of time (year or quarter of a year). A large fraction of the registered bioassay values are equal to zero. Thus, 50th percentile depends on the approach NIOSH uses to account for the zero values, low bioassay results and below reporting level values.

(1.2) Uncertainties Related to the MDA

The MDA for the median and extreme conditions were calculated for the period 1952–1971, and are presented in TKBS-0011-05 (2007). There is as much as a nine-fold difference between the MDA for the median conditions and the extreme conditions for plutonium for the years 1952 to 1971. The MDA was not discussed in OTIB-0038, and neither of the MDA values was applied to workers with zero monitoring results, low monitoring results, or discussed in relation to reporting levels. SC&A finds that uncertainties in the MDA values bring a great uncertainty to a model based on low monitoring excretion values.

(2) The Lognormal Distribution

In OTIB-0038, the bioassay monitoring data were grouped by quarter or year, depending on the amount of data available during the periods. A lognormal distribution was assumed as the best representation of all the RFP workers' bioassay results during a certain period of time (year or quarter of a year). After log transforming the data, the 50th and 84th percentiles were determined for each period of time.

(2.1) The Appropriate Representation of the Unmonitored Worker

As noted in OTIB-0038, "Statistical methods used to calculate co-worker intake values assume that bioassay results for group of workers have a lognormal distribution."

If the physical samples represent a statistical sample from a population we wish to characterize, it is important to know the statistical design (or lack thereof) of the procedure used to select the samples. In sample design, all members of the population must have a known (non-zero) probability of selection into the sample before the results can be considered as representative of the population. This simple requirement defines the population that the samples represent.

Using the estimated distribution to represent workers with unknown or zero probability of selection into the sample is a subjective decision, not a statistical one, and should be identified as such. Thus it is important to know how to place the unmonitored worker in the distribution.

In OTIB-0038, monitored and unmonitored workers are not compared by job types, radionuclide exposure lists, or contaminant air concentrations. Thus, it is possible that some workers who were not monitored received high doses and that some practices were only monitored after having been implemented for some time. Some jobs that might have presented radiation contamination risks might have been misjudged and workers might not have been monitored. It is also possible that some workers might have been exposed to high-fired oxides of Pu, and only monitored for a limited time by misjudgment of the significance of results below detection limits in urine samples.

(2.2) The Significance of the High Urinalysis Results

(2.2.1) Exclusion of Results

A coworker model needs to distinguish whether high excretion cases were routine samples, samples related to incidents, or samples following chelation. NIOSH has excluded the highest excretion data from the data file from which the OTIB-0038 model was derived, without explanation. If data from an incident is excluded, without known and well established criteria, then the distribution that remains without the missing data may not be the correct one, since the right ("high-end") tail of the distribution will be too thin without those values.

(2.2.2) The Misrepresentation of the High Urinalysis Results

The fitting of the data to a lognormal distribution was statistically acceptable, but many times did not represent well the data at the high-end of the results. There are significant discrepancies between the high "real" results and the ones generated by the curve. Depending on the year, these discrepancies may start at the 95th percentile level, as in 1958 (when, for example, in the first quarter, the 95th percentile calculated by the equation was 27.16 and the result that occupies the rank 95 is 55.3), or at the higher percentile, as in 1966. The analysis of the RFETS Table values for 1966, by quarters, provides the following results:

> **1st Quarter:** The 95th percentile as calculated by the equation is 1.6 dpm/24h and the 95th value (the result that occupies the rank 95, when results are placed in ascending values order) is 1.63. The R^2 for the equation is 0.64, with larger discrepancies on the high-end of the curve. There are 61 values that are higher than the 95th value, the largest one being 230 dpm/24h. There are 42 results at least 10 times higher than the 95th percentile. The 99th percentile as calculated by the equation is 3.23 dpm/24h and the 99th percentile value is 70 dpm/24h.
>
> **2nd Quarter:** The 95th percentile as calculated by the equation is 0.96 dpm/24h and the 95th value is 0.87. The R^2 for the equation is 0.65, with larger discrepancies on the high-end of the curve. There are 58 values that are higher than the 95th percentile value, the largest one being 140 dpm/24h. There are 24 results at least 10 times higher than the 95th

percentile. The 99th percentile as calculated by the equation is 1.7 dpm/24h and the 99th value is 5.17 dpm/24h.

3rd Quarter: The 95th percentile as calculated by the equation is 0.67 dpm/24h and the 95th value is 0.63. The R^2 for the equation is 0.73, with larger discrepancies on the high-end of the curve. There are 49 values that are higher than the 95th value, the largest one being 110 dpm/24h. Seven results are at least 10 times higher than the 95th percentile. The 99th percentile as calculated by the equation is 1.1 dpm/24h and the 99th percentile value is 55 dpm/24h.

4th Quarter: The 95th percentile as calculated by the equation is 1.129 dpm/24h and the 95th value is 0.95. The R^2 for the equation is 0.68, with larger discrepancies on the high-end of the curve. There are 56 values that are higher than the 95th value, the largest one being 160 dpm/24h. There are 23 results at least 10 times higher than the 95th percentile. The 99th percentile as calculated by the equation is 2.09 dpm/24h and the 99th value is 110 dpm/24h.

These high results were considered by NIOSH as routine monitoring results. The ones related to accidents or incidents were excluded from the analysis, as noted in item 2.2.1.

(3) The Intake Model

The IMBA Expert OCAS-Edition computer program was used to fit the 50th and 84th percentile bioassay results to a series of inhalation intakes. Data from 1952 through 1988 were fit as a series of chronic intakes, through inhalation, using a default breathing rate of 1.2 m^3/hr and a 5-µm AMAD particle size distribution. The IMBA fit was derived for a period of several consecutive years. Five intake periods were fit to the derived 50th and 84th percentile uranium excretion data. Four intake periods were fit to the data for Type M material and one was fit for Type S material to the derived 50th and 84th percentile plutonium excretion and americium lung burden data.

For Type M Pu, for example, just one intake rate was considered for the period of 1952 to 1961. This intake rate theoretically produces excretion rates for 1952 to 1961 which can be represented by the solid line shown in Figure , below (Figure B-21, page 29, OTIB-0038), comparing the theoretical fit for Type M materials to the individual 50th-percentile excretion rates. As can be observed, there are large discrepancies between the predicted bioassay results using the derived intake rates for the period (solid line) and the GM results for the different periods (blue dots). The red dots correspond to time periods after 1961.

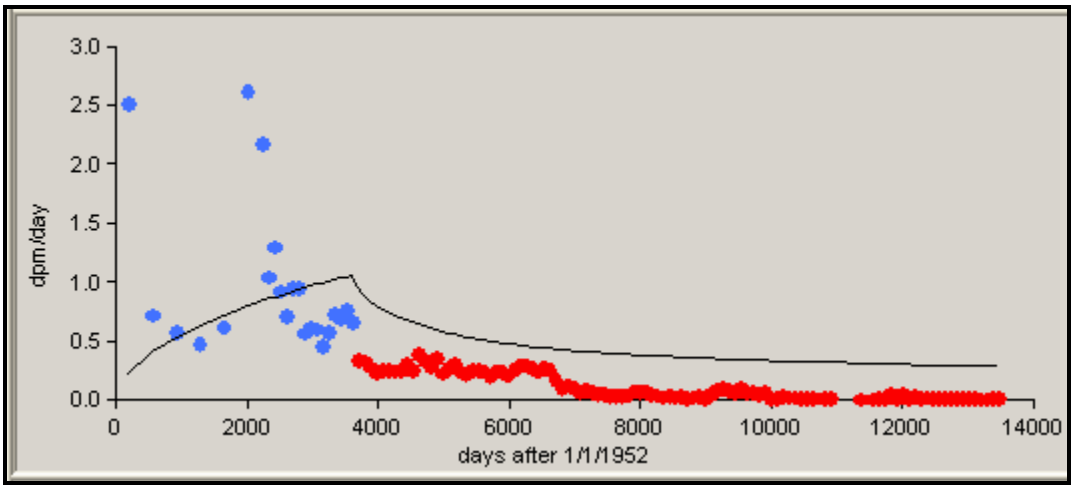


Figure 3.15-1: Predicted Plutonium Bioassay Results (line) Calculated using IMBA-Derived Pu Intake Rates Compared with Measured Pu-in-Urine Results (dots), January 1, 1952, to December 31, 1961, 50th Percentile, Type M
(Source: OTIB-0038, Figure B-21)

The model intake rates do not correspond to the 50th percentile of each period of time analyzed. As shown in Figure , in some time periods, the dose will be calculated using an intake rate that corresponds to urinary excretion values smaller than the 50th percentile of the excretion rates of the workers for that time period.

Thus, when NIOSH uses the 50th percentile dose distribution, it should not be understood as the 50th of the workers intake rates. They correspond to a model intake rate that will fit the chosen percentiles, with some periods of time when the urine excretion rates will be underestimated and some periods of time when they will be overestimated.

(4) The Database used by NIOSH to Derive the Intake Model Described in OTIB-0038: Comparison of HIS-20 Versus CEDR Database

OTIB-0038 was based on the CEDR database. NIOSH has investigated the differences between the CER and HIS20 databases for Rocky Flats workers, and has provided information presented to the Working Group in reports dated March 26 (Lochamy et al. 2006), April 6, 2006 (Lochamy 2006), and in October 2006 (Cragle 2006). These reports were used by NIOSH to demonstrate that there is good agreement in the parameter values calculated from either database and used for the generation of coworker data distributions. In those analyses, NIOSH has provided a comparison of the number of records in each database.

The comparisons using the CER database instead of the HIS-20 database (to illustrate their similarities) focuses on the values of the GM and GSD. In both databases, there are a large number of zero results that bring the GM to a very low value, most of the time below MDA or reporting levels. Because the lognormal distribution derived for most of these years excludes the higher recorded values, as explained in Item 2, the GSD is also not representative of the variation that includes the high excretion values.

(5) High-Fired Plutonium Oxides

There were numerous fires at the RFP plant over its history, large and small. Such fires have been shown to involve "high-fired" plutonium oxide, which have exhibited long-term retention in the lung exceeding that predicted by the standard Type S model. The workers involved in such fires would likely either contribute to the zero entries in urine bioassay or would not have been further monitored, because their earlier bioassay samples were below detection limits. There is no cross-referencing between the OTIB-0049 (*Estimating Lung Doses for Plutonium Strongly Retained in the Lung*) and OTIB-0038 models, although it is understood that under OTIB-0049, all workers exposed or potentially exposed to plutonium are treated as if they were exposed to the high-fired form. In OTIB-0038, plutonium intakes are calculated either as Type M or Type S, with no mention of unmonitored worker exposure to high-fired nuclides and how that would be addressed.

3.15.5 Conclusions

SC&A examined OTIB-0038 in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. SC&A accepts NIOSH's position that it is possible to derive a surrogate exposure model for the unmonitored worker based on the distribution of internal doses received by the monitored workers at RFP. However, the use of a model based on the 50^{th} percentile of the excretion rates of the workers, in the way it was derived by NIOSH in the model, may misrepresent the higher exposures experienced by unmonitored workers at RFP. The uncertainties related to a model based on the 50^{th} percentile excretion rates of the workers are large and, as a consequence, dose reconstruction cannot be accomplished with sufficient accuracy.

OTIB-0038 should contain information on how potential unmonitored worker exposures to high-fired plutonium should be addressed from the coworker standpoint, given that workers could have been exposed to high-fired oxides or its residues without that recognition.

3.15.6 References

42 CFR Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

Cragle, D. 2006. Oak Ridge Associated Universities (ORAU), Informal White Paper, *Comparison of the CEDR and HIS-20 Databases,* October 2006.

Lochamy 2006. *Follow-Up Evaluation of Rocky Flats Plant HIS-20 and CEDR Databases For Coworker Bioassay Assessments,* Informal white paper, Oak Ridge Associated Universities, Cincinnati, Ohio. April 6, 2006.

Lochamy, J.C., M.H. Smith and D.W. Hearnsberger. 2006. *Comparison of Rocky Flats Plant HIS-20 and CEDR Databases for Coworker Bioassay Assessments,* Informal white paper. Oak Ridge Associated Universities, Cincinnati, Ohio. March 26, 2006.

ORAUT-OTIB-0038. 2006. *Internal Dosimetry Coworker Data for Rocky Flats Environmental Technology Site*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. August 3, 2006.

ORAUT-OTIB-0049. 2007. *Estimating Doses for Plutonium Strongly Retained in the Lung*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 6, 2007.

ORAUT-TKBS-0011-05. 2007. *Rocky Flats Plant – Occupational Internal Dose*. Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 1, 2007.

3.16 ORAUT-OTIB-0039: INTERNAL DOSIMETRY COWORKER DATA FOR THE HANFORD SITE

The review of ORAUT-OTIB-0039, *Internal Dosimetry Coworker Data for the Hanford Site*, Rev. 00 PC-2, dated January 31, 2007, was prepared by Joyce Lipsztein, PhD.

3.16.1 Purpose of the Technical Information Bulletin

The stated purpose of this Technical Information Bulletin (TIB) is to provide the details of the calculation and assignment of intakes based on coworker data from the Hanford site [including the Pacific Northwest National Laboratory (PNNL)] for the purpose of estimating unmonitored exposures.

3.16.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0039 is summarized in Table below. Table is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the TIB adequately supports the dose reconstruction process as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.16-1: ORAUT-OTIB-0039 Review Outline/Checklist

Document No.: ORAUT-OTIB-0039, Rev. 00 PC-2	**Date:** 01/31/2007
Document Title: Internal Dosimetry Coworker Data for the Hanford Site	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as requiredunder the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	See Review Comments
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	2	
3.2.3	Missing dosimetry data	2	
3.2.4	Unmonitored periods of exposure	2	

Table 3.16-1: ORAUT-OTIB-0039 Review Outline/Checklist

Document No.: ORAUT-OTIB-0039, Rev. 00 PC-2	**Date:** 01/31/2007
Document Title: Internal Dosimetry Coworker Data for the Hanford Site	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1-5*	Comments
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?	4	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	3	In-vivo monitoring results were not used for Pu and thorium exposures. See review comments related to objective 7.
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?	2	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	2	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	2	
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)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	4	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	2	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.16.3 General Comments

This document is meant to be used together with ORAUT-TKBS-0006-5, 2004 Section 5.6, Unmonitored Workers.

OTIB-0039 provides the assignment of intakes to unmonitored workers that could have been occupationally exposed to plutonium, uranium and thorium, strontium, promethium, zinc, sodium and cesium, for times up to 1988. As stated in OTIB-0039 (page 10):

> *As is typical of a site with large operating reactors and spent fuel dissolution operations, there was potential for exposure at Hanford to many radionuclides including fission and activation products, plutonium, uranium, and tritium. In addition, Hanford handled thorium for part of its history.*

Assignment of intakes to unmonitored workers that might have been exposed to tritium, I-131, U-233 and Rn-220 are given in ORAUT-TKBS-0006-5, 2004. In addition, ORAUT-TKBS-0006-5 contains information on how to handle mixtures of various nuclides, including instructions to use OTIB-0054 for fission /activation products. Assignment of exposures to D&D radiological workers is also given in ORAUT-TKBS-0006-5. As stated in ORAUT-OTIB-0039 (page 35), "Assignment of radionuclides not analyzed in this study should be in accordance with guidance in the Unmonitored Worker section of the current version of the Hanford internal dosimetry technical basis document."

This review refers only to the specific assignment of intakes and doses covered in ORAUT-OTIB-0039. The assignment of intakes to unmonitored workers according to the different installations, as well as radionuclides that are only covered in ORAUT-TKBS-0006-5 and OTIB-0054, are not addressed in this work.

Assignment of intakes to plutonium, uranium, strontium, and promethium was based on bioassay urinalysis. Thorium intakes were based on uranium intakes. Assignment of intakes to Cs-137, Na-24, and Zn-65 were based on whole-body counting. Bioassay results for Hanford were obtained as a copy of the Hanford Radiological Exposure Records (REX) database.

3.16.4 Review Comments

Review Objectives 1.1 through 1.5

As stated above, OTIB-0039 is to be used together with ORAUT-TKBS-0006-5 (2004), Section 5.6, Unmonitored Workers, which defines the installations where intakes derived in OTIB-0039 should be applied, and when and how they should be applied. ORAUT-TKBS-0006-5 (2007) also references OTIB-0054 for the assignment of intakes from fission/activation products, for the unmonitored worker.

In addition, to understand the information given for each radionuclide in OTIB-0039, it is necessary to have previous knowledge of the ORAUT-TKBS-0006-5 (2004) and all other documents cited in the TBD.

There are conflicting guidelines between the assignment of intakes and doses using the methods described in OTIB-0039 and ORAUT-TKBS-0006-5 (2004) with the ones described in ORAUT-OTIB-0002 (2007), *Maximum Internal Dose Estimates for Certain DOE Complex Claims*, which specifies "overestimate of internal dose for an unmonitored worker or a worker with no bioassay results exceeding detection limits." OTIB-0002, Attachment A, provides "the basis for applying

the assumptions, conditions, and results of this TIB to claims for Hanford Site employees before 1970."

Although OTIB-0039, Section 6, provides a detailed description on the assignment of intakes and doses, subjective decisions from the dose reconstructor are still required for Type S plutonium. In this case, a minimizing intake was calculated for Type S Pu. If the application of Type M or the application of this minimizing intake do not result in a draft POC > 50%, the dose reconstructor is expected to manually fit the coworker data for the time frame of interest for the employee, using Type S plutonium and assigning acute or chronic intakes, depending on the patterns in the data. This manual fit will probably require subjective decisions from the dose reconstructor.

Review Objective 3.2

OTIB-0039 is meant to address site-specific data pertaining to in-vivo/in-vitro bioassay data, missing dosimetry data, and unmonitored periods of exposure. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 5.1, 5.2, and 5.3

OTIB-0039 is meant to provide the details of the calculation and assignment of intakes for Hanford employees that were not monitored for internal ionizing radiation exposure or the records of such monitoring are incomplete or unavailable, based on coworker data. The technical review of methods used in this TIB is addressed below under the Review Objective 7.3 comments.

Review Objectives 6.1 and 6.2

Although OTIB-0039 provides adequate guidance for selecting the types of probability distributions, SC&A does not concur with the distributions that were used, in many circumstances, as described in the Review Objective 7.3 comments.

Review Objective 7.3

The SC&A review of OTIB-0039 revealed several areas of concerns with the validity of the scientific protocols that were employed.

SC&A reviewed the bioassay Excel results available in the ORAU term server O-Drive, under Coworker, Approved Files (O:\CoWorker Data\Approved Files\Internal Dose Data\Hanford). Those files contain the bioassay data for seven different radionuclides: plutonium, uranium, strontium-90 (Sr-90), promethium-147 (Pm-147), zinc-65 (Zn-65), sodium-24 (Na-24), and cesium-137 (Cs-137), presented on a quarterly, semi-annual, or annual basis, depending on the total number of samples in each period. The files also contain the statistical analysis that was performed by NIOSH for each radionuclide for each period, including the lognormal regression analysis of the data and the calculation of the 50^{th} percentile (GM) and 84^{th} percentile (GSD) from the lognormal equation. The numerical results of this SC&A review of the individual Excel Hanford bioassay data files are too detailed to be included in this review. Rather, this review

discusses the conclusions regarding the NIOSH Hanford bioassay analysis that SC&A has drawn from those detailed results, for each radionuclide.

(1) Plutonium

(1.1) Plutonium Urinalysis Statistical Results:

Among the plutonium bioassay data, there were a great number of results that were recorded as blanks, zeros, or reporting level values. The following text was extracted from OTIB-0039:

> *In general, Hanford used reporting levels for plutonium urinalysis results until September 1981. Whether a value recorded at the reporting level meant no detection, or whether the reporting level or higher was a true detection and nondetections were recorded as zero or blank, was indeterminate at the broad level.*
>
> *The meanings of the reporting level, zero, and blanks had to be determined on a year-by-year basis, and the decision was included in the specific instructions on how to rank such sample results. For example, the 1966 to 1974 reporting level was 1.1 × 10-8 μCi/sample* ***(0.244*** *dpm/sample) and the 1975 to 1981 reporting level was 0.025 dpm/sample. These numbers were considered to be one-half of the detection level and were used to indicate no detection of plutonium.* ***The linear distribution was used to distribute and rank blanks, zeros, and values at these reporting levels.*** *For other years, however, the reporting level was less apparent because there were many values that were probably a reporting level, but other values were less than the reporting level.* ***The latter samples were included in the linear fit, and the apparent reporting level was set as the top of the linear distribution*** (ORAUT-OTIB-0039) (Emphasis added).

The values presented as the top of the linear distribution in a non numbered Table on page 13 of ORAUT-OTIB-0039 are not consistent with the values listed in Table 5-2, ORAUT-TKBS-0006-5, and with the ones that were really used as top of the linear distributions.

SC&A analysis of the statistical distributions derived by NIOSH are presented below, divided by periods of time:

Period 1946–1957:

For this period of time, the uncertainties associated with the statistical model proposed by NIOSH are unacceptable high:

- The uncertainties related to the values reported below or at the reporting levels were not resolved in a satisfactory way.
- The reporting level is in general lower than the MDA. Results below the MDA should be used with caution, because of the uncertainties related to them. NIOSH does not address this problem.

- The number of reported positive results is very small for each data group analyzed. The number of bioassay results recorded as blanks, zeros, or reporting level values, constituted more than 95% of the total number of results, many times >99%. These results were artificially transformed into values that fitted a linear distribution, using the assumed reporting level as the top of the distribution. The assumption of imposing a lognormal distribution fit to a set of data, with more than 95% of the values artificially belonging to a perfect linear distribution, needs further justification from NIOSH.

- The calculated urine excretion geometric median values, as a result of this biased statistical analysis, are very low, in general less than ½ of the reported levels, and equal to an even lower fraction of the MDAs. Therefore, the intakes and doses to the unmonitored worker are assigned based on urine excretion values, which are equal to a low fraction of the reporting levels. These low excretion values are artificial values and are independent of the real positive results gathered during each period of time.

Period 1958–1981:

In the second quarter of 1958, the reporting level changed to a lower value than in the previous years, 0.025 dpm/sample. The proportion of zeros, blanks, and results equal to or below reporting levels dropped to around 80%, theoretically improving the lognormal fit. Even with this improvement, the lognormal model proposed by NIOSH, does not represent well the positive results. The regression equations do not cover the highest results. In general, the regression equations misrepresent the higher excretion rates. This misrepresentation is higher for the years until 1961, but it is still true for all following years.

It is important to notice that in 1958, the number of urinalysis samples decreased to about ½ of the number of samples in 1955, 1956, and 1957. During the entire period 1958–1981 the number of urine samples continued to decrease to about a little more than $1/10^{th}$ of number of samples in 1955, 1957 and 1958. NIOSH does not address this decrease, or the job performed by the workers whose urine samples were collected, or the reason the samples were collected. NIOSH does not mention the size of the monitored population nor the criteria for monitoring through in-vitro analysis and/or in-vivo monitoring. In this way it is very difficult to know how well the values used in the statistical analysis represented the exposed working population.

SC&A is concerned about the scientific validity of the statistical distribution that was used to calculate the excretion rates associated to the intakes assigned to the unmonitored workers.

Period 1982–1988:

During 1982–1988, the same concerns about the monitoring program and the number of workers that were monitored through in-vivo counting, urinalysis, and feces analysis (ORAUT-TKBS-0006-5 states that, “routine fecal sampling was used for some high-risk plutonium workers, mostly operators at PUREX and the Plutonium Finishing Plant, from 1986 through June 1989)” are repeated. The number of results used to derive the lognormal distribution model is about 13%–14% of the number of results used in 1955, 1956, and 1957. NIOSH should address this issue, giving an evaluation of how well the values used in the lognormal distribution represent the worker’s population monitored for plutonium.

(1.2) In-vivo Counting Results:

SC&A acknowledges the difficulties encountered by NIOSH in the use of in-vivo results for Pu dose reconstructions. In ORAUT-TKBS-0006-5, this difficulty is clearly expressed:

> *Because the uncertainty in the ^{241}Am to Pu alpha ratio can vary nearly two orders of magnitude, plutonium intakes should not be determined solely by chest counting data if possible. If no information concerning the isotopic mixture of an intake is available and a default mixture is assumed, then a GSD of 5 uncertainty should be associated with an intake determined by chest counting.*

However, the use of urine excretion rates to calculate lung doses introduce uncertainties that may be as large or even larger than the ones introduced by the use of in-vivo counting. The correlation of Pu retention in the lungs with the excretion rate in urine is indirect and depends on the chemical and physical forms. Different matrix materials containing Pu may have specific dissolution behavior. The method of formation of the material and its history (temperature, specific surface area) can influence the fraction rapidly absorbed and the long-term retention half-time. As a consequence, there is an increased uncertainty in the association of the urinary excretion rate with lung retention or lung deposition.

For respiratory organ dose calculations, ORAUT-OTIB-0039 recommends applying Type M Pu, followed by the minimizing Type S intake. If both actions do not yield a POC >50%, NIOSH recommends manually fitting the coworker bioassay data for the timeframe of interest for the employee, using the assumption of Type S material.

SC&A considers that the uncertainties related to respiratory organ dose calculations were not properly resolved by NIOSH, in OTIB-0039.

(1.3) Intake Modeling:

(1.3.1) Material Types:

The IMBA Expert OCAS-Edition computer program was used to fit the 50th percentile bioassay results to a series of inhalation intakes. Exposure to Type M and Type S plutonium compounds were considered.

There is no mention to exposure to "high-fired" plutonium oxide, which have exhibited long-term retention in the lung exceeding that predicted by the standard Type S model. OTIB-0049 (*Estimating Lung Doses for Plutonium Strongly Retained in the Lung*) uses the data from a Hanford worker to derive the dose correction factors, recommended for use for all workers exposed to high-fired oxides.

(1.3.2) The Intake Model:

The model intake rates do not correspond to the 50th percentile of each period of time analyzed. In some time periods, the dose will be calculated using an intake rate that corresponds to urinary excretion values smaller than the 50th percentile of the excretion rates of the workers for that

time period. For example, the intake rate for the year 1946 is obtained by fitting the GM excretion levels for 1946, 1947, and 1948, using an assumption of a continuous intake. The Pu-239 intake rate to be used for 1946, 1947 and 1948 is 57.7dpm/d. This intake rate underestimates the GM excretion rate for 1946, as shown in Figure A-1, page 39 of OTIB-0039. The intake rate of 57.7 dpm/d will produce an excretion rate of 0.157 dpm/d of Pu-239, after 1-year exposure, corresponding to 0.21dpm/d excretion rate of the Pu mixture. Thus, the unmonitored worker will be assigned with a dose for the year of 1946, corresponding to 22% of the reporting level for 1946. Figures A-2, page 39 of OTIB-0039, illustrates the same problem occurring for 1949 and 1950.

The intake rates for the years 1953, 1954, 1955, 1956, 1957, and 1958 were obtained by assuming a continuous constant intake rate for the years 1953–1981. A distortion was produced as a result of this procedure: the predicted excretion rate for a number of years, using this constant intake rate, is smaller than the GM excretion rates calculated from the fit of lognormal distributions to the excretion rates in each year. For 1953 to 1958, the predicted excretion rates are between 15% and 55% of the geometric medians calculated from the lognormal distributions.

Thus, when NIOSH suggests the use of intake rates for the 50^{th} percentile to calculate doses, it should not be understood that those intake rates correspond, for each period of time, to the 50^{th} percentile of the excretion rates of the workers. They correspond to a model intake rate that will fit the chosen percentiles, with some periods of time when the urine excretion rates will be underestimated. This is illustrated in Figures A-1, A-2, and A-3. NIOSH repeatedly uses assumptions that are not claimant favorable.

(1.3.3) The Intake Rates for 1944–1946:

The extrapolation of intake rates to the period 1944–1946 needs further justification, since the tolerance air concentration for Pu was implemented at an unknown time, "at least by October 1945," as stated in OTIB-0039.

(1.4) SC&A Conclusion:

SC&A considers that the mathematical procedures to calculate representative coworkers' excretion rates and intake rates are not claimant favorable. SC&A considers that NIOSH did not resolve the uncertainties related to statistical analysis of the data in a satisfying scientific valid protocol. SC&A is concerned that as a consequence of those uncertainties, Pu dose reconstruction for unmonitored workers cannot be accomplished in the way presented in OTIB-0039.

(2) Uranium, Thorium, and Recycled Uranium Impurities

(2.1) Uranium:

The number of results included in the database used in OTIB-0039 was relatively small. In this database, the number of employees monitored per quarter in 1963–1966 dropped to a maximum of 80 workers. In 1969, less than 42 workers per quarter of the year have uranium urinalysis results in the database. In 1970, (entire year) only 70 workers had results in the database. The number of workers is also small for 1971–1976, some of those years with less than 100 workers:

1972 (97 workers), 1973 (62 workers), 1976 (76 workers). In OTIB-0039 the small number of samples collected in 1973 is mentioned. NIOSH does not give any indication on the total number of personnel working in the production facilities, at UO_3 Plant, and at the 300 Area fabrication plants, potentially exposed to uranium.

Until 1951, uranium results are treated as natural uranium (0.70 pCi/ug). After 1952, uranium results are treated as recycled uranium (0.9099 pCi/g).

In ORAUT-TKBS-0006-5, the monitoring practice for uranium is described:

> *A note about sampling of UO_3 Plant workers: Because chemical toxicity was the principal concern for uranium exposures at the UO3 Plant, one sampling scheme used was to obtain both a Friday evening sample and Monday morning sample. The period of this sampling scheme was not established, other than in the 1970s and maybe earlier. This scheme was changed to Monday-morning-only sampling about the early 1980s. Changeover should be clear in the records. The Friday/Monday sampling scheme was also used in 1962 and 1963 for 313 and 314 Building Workers.*

There is no mention in OTIB-0039 of this monitoring practice, or even a description of the work performed by the employees whose samples are included in the database. For Type F uranium exposures, activity in samples collected after the weekend are expected to present results much lower than the ones collected on Friday. If the sample was collected after the weekend, the urine results for Type F uranium would produce intake rates 3 times higher than the ones calculated using continuous exposures as in OTIB-0039, after one year of work. For Type M uranium, the calculated intakes for samples collected after the weekend would have been 1.6 higher than the intakes calculated by NIOSH.

(2.2) Thorium:

Exposures to thorium are calculated based on the uranium exposures. NIOSH assumes the same mass intake rates for thorium and uranium and describes this practice as claimant favorable, but does not offer any monitoring or measurement values as explanation. The in-vivo bioassay data are not mentioned in OTIB-0039.

The equilibrium factors used between Th-232 and daughters are not claimant favorable. OTIB-0039 uses the equilibrium factors from ORAUT-TKBS-0006-5, which are claimant favorable only for the monitoring results described in the TBD:

> *The degree of equilibrium between ^{232}Th and decay products including ^{228}Th would have been variable. As explained in the Hanford internal dosimetry TBD* [ORAUT-TKBS-0006-5], *a time since purification of 0.5 yr was assumed.*

ORAUT-TKBS-0006-5 (2007) states the following:

> *Radium-228, the first progeny of ^{232}Th would have been removed, either during the processing of the ore at Fernald or during baking and sintering in the 300 Area, so the progeny would not have been in equilibrium (West 1965).*

Workers could have been exposed to thorium in a mixture of ages (i.e., time since purification), but most of the material would have been fairly young. It is favorable to claimants to assume younger material when whole body counting is the bioassay method (explained below); hence, the thorium was assumed to be 0.5 yr since purification.

In OTIB-0039, intake results are being used, not whole-body counting results which uses the daughters to account for the parent activity: the assumption of 0.5 yr since purification is no longer claimant favorable, in the assignment of intakes in OTIB-0039.

(2.3) Recycled Uranium Impurities:

The inclusion of impurities must be updated. It will probably follow Table 5-13 of ORAUT-TKBS-0006-5. The values in Table 5-13 were not well explained. As an example, the level chosen for Th seems arbitrarily chosen.

(2.4) SC&A Conclusion:

SC&A is concerned that the data and the information presented in OTIB-0039 for uranium are not sufficient to sustain the assignment of intakes to unmonitored workers, based on coworker information. SC&A concludes that uranium dose reconstruction for unmonitored workers cannot be accomplished in the way presented in OTIB-0039. As a consequence, and aggravated by other technical issues, as described above, SC&A concludes that thorium dose reconstruction for unmonitored workers cannot be accomplished in the way presented in OTIB-0039. This conclusion extends to the dose reconstruction for the unmonitored worker from impurities present in recycled uranium.

(3) Strontium-90

According to OTIB-0039, both Sr-90 and Sr-89 could have been counted. All results were assumed to be Sr-90.

(3.1) Strontium Urinalysis Statistics:

Strontium urinalysis results are analyzed from 1965 to 1988. Through 1981, zero or less-than results were treated as non detections and included in the linear distribution. Reporting levels, treated as the top of the linear distribution, are given in a non-numbered table in Section 4.1.3 of OTIB-0039.

Period 1965–1967:

There were 634 results. Ninety-seven percent (97%) of the results were below detection limits and were artificially transformed into values that fitted a linear distribution. The assumption of a lognormal distribution, with 97% of the results belonging to a perfect linear distribution needs further justification. The calculated geometric median from this biased distribution is less than 40% of the reported level.

Period 1968–1970:

Some technical problems are reported for these years.

The reporting level in 1968 and 1969 was 1.67E-5 µCi/L or 51.4 dpm/24h sample (ORAUT-OTIB-0039, Section 4.1.3). The reporting level in 1970 was 1.00E-6 µCi/L or 3.08 dpm/sample (ORAUT-OTIB-0039, Section 4.1.3).

Looking at the data posted for Sr in the NIOSH- ORAUCOC termserver O_Drive (O:\CoWorker Data\Approved Files\Internal Dose Data\Hanford), a linear distribution was not applied for the data below 3.08 dpm/sample. For unexplained reasons, a linear distribution was apparently applied to data in rank positions 93 to 120 and from 123 to 143. The values follow each other with a constant difference of 0.519036. This last rank, 143, roughly corresponds to the 51.4 dpm/24h reporting level for 1968 and 1969.

The lognormal distribution as given needs further justification.

Period 1971, 1972:

There are some technical problems in trying to reproduce the values in OTIB-0039 from the Excel tables in the NIOSH –ORAUCOC termserver ODrive (O:\CoWorker Data\Approved Files\Internal Dose Data\Hanford\Sr\ Hanford Sr 1971-1978 version 4). The problem is related to the units used in the tables: dpm/L versus dpm/d.

Period 1973, 1974, 1975, 1976, 1977:

The number of urinalysis results used to derive the model distribution was small, varying from 38 results to 108 results. There are very few results above the reporting level. The GMs are calculated mostly from a distribution of artificial numbers. NIOSH should justify the use of the lognormal distribution and of the GM as the best representation of the worker's exposure to Sr during this period of time.

Period 1978, 1979, 1980, 1981:

The same problem occurs in 1978–1981, although there was a substantial increase in the amount of data. There were few results above reporting levels. The linear distribution was artificially fitted to more than 95% of the values, which were below reporting level. The assumption of a lognormal distribution, with more than 95% of the results belonging to a perfect linear distribution requires further justification. The calculated GM is 40%–50% of the reporting level. The lognormal distributions, in general, do not represent well the high real results that were obtained for each year.

Period 1982–1988:

The lognormal distributions for the each year or fraction of the year during this period of time included all reported results in the distribution, independent of their representation of a real measurement or not. The unmonitored worker dose in this case, is assigned based on the reporting practice of the year, instead of being calculated based on the exposure of their peers.

As a consequence, the GM for the years 1982–1983 dropped to very low values, much lower than the following years, because in 1982 and 1983 negative values were reported.

(3.2) SC&A Conclusion:

SC&A considers that the mathematical procedures to calculate representative coworker excretion rates are not claimant favorable. SC&A considers that NIOSH did not resolve the uncertainties related to statistical analysis of the data in a satisfying scientific valid protocol. SC&A is concerned that as a consequence of those uncertainties, Sr dose reconstruction for unmonitored workers cannot be accomplished in the way presented in OTIB-0039.

(4) Pm-147

According to ORAUT-OTIB-0039:

> *…specific bioassay for 147Pm was initiated when the Pacific Northwest Laboratory (now PNNL) began manufacturing 147Pm heat sources in the 325 Building in 1966. Some exposure to 147Pm also occurred in the 308 Fuels Laboratory. The number of workers in the bioassay program and the number of samples were small in comparison to the numbers for the plutonium, uranium, or strontium bioassays, with a high of 65 workers in 1968. There was almost no sampling from 1972 to 1975, which probably indicates a cessation of the original heat source program, and only 20 workers were sampled from 1976 to 1979. The exact end date of the heat source program has not been determined. For purposes of this study, it was assumed that exposure occurred from 1966 to 1979, although it is likely that any exposure from 1972 to 1975 was only due to residual activity.*

(4.1) Pm-147 Statistical Analysis:

The number of results is very low. For the period of 1975 to 1979, there were 103 results, but only 5 above the reporting level. A linear distribution was artificially fitted to the 98 results, which were below reporting level. The assumption of a lognormal distribution, with 95% of the results belonging to a perfect linear distribution is doubtful. In the period of March 31–December 31, 1970, and 1971, there were only 39 measurements with only 2 results above reporting level. NIOSH should further explain the scientific reasons to apply an artificial linear distribution to 37 results and then apply a lognormal distribution over the results obtained from the linear distribution, plus the two results above detection limit.

(4.2) SC&A Conclusion:

SC&A considers that the mathematical procedure to calculate representative coworker excretion rates, from the statistical analysis of the data requires further explanation. SC&A is concerned that as a consequence, Pm-147 dose reconstruction for unmonitored workers cannot be accomplished in the way presented in OTIB-0039.

(5) Zn-65

Zn-65 was reported in whole-body counts from 1960 to 1983. There were about 370 results in 1984, and these results were included in the statistical analysis.

(5.1) Statistical Analysis:

Period 1961, 1962, 1963, 1964, 1966, 1967, 1968, 1969, 1970, 1971, 1972, 1973:

The fitting of the data using the lognormal distribution presented good correlation coefficients. There were a number of high results, suggesting that the use of the 95th percentile to represent, in a claimant-favorable manner, the unmonitored worker is more adequate than the GM.

(5.2) The Intake Model:

The model intake rates do not correspond to the 50th percentile of each period of time analyzed. In some time periods, the dose will be calculated using an intake rate that corresponds to urinary excretion values smaller than the 50th percentile of the excretion rates of the workers for that time period.

The assigned intake rates for the period 1944–1959 require further justification from NIOSH.

(5.3) SC&A Conclusion:

SC&A accepts NIOSH's position that it is possible to assign intakes and doses due to exposure to Zn-65 to the unmonitored worker based on the coworker data, for the period 1960–1984. However, the use of a model based on the 50th percentile of the monitoring results, in the way it was derived by NIOSH, may misrepresent the higher exposures experienced by unmonitored workers.

NIOSH should further explain the assignment of intakes for the period 1944–1959.

(6) Na-24

Whole-body counting results were reported for Na-24 from 1960–1983. NIOSH has included the results taken in 1984, although the much smaller number of results.

(6.1) Statistical Analysis of the Data:

Except for the 1962 results, the whole-body counting measurements were well represented by a lognormal distribution. In the first quarter of 1962, the real results are not well represented by the regression line for the lognormal distribution. In the last quarter of 1962, only 8 of the 103 results may be considered real measured results. The lognormal distribution, as derived by NIOSH, does not represent well the exposures.

(6.2) The Intake Model:

The assigned intake rates for the period 1944–1959 require further justification from NIOSH.

(6.3) SC&A Conclusion:

SC&A accepts NIOSH's position that it is possible to assign intake and dose due to exposure to Na-24 to the unmonitored worker based on the coworker data, for the period 1960–1984. NIOSH should refine the assignment of intakes for the year of 1962.

The use of a model based on the 50th percentile of the monitoring results, misrepresents the higher exposures experienced by unmonitored workers.

NIOSH should further explain the assignment of intakes for the period 1944–1959.

(7) Cs-137

Cesium-137 was reported routinely with every whole-body count from 1960 to 1983. For 1984–1988, the nuclide was recorded if it was detected above a reporting level:

> *For this period the total number of whole-body counts given was determined by tallying the number of 40K counts, which were recorded for every valid whole-body count. Each whole-body count for which 137Cs was not listed was considered the same as a whole-body count with a blank or zero result for 137Cs.*

(7.1) Statistical Analysis:

The statistical representation of the Cs-137 measurement results for 1960, 1961, 1962, 1963, 1964, 1965, 1966, 1967, and 1968, using the "rank method," as described in OTIB-0039, to derive the lognormal curve is appropriate. For 1969, 1970, 1971, 1972, 1973, 1974, 1976, 1977, 1978, 1979, 1980, and 1983, the lognormal distribution is reasonable but misrepresents some high results. In 1981 and 1982, the raw 50th percentile is the MDA 0.65nCi (NIOSH-ORAUCOC termserver O-Drive, O:\CoWorker Data\Approved Files\Internal Dose Data\Hanford O Drive). This is different from the numbers used in Table 4-9.

The statistical results derived for 1984–1988 are "biased," although OTIB-0039 states that the use of a linear distribution for these years produces a distribution that is "less biased" than the use of the "rank only method." The number of artificially produced results is very high and the number of real measurements results very low, generally less than 2%, of the total, as stated in OTIB-0039. The end result of using this distribution to assign intakes to the unmonitored workers is that their doses will be calculated from artificially produced values, lower than the detection level.

(7.2) The Intake Model:

The assigned intake rates for the period 1944–1959 require further justification from NIOSH

(7.3) SC&A Conclusion:

SC&A accepts NIOSH's position that it is possible to assign intakes and doses due to exposure to Cs-137 to the unmonitored worker based on the coworker data, for the period 1960–1983.

The use of a model based on the 50th percentile of the monitoring results, may misrepresent the higher exposures experienced by unmonitored workers.

NIOSH should further explain the assignment of intakes for the period 1944–1959.

NIOSH should redefine the assigned intakes for 1984–1988.

3.16.5 References

42 CFR Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0002. 2004. *Technical Information Bulletin – Maximum Internal Dose Estimates for Certain DOE Complex Claims*, Rev. 01, PC-2, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 7, 2004.

ORAUT-OTIB-0039. 2007. *Internal Dosimetry Coworker Data for the Hanford Site*, Rev. 00 PC-2, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 31, 2007.

ORAUT-OTIB-0049. 2007. *Estimating Doses for Plutonium Strongly Retained in the Lung*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 6, 2007.

ORAUT-OTIB-0054. 2007. *Fission and Activation Product Assignment for Internal Dose-Related Gross Beta and Gross Gamma Analyses*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 11, 2007.

ORAUT-TKBS-0006-5. 2004. *Technical Basis Document for the Hanford Site – Occupational Internal Dose*, ORAUT-TKBS-0006-5, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 14, 2004.

ORAUT-TKBS-0006-5. 2007. *Technical Basis Document for the Hanford Site – Occupational Internal Dose*, ORAUT-TKBS-0006-5, Rev. 02, Oak Ridge Associated Universities Team, Cincinnati, Ohio. June 22, 2007.

West, C.M., 1965. "Health Physics Considerations Associated with Thorium Processing," Y-KB-53, Y-12 Plant, Oak Ridge, Tennessee. [SRDB Ref ID 11596]

3.17 ORAUT-OTIB-0043: CHARACTERIZATION OF OCCUPATIONAL EXPOSURE TO RADIUM AND RADON PROGENY DURING RECOVERY OF URANIUM FROM PHOSPHATE MATERIALS

The review of ORAUT-OTIB-0043, *Characterization of Occupational Exposure to Radium and Radon Progeny During Recovery of Uranium from Phosphate Materials*, Rev. 00, dated January 6, 2006, was prepared by Charles Phillips.

3.17.1 Purpose of the Technical Information Bulletin

The purpose of this TIB is to characterize "occupational radiation exposure from the extraction of uranium during nonmonazite phosphate processing at atomic weapons employer (AWE) facilities. Exposure models and associated data have been acquired and/or extrapolated from existing published scientific research and Federal studies."

3.17.2 Review Protocol

SC&A's evaluation of OTIB-0043 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the OTIB adequately supports the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.17-1: ORAUT-OTIB-0043 Review Outline/Checklist

Document No.: ORAUT-OTIB-0043, Rev. 00	**Date:** 01/06/2006
Document Title: Characterization of Occupational Exposure to Radium and Radon Progeny During Recovery of Uranium from Phosphate Materials	
Auditor: Charles Phillips	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	

Table 3.17-1: ORAUT-OTIB-0043 Review Outline/Checklist

Document No.: ORAUT-OTIB-0043, Rev. 00	**Date:** 01/06/2006
Document Title: Characterization of Occupational Exposure to Radium and Radon Progeny During Recovery of Uranium from Phosphate Materials	
Auditor: Charles Phillips	

No.	Description of Objective	Rating 1-5*	Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	See Review 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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	

Table 3.17-1: ORAUT-OTIB-0043 Review Outline/Checklist

Document No.: ORAUT-OTIB-0043, Rev. 00	**Date:** 01/06/2006
Document Title: Characterization of Occupational Exposure to Radium and Radon Progeny During Recovery of Uranium from Phosphate Materials	
Auditor: Charles Phillips	

No.	Description of Objective	Rating 1-5*	Comments
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.17.3 Review Comments

Review Objective 1.1

The title of OTIB-0043 is misleading in that it implies that only radium and radon progeny doses are considered in the document, whereas Th-232 exposures are also included in the OTIB. However, the OTIB fails to consider Th-230 as a possible contributor to the doses encountered in uranium recovery from phosphoric acid processing facilities. The OTIB uses data from Guimond et al. (1977) to determine internal doses from Th-232, but fails to recognize the same reference measured Th-230 concentrations that were equal to U-238 concentrations in phosphoric acid. If the OTIB intends to provide guidance for doses associated with thorium, it should consider those associated with Th-230, or explain why they are omitted.

Section 2.0 of the OTIB would be made more readable by making the last paragraph in that section the opening paragraph.

Review Objective 1.3

OTIB-0043 references several documents, primarily those produced by the Florida Institute of Phosphate Research (FIPR), which are appropriate for estimating doses in the phosphate industry. However, an important reference by Keaton (1987), which was included in the FIPR documents, was not included in the OTIB. This publication contains data on phosphate industry exposures that are potentially more representative in time than those considered in ORAUT-OTIB-0043.

Review Objective 4.1

Doses are assigned to AWE workers in uranium recovery operations associated with phosphate production plants in the 1950s era based on relatively recent information and measurements

made in phosphate facilities. The approach to the use of this information is prescriptive and easily understood.

Review Objective 4.2

The hierarchical process as defined in 42 CFR 82.2 is applied in OTIB-0043. Bioassay and dosimetry data are generally not available for AWE workers involved in uranium recovery operations in phosphate plants; thus, surrogate information for phosphate plant workers is proposed.

Review Objectives 5.1 through 5.3

These review objectives evaluate the degree to which OTIB-0043 is claimant favorable in its approach to assigning doses where there is an absence of monitoring data or there are unknown factors affecting monitoring data for the assignment of individual doses to AWE workers.

There is generally a lack of monitoring and bioassay data for the workers affected by this OTIB during the period covered by their employment extracting uranium from phosphoric acid. The approach of ORAUT-OTIB-0043 is to use data collected on doses to workers at phosphate production plants at times, generally, much later than the time frame when uranium was extracted at these production facilities. The basis of the applicability of the data used to the time frame for uranium extraction, as stated in Section 4.2 of OTIB-0043, is that there have been no significant changes in phosphate plants or radon exposures since uranium extraction was performed on phosphate plant products. The basis of this assertion was an e-mail communication from B. Birky of FIPR. Given all the studies conducted during the 1970s and 1980s on radon exposure in the phosphate industry and recommendations offered as a result of those studies, it would appear that a more firm basis is needed to assure that the dosimetric information used in the OTIB is claimant favorable. If changes were made at the plants to reduce worker exposures, the data from the plants taken after these changes would underestimate worker exposures during the period when uranium was recovered from phosphoric acid.

OTIB-0043 should explicitly include Th-230 in the exposure matrix. The OTIB seems to have overlooked the possibility that Th-230 also partitioned to the phosphoric acid stream along with uranium. If this occurred, Th-230 could have contributed significantly to the internal doses for uranium extraction workers; hence, the possibility of an important missed dose.

It is not apparent that 0.036 WLM/yr, which is adopted in the OTIB-0043 for deriving upper-bound internal doses from radon and its short-lived progeny, is a plausible and bounding exposure rate for uranium extraction workers. The OTIB based its default value by selecting the best estimate of a vast amount of data gathered at phosphate mining and processing facilities in Florida, and makes an effort to select data that might be applicable to facilities contracted by the AEC to separate uranium from phosphate plant products. However, additional information is needed regarding the location, size, and characteristics of the tailings piles, which contain the radium, at a given facility and at the Florida facilities in order to support the default value adopted in the TBD. If such information is not available, the upper 95^{th} percentile values reported in OTIB-0043 might be more appropriate for use as default bounding values for exposure to radon and its short-lived progeny.

3.17.4 Technical Issues

In Table 4-3 of OTIB-0043, Th-232 intake rates are calculated using U-238 to Th-232 ratios in phosphate rock. Since the ratio of the concentration of U-238 to Th-232 in phosphoric acid is reported to be as high as about 10:1, the high-end default intake rate of Th-232 and Th-228 adopted in the TBD should be about 8.2 pCi/day, instead of 1.1 pCi/day. NIOSH adopted an intake rate of 1.1 pCi/day for Th-232 and Th-228 based on the ratio of U-238 to Th-232 observed in phosphate ore concentrate, which, on face value, would appear to be an appropriate approach. However, it appears that, based on the report by Guimond et al. (1977), Th-232 might be more efficiently partitioned to the phosphoric acid stream than uranium, resulting in an enrichment of Th-232 relative to that of U-238.

3.17.5 References

42 CFR Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

Birkey, B., 2005. E-mail communications from B. Birkey, Florida Institute of Phosphate Research in Bartow, Florida, to R. Gard, Oak Ridge Associated Universities Team, regarding Phosphate Plant Radon Levels, September 1 and September 2, 2005.

Guimond, R.J., Mills, W.A., and Windham, S.T. 1977. "Radiation Exposures in the Florida Phosphate Industry," *International Radiation Protection Association Meeting #4, Paris, France*, Vol. 3, pp. 1049–1052.

Keaton H. 1987. An assessment of radiological hazards associated with the operation and maintenance of the gypsum filtration system at wet-process phosphoric acid plants. In: *Natural radiation and technologically enhanced natural radiation in Florida*. Proceedings of a symposium held May 6–8, 1987, Daytona Beach, Florida. Published by the Florida Chapter of the Health Physics Society.

ORAUT-OTIB-0043, *Characterization of Occupational Exposure to Radium and Radon Progeny During Recovery of Uranium from Phosphate Materials*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 6, 2006.

3.18 ORAUT-OTIB-0045: HISTORICAL EVALUATION OF THE FILM BADGE PROGRAM AT THE Y-12 FACILITY IN OAK RIDGE, TENNESSEE: PART 2 - NEUTRON RADIATION

This OTIB has not been issued by ORAUT. It is suggested that review of this document be deferred until next fiscal year, after it has been issued by NIOSH.

3.19 ORAUT-OTIB-0047: EXTERNAL RADIATION MONITORING AT THE Y-12 FACILITY DURING THE 1948–1949 PERIOD

The review of ORAUT-OTIB-0047, *External Radiation Monitoring at the Y-12 Facility During the 1948–1949 Period*, Rev. 00, dated September 20, 2005, was prepared by Robert Barton.

3.19.1 Purpose of the Technical Information Bulletin

The stated purpose of this OTIB is as follows:

> *…to discuss and summarize the 1948–1949 external monitoring data that are now available for use in the NIOSH Dose Reconstruction Project for workers at facilities operated by the U.S. Department of Energy (DOE) and its predecessor agencies.*

3.19.2 Review Protocol

Our evaluation of OTIB-0047 is summarized in Table. Table presents a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether a procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 3.19-1: ORAUT-OTIB-0047 Review Outline/Checklist

Document No.: ORAUT-OTIB-0047, Rev. 00	**Effective Date:** 09/20/2005
Document Title: External Radiation Monitoring at the Y-12 Facility During the 1948–1949 Period	
Auditor: Robert Barton	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	N/A	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	N/A	

Table 3.19-1: ORAUT-OTIB-0047 Review Outline/Checklist

Document No.: ORAUT-OTIB-0047, Rev. 00	**Effective Date:** 09/20/2005
Document Title: External Radiation Monitoring at the Y-12 Facility During the 1948–1949 Period	
Auditor: Robert Barton	

No.	Description of Objective	Rating 1-5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	

Table 3.19-1: ORAUT-OTIB-0047 Review Outline/Checklist

Document No.: ORAUT-OTIB-0047, Rev. 00	**Effective Date:** 09/20/2005
Document Title: External Radiation Monitoring at the Y-12 Facility During the 1948–1949 Period	
Auditor: Robert Barton	

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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	2	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.19.3 General Comments

The purpose of this document is to analyze recently uncovered dose records for the years of 1948–1949 at the Y-12 complex. The ultimate goal of this OTIB is to characterize the doses statistically, and, if necessary recommend modification of the dose reconstruction process to account for the new data. The OTIB comes to the conclusion that the dose records do not represent a claimant-favorable approach and so should not be used to replace the current recommendations for applying dose to this period (found in RPRT-0032).

SC&A was able to recreate this statistical analysis with no significant discrepancies (see Section 7.3.1 for minor issues found). However, the conclusions of the OTIB with regard to the use of surrogate data developed in RPRT-0032 in place of the actual monitoring records is questionable (see complete discussion in Review Objective 7.3).

3.19.4 Review Comments

Review Objective 1.3

The finding of OTIB-0047 concludes that the recovery of these dose records does not affect the dose reconstruction process that has been employed thus far. After analyzing the dose records, the OTIB concludes that the treatment found in ORAUT-OTIB-0045 *Technical Information Bulletin: Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 – Neutron Radiation*, gives a more claimant-favorable approach to external dose to workers. This OTIB would benefit from a more substantive discussion of the

conclusions of OTIB-0045 and give quantitative examples of how the older document is a more claimant-favorable approach. However, OTIB-0045 no longer exists in its original form, but is currently titled ORAUT-RPRT-0033; the TIB should be updated to reflect this change in document organization.

Review Objective 7.3

Statistical Analysis Issues:

Issue 1: The OTIB states that there were "240 distinct ID Badges identified," however, SC&A was only able to identify 229 distinct badge numbers. It is not clear where this discrepancy arises. However, this does not affect the statistics of the OTIB nor its conclusions and so it is of minor importance.

Issue 2: The statistical analysis for each of the dose inputs (R1–R4) states that all "NR" readings were excluded. Based on an email response via NIOSH, it was found that doses that were recorded as "0" were not excluded from the original statistical treatment. However, upon recreation of the statistics for each dose input, it was apparent that this was not the case for three of the four dose inputs. For the doses recorded for R1–R3, any doses listed as "0" were not included in the analysis; however, the R4 did include zero readings in its analysis.

Validation of the OTIB's Conclusions:

This section reviews the OTIB's conclusion that the dose values developed by ORAUT-RPRT-0032 are more claimant favorable than the dose records recovered for the years 1948–1949. Upon inspection of ORAUT-RPRT-0032 the following recommended dose values were found. The results are shown in Table as an abridged version of the table found in ORAUT-RPRT-0032.

Table 3.19-2: Abridged Version of Table 5 found in ORAUT-RPRT-0032

Year	Qtr	μ	σ	GM(reg)	GSD(reg)	E(dose)
1948	1	5.2077	1.1709	182.6697	3.2248	362.5419
1948	2	5.1773	1.1708	177.2026	3.2245	351.6610
1948	3	5.1469	1.1707	171.9009	3.2243	341.1072
1948	4	5.1165	1.1706	166.7578	3.2240	330.8709
			1948 Total:			**1386.181**
1949	1	5.0862	1.1706	161.7685	3.2238	320.9423
1949	2	5.0558	1.1705	156.9285	3.2235	311.3123
1949	3	5.0254	1.1704	152.2334	3.2233	301.9717
1949	4	4.8735	1.1701	134.8161	3.2224	267.3344
			1949 Total:			**1201.561**
			Total:			**2587.742**

Table contains the maximum doses found in the dose records. The maximum dose for a quarter was calculated by summing the maximum exposure recording found in each month of the dose records for the given quarter. Also included in the final column of Table are the values found in RPRT-0032, which can be used as a comparison.

Table 3.19-3: Maximum Exposures from Monitoring Data Compared to RPRT-0032

Year	Quarter	R1	R2	R3	R4	RPRT Max Dose
1948	1	0	0	0	0	362.5419
1948	2	148	115	85	55	351.6610
1948	3	140	900	700	90	341.1072
1948	4	205	90	90	90	330.8709
1948 Total		**493**	**1105**	**875**	**235**	**1386.181**
1949	1	260	5250	90	90	320.9423
1949	2	265	90	0	0	311.3123
1949	3	220	90	0	0	301.9717
1949	4	210	90	0	0	267.3344
1949 Total		**955**	5520	**90**	**90**	**1201.561**
Total		**1448**	**6625**	**965**	**325**	**2587.742**

As one can see from Table, the gamma dose given in the RPRT-0032 is larger than the maximum recorded dose in most cases. It is important to note that the values listed in RPRT-0032 are for gamma exposures only and do not take into account the beta component. Therefore, the most meaningful comparisons should be made with R1 (representing the dose recorded by pocket ionization chambers or PICs), R3 (representing a shielded film badge), and R4 (representing an insensitive film badge with a MDL of 500 mrem). The recorded dose for R2 represents an open window-type film badge, which would record both the beta and gamma contribution.

The doses recorded for R1 and R4 are less than the values found in RPRT-0032 in all instances. The doses for R3 are all less than the RPRT-0032 values with the exception of the third quarter of 1948. This is due to an unusually large dose to a worker in July of 1948, which registered as 640 mrem for R3 (the next highest dose for R3 in July of 1948 was 55 mrem). The TIB addresses this issue in the following manner:

> *The high R2 reading for another worker in the Fire Department (Dept. 2093) in July 1948 appears to be an artifact for a couple of reasons: (1) the R2 and R3 readings for the skin and whole-body doses are nearly equal (…), and (2) the high R3 reading for the whole-body dose is not observed in either the R1 or R4 readings for the worker (…). The Recorded R3 dose of 640 mrem was greater than either the R1 MDL of 5 mrem or the R4 MDL of 500 mrem* (OTIB-0047, pg. 12).

This is consistent with SC&A's review of the dose records, and so it is reasonable to characterize this unusually high dose as an outlier and not an accurate representation of the exposure scenarios.

The readings for R2 are larger for the third quarter of 1948 and the first quarter of 1949. The larger reading for the third quarter of 1948 is, again, due to the large dose to the Fire Department worker in July of 1948. If this outlier is ignored, then the total dose for this quarter falls to 270 mrem, which is lower than the RPRT-0032 value of ~341 mrem. In the first quarter of 1949, the recorded R2 maximum is much larger than the RPRT-0032 value (larger by a factor greater

than 10). This is mainly due to a worker who received 2.5 rem in January and again in February. The TIB addresses this issue in the following manner:

> *The two very high R2 doses in January and February 1949 to a worker in the Chemical Department (Dept. 2619) suggest a large skin dose that may not have been detected by the PICs. These two high R2 doses do not appear to be due to beta particles because the ratio of R2 to R3 of approximately 100:1 is much larger than the expected beta-to-gamma dose ratio from exposure to uranium* (OTIB-0047, pp. 8–9).

The report goes on to explain the unusually high exposure in the following:

> *The two high R2 readings in January and February 1949 are more likely the result of exposure to very-low energy photons leaking from an X-ray spectrograph or other devices, a problem that was noted in early Health Physics reports (Struxness, 1948b 1948c).* (OTIB-0047, pp. 9 and 12)

The sited references refer to Health Physics: Industrial Hygiene Reports from September and November of 1948, not the Industrial Hygiene Reports from January and February of 1949. In the September 1948 report it states:

> *An investigation of these instruments indicated that the level of x-rays coming from the sides and top is several times tolerance allowed for continuous eight hour exposure. A procedure has been set up so that each person operating the dummy load will wear an x-ray film badge.* (Struxness 1948b, pg. 6)

This is consistent with the explanation provided by OTIB-0047; also, the Industrial Hygiene report for September (Struxness 1948a) gives a similar statement regarding exposure to x-rays. However, it is interesting to note that no mention is made in the January and February industrial hygiene reports concerning unusually high levels of x-ray exposure, which would be expected, given that the large exposure occurred during this time (Struxness 1949).

It is clear that comparing the dose records in the context of a single maximum exposure to the recommended gamma dose from RPRT-0032 shows that the values in RPRT-0032 represent a more claimant-favorable approach. However, as noted in the TIB, the 75th percentile dose for each dose record was generally around 30 mrem. This is especially true for the doses recorded by the PICs which the TIB states were the doses of record for the period in question. Considering that each dose record represented an exposure period of 1 week, this would mean the 75th percentile would likely receive 120 mrem in a month, which translates to 360 mrem in a quarter. This quarterly dose estimate surpasses all but one of the recommended dose values found in RPRT-0032 (ironically this is the first quarter of 1948 which had no non-zero doses recorded). Given that 30 mrem is the minimum detectable activity (MDA) for the film badges, this does not seem like an unreasonable value to assume as claimant favorable for exposure. Therefore, the TIB certainly warrants a more substantive and quantitative discussion as to why these dose records should be ignored, while the values developed in RPRT-0032 should be used.

3.19.5 References

42 CFR Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-RPRT-0032. 2005. *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 1 – Gamma Radiation*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. March 21, 2005.

ORAUT-RPRT-0033. 2005, *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 – Neutron Radiation*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. April 13, 2005.

ORAUT-OTIB-0044. 2005. *Technical Information Bulletin: Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 – Neutron Radiation*, Oak Ridge Associated Universities Team, Cincinnati, Ohio. July 2005.

ORAUT-OTIB-0047. 2005. *Technical Information Bulletin: External Radiation Monitoring at the Y-12 Facility During the 1948–1949 Period*, Rev. 00, September 20, 2005. Oak Ridge Associated Universities Team, Cincinnati, Ohio. Oak Ridge, Tennessee.

Struxness, E.G. 1948a. *Health Physics – Industrial Hygiene Progress Report, May 1–31, 1948*. Y-181/1R, Y-12 Plant, Oak Ridge, Tennessee – Carbide and Carbon Chemicals Co., June 16.

Struxness, E.G. 1948b. *Health Physics – Industrial Hygiene Progress Report, September 1–30 1948*. Y-259, Y-12 Plant, Oak Ridge, Tennessee – Carbide and Carbon Chemicals Co., October 8.

Struxness, E.G. 1948c. *Health Physics – Industrial Hygiene Progress Report, November 1–30 1948*. Y-300/1R, Y-12 Plant, Oak Ridge, Tennessee – Carbide and Carbon Chemicals Co., December 15.

Struxness, E.G. 1949. *Health Physics – Industrial Hygiene Progress Report, December 1–31, 1948*. Y-318/1R, Y-12 Plant, Oak Ridge, Tennessee – Carbide and Carbon Chemicals Co., January 11, 1949.

3.20 ORAUT-OTIB-0049: ESTIMATING DOSES FOR PLUTONIUM STRONGLY RETAINED IN THE LUNG

The review of ORAUT-OTIB-0049, *Estimating Doses for Plutonium Strongly Retained in the Lung*, Rev. 00, dated February 6, 2007, was prepared by Joyce Lipsztein, PhD.

3.20.1 Purpose of the Technical Information Bulletin

The stated purpose of OTIB-0049 is to provide a method for calculating a best estimate (for the purposes of this project) of the annual organ doses for intakes of plutonium that are retained in

the lung longer than predicted by the normal absorption Type S model and to describe the conditions for applicability of this method.

3.20.2 Review Protocol

SC&A's evaluation of OTIB-0049 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the OTIB adequately support the dose reconstruction process as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.20-1: ORAUT-OTIB-0049 Review Outline/Checklist

Document No.: ORAUT-OTIB-0049, Rev. 00	**Date:** 02/06/2007
Document Title: Estimating Doses for Plutonium Strongly Retained in the Lung	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as requiredunder the Privacy Act?	N/A	

Table 3.20-1: ORAUT-OTIB-0049 Review Outline/Checklist

Document No.: ORAUT-OTIB-0049, Rev. 00	**Date:** 02/06/2007
Document Title: Estimating Doses for Plutonium Strongly Retained in the Lung	
Auditor: Joyce Lipsztein, PhD	

No.	Description of Objective	Rating 1-5*	Comments
3.2	Adequacy and use of site-specific data pertaining to:	-----	See Review Comments
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	4	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	4	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	4	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.20.3 General Comments

Studies of the behavior of various oxide forms of Pu in the respiratory tract show two distinct phases of absorption to blood; a small fraction, typically less than 1% of the inhaled amount, is

absorbed within about a day, with the remainder being cleared from the lung with half-times of the order of years. Both the fraction rapidly absorbed and the long-term retention half-time can be influenced by the method of formation of the material and its history. Plutonium dioxide ($^{239}PuO_2$), formed by complete oxidation of the metal or salt at about 1,000°C (high–fired) has repeatedly demonstrated the very low absorption generally associated with Type S (ICRP 71, 1995).

In addition, in several cases of inhalation of plutonium high-fired oxides, it has been shown that there is a longer retention in the lung than currently predicted using default Type S parameters. High-fired plutonium oxide is transferred at an extremely slow rate from the lung into the systemic circulation in many cases. There is a component of retention in the lung that is not currently described by the current ICRP 66 Human Respiratory Tract Model.

OTIB-0049 recognizes that:

> … *with the depletion of the fast-removal components, the rate of removal of plutonium from the lung is slower than that predicted by Type S material for some people under some conditions; as a consequence, the total dose to an organ accumulated over many years is greater. This phenomenon has been popularly referred to as "Type Super S" (or "Type SS" for short), although it is not established that it necessarily is caused only by slower absorption of the plutonium into the blood* (OTIB-0049, pg. 6).

The ICRP at present does not address specifically the case of inhalation exposures to high-fired plutonium oxides. Although the long-term retention of the high-fired oxides has been reviewed in the scientific literature, there is not a consensus among authors on how to address this issue. Meanwhile NIOSH has proposed, in OTIB-0049, an alternate approach to estimate doses for high-fired plutonium oxides.

The OTIB-0049 does not propose a model to account for the longer retention of the high-fired oxides of plutonium.

> *This TIB does not propose a new class of material for general modeling purposes or propose a new variation of the lung model. Rather, to account for the increased organ doses, the TIB analysis developed empirical "dose adjustment factors" from selected cases from RFP and Hanford that exhibited Type SS behavior following intakes of ^{239}Pu mixtures* (OTIB-0049, pg. 7).
>
> *The standard approach adopted in this TIB is to first calculate doses to the organs of interest by applying the standard Type S model to the available bioassay data or air monitoring data. Then, one or more adjustment factors are applied to this dose in order to account for the longer retention of Type SS material in the lungs and, in the case of urine bioassay data, the lower urinary excretion per unit intake of Type SS material compared to Type S material* (OTIB-0049, pg. 7).

> *The derivation of lung dose adjustment factors is based on an empirical comparison of the plutonium retained in the lungs for 10 well-documented cases involving acute intakes of plutonium (nine from RFP and one from Hanford) in relation to the amount projected for each case using the default Type S model for the same intake* (OTIB-0049, pg. 32).

The 10 cases used to derive the adjustment factors were called the design cases.

> *The data for the design cases were custom modeled in the IMBA computer code to get a curve fit to plutonium lung data that could be used to generate, analytically, the plutonium retention in the lungs at any time and for any intake scenario using the IMBA Intake-to-Bioassay feature. For the given intake scenario and the same intake, the plutonium lung retention was calculated for the default ICRP Type S model. The annual dose adjustment factors are the ratios of the plutonium lung retentions projected annually for the actual case to those projected for the default Type S model. … In relation to Type S, the design cases tend to exhibit a higher retention of plutonium in the lungs, especially after the first several years, with a similar flatness of the retention curves after 10 years. Two cases represent a similar upper bound, one from RFP (RFP 872) and one from Hanford (HAN-1)* (OTIB-0049, pg. 32).

> *The dose adjustment factor is the ratio of the plutonium retention for the highest of the design cases (RFP 872 or HAN-1) and the plutonium retention predicted by the default Type S model any year after an acute intake or start of a chronic intake* (OTIB-0049, pg. 33).

3.20.4 Review Comments

Review Objectives 1.1 through 1.5

Our review has identified that the document in general is written in a style that is clear and unambiguous. Some paragraphs need clarification, but in general, it presents data in a logical understandable sequence.

Some of the sources of information in the document are not referenced.

The OTIB is consistent with all other OTIBs and procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. OTIB-0049 is sufficiently prescriptive to minimize the need for subjective decisions.

Review Objective 3.2

OTIB-0049 is meant to address potential exposures to a specific compound, plutonium high-fired oxides, formed by the complete oxidation of the nuclide, at high temperatures, as for example in a fire. OTIB-0049 adjustment factors are meant to ensure that resultant doses, calculated from in-vivo/in-vitro bioassay data, are conservative. OTIB-0049 states that its methods "can be applied to doses from coworker studies for sites where Type SS absorption is appropriate, but

only Type S intakes were assessed" (pg 12), thus providing a method to estimate doses at sites that would have been otherwise unmonitored.

Review Objectives 5.0

The procedure is claimant favorable in instances of missing information, since it is mentioned in OTIB-0049 that it is favorable to apply the methods described in the document if the intake material is unknown and plutonium oxide is a possibility. The document is based on the two upper bound lung retention design cases and was shown to be claimant favorable, as addressed below under the Review Objective 7.3 comments.

Review Objective 7.3

SC&A has conducted a thorough review of the methodology proposed by NIOSH in terms of its scientific merit and the degree to which outstanding uncertainties are bounded by assumptions that give the benefit of doubt to the claimant. SC&A reviewed the methods used by NIOSH to derive the lung dose adjustment factors from in-vivo bioassay results and from urine results, as well as the adjustment factors for systemic organs, GI tract, and the extra-thoracic regions. The revision included comparisons of autopsy data for lung, liver, and skeletal plutonium content to the predicted values derived using lung count data and urinary excretion data, using the OTIB-0049 empirical model, for a representative number of RFP cases.

(1) SC&A Review of the Design Cases

NIOSH derived empirical models to reproduce lung contents and urinary excretion of the design cases, by customization of absorption parameters, particle transport rates, and deposition fractions in the pulmonary regions. These modifications on the HRTM do not produce biologically plausible models, and are meant only for the specific derivation of the adjustment factors in OTIB-0049.

SC&A has reviewed the design case data and concludes that the empirically derived parameters for each design case fit the bioassay data for those cases. In three of the design cases, not all bioassay urine data were used. The data that were used were bioassays representing later excretions, which more accurately characterize the long-term retention in the lung. The early time urine excretions were not included in these cases.

The two cases that were used to derive the adjustment factors are HAN-1 and RFP 872. From all empirically derived parameters, those two cases present the highest fractions that are cleared with this very slow transport rate.

SC&A reviewed the representativeness of the design model cases, upon which OTIB-0049 is based, by comparing the lung and excretion data from the design cases to 19 other cases from the 1965 RFP fire. Based on its review of all the workers involved in the 1965 fire, SC&A concludes that the design model cases chosen by NIOSH as a basis for OTIB-0049 are sufficiently conservative for broad use.

(2) SC&A Review of the Derivation of Lung Dose Adjustment Factors

SC&A has reviewed and reproduced the lung adjustment factors as provided. The parameters used to derive empirical lung contents and urinary excretions were not used by NIOSH to calculate equivalent doses to the lung. The current ICRP dose model is used to calculate doses for Type S compounds, and the resultant doses must be multiplied by adjustment factors. SC&A considers this approach as appropriate because the parameters used to empirically match lung and urinary excretion from exposed workers do not correctly describe the partition of activity in the human respiratory tract regions and in tissues containing target cells for dose calculations.

(3) SC&A Review of Possible Effects of Smoking

The ICRP Human Respiratory Tract Model suggests that smoking modifies the mechanical transfer rates of deposited particles, decreasing the mechanical transfer rates of deposited particles from the AI compartments (*ICRP Supporting Guidance 3*, 2002). According to an RFP site expert, many of the workers at RFP during this time period were smokers, some of them heavy smokers, smoking as many as two to three packs of cigarettes a day. Although there is no mention of the effect of smoking in OTIB-0049, the NIOSH approach is sufficiently conservative to accommodate this issue, since the transport rates used in the empirical model are much smaller than the ones suggested by the ICRP for smokers. SC&A, therefore, concludes that any effect from smoking is covered by the NIOSH approach.

(4) SC&A Review of the Intake Adjustment from Urinalysis Data

OTIB-0049 correctly mentions the difficulty in deriving a bounding adjustment factor to correct intakes calculated from urinalysis results:

> *Type SS material is absorbed into the blood stream at a slower rate than Type S material. This causes less material to be deposited in the systemic organs, as well as less plutonium being eliminated through the urine. Per unit intake, the difference between predicted urine content for Type S and Type SS varies considerably. This makes determining a correction factor difficult because the value of the correction factor is dependent on the time after intake and the length of exposure for each urine sample result* (OTIB-0049, pg. 36).

SC&A has reviewed the intake adjustment factors for doses calculated from urine bioassay data and has concluded that the approach proposed by NIOSH is reasonable and sufficiently conservative for broad use.

(5) SC&A Review of the Procedures used for Calculating Doses to the Lung, Systemic Organs, Extra-Thoracic Region, and GI Tract

SC&A reviewed the procedure for calculating doses to the lung, systemic organs, extra-thoracic region, and GI tract, from lung monitoring results, urine excretion data, and air monitoring results. SC&A agrees with the assumptions made by NIOSH, and considers the adjustment factors described in OTIB-0049 appropriate to correct doses derived from Type S intakes of plutonium.

SC&A concurs with NIOSH notes on the applicability and limitations of the dose adjustment factors, as follows:

- *Applies only to doses resulting from the intake of plutonium oxide; however, it is favorable to the claimant to apply it if the intake material is unknown and plutonium oxide is a possibility. Considering the uncertainty in the nature of the material, long-term (years) air oxidation of formerly Type M plutonium can be considered to apply.*

- *Applies only to doses resulting from intakes of plutonium for which the activity isotopic ratio of $^{239+240}$Pu to ^{238}Pu is greater than 1. This restriction is based on the observed behavior of relatively pure ^{238}Pu, which tends to be more soluble than ^{239}Pu. When this condition is met, SS behavior applies to all isotopes in the plutonium mixture.*

- *Applies to the dose from ^{241}Am in the mixture when the activity ratio of $^{239+240}$Pu to ^{241}Am is greater than 1.*

- *Does not apply to situations where the plutonium is a minor constituent by mass in another matrix, such as in recycled uranium.*

- *May be applied to chest count data (using the adjustment discussed in Section 4) except when there are multiple positive chest count results that occur in more than one year. The case should be evaluated to determine if a best fit to the actual data should be performed in such cases.*

- *Because the highest of the various dose adjustment factors was used for Attachment C, no additional uncertainty should be applied to the lung dose calculation; i.e., use the same uncertainty distribution as was applicable to the Type S dose calculation.*

- *The methods described in this TIB can be applied to doses from coworker studies for sites where Type SS absorption is appropriate, but only Type S intakes were assessed. The types of adjustments made to the Type S intakes and doses should be based on the method used to create the coworker study (i.e., whether the intakes are based on urinalysis or chest counts)* (OTIB-0049, pg. 12).

SC&A agrees with NIOSH that:

> *Doses to systemic organs should be based on urine bioassay data when possible. If it is necessary to calculate these doses from chest count data, the Type S model should be used with no adjustments* (OTIB-0049, pg. 9).

SC&A has compared intakes derived from the model design cases per unit lung counts with Type S derived intakes. It is true that, depending on the time elapsed between measurements and exposure, Type S intakes are higher or equal to the ones derived using the empirical model. Theoretically, no intake corrections are needed.

On the other hand, doses to systemic organs are calculated from lung monitoring results without an adjustment factor to envelope the conclusions taken from the empirical model. The relationship between systemic organs content and lung content in OTIB-0049 were derived from an empirical model, and the true transport and absorption rates from the lung are probably different from the empirical model. Some models presented in the literature to explain the high-fired biokinetics use absorption parameters that are higher than the ones used in the Type S model, compensating for this effect by introducing a lung compartment with infinite half time (Khokhryakov et al. 2005). Depending on the time after intake, the activities in systemic organs may be higher than expected using default Type S. Thus, SC&A concurs that the NIOSH approach to systemic organs should be based on urine bioassay data when possible.

(6) SC&A Review of the Comparison of Predicted Activities in Lung, Liver, and Skeleton, Applying the NIOSH Approach, with Autopsy Data from USTUR

NIOSH evaluated if the adjustment factors in OTIB-0049 provided plausible bounding results, by analyzing autopsy and bioassay data from the United States Transuranium and Uranium Registry (USTUR) obtained for a number of Rocky Flats workers with confirmed plutonium intakes:

> *Seven cases were selected that had detectable values for both lung and urine bioassay measurements* (OTIB-0049, pg. 38).

The expected lung content and liver content at autopsy was estimated using standard Type S parameters. The lung content was corrected using the adjustments factors and the liver content was not adjusted. These estimated contents were compared to autopsy data, and NIOSH concluded that the adjustments are bounding.

SC&A has independently reviewed autopsy and bioassay data from the USTUR for eight Rocky Flats workers with confirmed plutonium intakes. Cases included individuals who had intakes of the high-fired plutonium oxide and other types of exposures to plutonium oxides. The observed lung, liver and skeleton burdens at death were compared with values calculated based on the lung measurements and on the urinary excretion of plutonium in these cases. SC&A relied on the USTUR results for bioassay and for autopsy, including the calculation done by the USTUR to extrapolate the skeleton content. SC&A has followed the procedures presented in OTIB-0049 to predict the activities in systemic organs and in the lung from individual bioassay measurement results. SC&A used the lung measurement results and the urine bioassay results, independently, to test each individual approach.

The theoretical contents in liver, bone, and lung, calculated using the approach described in OTIB-0049, in general produced results that overestimated the autopsy data. There was only one exception among the cases that were reviewed: the derivation of the liver and bone content, from the MDA in lung, as lung measurement results were reported as below detection level for this case.

3.20.5 Conclusions

SC&A examined OTIB-0049 in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. SC&A is in agreement with the NIOSH approach for estimating annual dose from intakes of Pu-239 that are retained in the lung longer than predicted by the normal absorption Type S model, based on the applicability of empirically derived adjustment factors for the lung, systemic organs, GI tract organs and tissues, and extra-thoracic regions.

3.20.6 References

42 CFR Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ICRP (International Commission on Radiological Protection) 1995. *ICRP Publication 66: Human Respiratory Tract Model for Radiological Protection*, Annals of the ICRP Volume 24/1-3, 1995.

ICRP (International Commission on Radiological Protection) 1995. *ICRP Publication 71: Age-dependent Doses to the Members of the Public from Intake of Radionuclides*: Part 4, Inhalation Dose Coefficients, Annals of the ICRP Volume 25/3-4, 1995.

ICRP (International Commission on Radiological Protection) 2002. *ICRP Supporting Guidance 3: Guide for the Practical Application of the ICRP Human Respiratory Tract Model*, Annals of the ICRP, Vol. 32/1-2, Oxford, England.

Khokhryakov, V.F., Suslova K. G., Vostrotin V. V., Romanov S. A., Eckerman, K. F., Krahenbuhl M. P., and Miller S. C. 2005. *Adaptation of ICRP 66 respiratory tract model to data on plutonium biokinetics for Mayak workers*, Health Physics, Volume 88, Number 2, pp. 125–132.

ORAUT-OTIB-0049, *Estimating Doses for Plutonium Strongly Retained in the Lung*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 6, 2007.

3.21 ORAUT-OTIB-0050: THE USE OF ROCKY FLATS NEUTRON DOSE RECONSTRUCTION PROJECT DATA IN DOSE RECONSTRUCTIONS

The review of ORAUT-OTIB-0050, *The Use of Rocky Flats Neutron Dose Reconstruction Project Data in Dose Reconstruction*, Rev. 00, dated December 13, 2005, was prepared by Ron Buchanan, PhD, CHP.

3.21.1 Purpose of the Technical Information Bulletin

The purpose of this OTIB is to provide guidance on the application of neutron dose from the Rocky Flats Neutron Dose Reconstruction Project (NDRP) to NIOSH dose reconstructions. In addition to neutron dose guidance, this OTIB includes information about NDRP reconstructed

gamma dose and methods to determine missed gamma dose utilizing the NDRP reconstructed gamma dose.

3.21.2 Review Protocol

SC&A's evaluation of OTIB-0050 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the OTIB adequately supports the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.21-1: ORAUT-OTIB-0050 Review Outline/Checklist

Document No.: ORAUT-OTIB-0050, Rev. 00	**Effective Date:** 12/13/2005
Document Title: The Use of Rocky Flats Neutron Dose Reconstruction Project Data in Dose Reconstructions	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	

Table 3.21-1: ORAUT-OTIB-0050 Review Outline/Checklist

Document No.: ORAUT-OTIB-0050, Rev. 00	**Effective Date:** 12/13/2005
Document Title: The Use of Rocky Flats Neutron Dose Reconstruction Project Data in Dose Reconstructions	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.21.3 Review Comments

Review Objective 1.1

The procedure was well written, except for two sections in which the wording was confusing and the directions difficult to follow. This occurred in Section 3.0 on page 6 concerning *Non-affected original neutron dose - NDRP neutron dose - Notional neutron dose*, and Section 4.1.5 concerning *Missed Neutron Dose*.

- Section 3.0 - The details of the entries on page 6 concerning the three different neutron doses—especially concerning blanks—are difficult to follow. This is a hard concept to put into text; perhaps a table to illustrate the different entries would be helpful to the DR and help prevent confusion.

- Section 4.1.5 – The description of the zero entries and their significance is difficult to follow. In the second and third sentences it is stated, "If there is **no entry** for the NDRP or notional dose, it should not be assumed to be a zero. However, if there is a zero in…" [Emphasis added]. It then goes on to discuss what to do if there is a zero, but never comes back to tell what to do if there is ***no entry***.

Review Objective 1.3

The last paragraph in Section 3.0 discusses error values and types of distributions. However, in the last sentence, it states that the DR must calculate the error associated with this component in accordance with OCAS-IG-001 and OTIB-0027. There are insufficient instructions and details for the DR to perform this function in an expeditious and timely manner.

Review Objective 1.4

In Section 2.0, page 5, it is stated that, "Except for the application of n/p ratios as described in Section 4.1.6, the methods described in this OTIB apply only to workers at Rocky Flats Plant (RFP) plutonium facilities during the period from 1952 to 1970." According to the NDRP report (ORISE 2005), page 10, all the NTP and NTA films that were available were retrieved for possible use in the NDRP project. Because the concern in the 1950s and 1960s was neutron exposure in the Pu facilities, most of the NTP and NTA film were from Pu workers. However, any that were rereadable were included in the NDRP project regardless of job location. This would include any plates and films for workers involved in other areas besides the Pu areas. This issue is important because it affects the validity of applying the coworker dose data to unmonitored workers, especially to non-Pu workers. If only Pu workers' NTP/NTA films were reread, or only Pu workers worn NTP/NTA badges, then the results of the NDRP study may not be directly applicable to non-Pu workers and an adjustment factor may be needed. If the NDRP study did include non-Pu workers, then it may contain dose data that can be used to assign neutron doses to unmonitored non-Pu workers, or separate out neutron and photon dose from composite dose.

Review Objective 7.3

Section 4.16, page 8, provides instructions to the DR concerning separating out a worker's neutron and photon dose from the composite dose for 1970–1976 using an n/p ratio of 0.42. This was the recommended procedure at the time of the writing of this OTIB (December 13, 2005). However, a look at the n/p values during other periods at the RFP, and other facilities, would indicate that the use of an n/p ratio of 0.42 could underestimate the neutron dose in a significant number of cases. Recent data published in OTIB-0058 Rev. 01, January 8, 2007, Table 6-2, provides neutron and photon dose data for most workers and more realistic average n/p values of approximately 1.5 for Building 771 and 2.4 for all other buildings for calculating unmonitored workers' doses. The more realistic n/p data needs to be incorporated in a revised OTIB-0050.

3.21.4 References

42 CFR Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

OCAS-IG-001. 2002. *External Dose Reconstruction Implementation Guideline*, Rev. 1., August 2002. National Institute for Occupational Safety and Health (NIOSH), Office of Compensation Analysis and Support, Cincinnati, Ohio.

ORAUT-OTIB-0027. 2005. *Supplementary External Dose Information for Rocky Flats Plant*, Rev. 00, May 19, 2005. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-OTIB-0058. 2007. *External Coworker Dosimetry Data for the Rocky Flats Plant*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 8, 2007.

ORAUT-TKBS-0050. 2005. *Use of Rocky Flats Neutron Dose Reconstruction Project Data in Dose Reconstructions*, Rev. 00, December 13, 2005. Oak Ridge Associated Universities Team, Cincinnati, Ohio. Oak Ridge, Tennessee.

ORISE (Oak Ridge Institute of Science and Education) 2005. *Technical Basis Document for the Neutron Dose Reconstruction Project*, ORISE 05-0199, February 7, 2005. Oak Ridge, Tennessee.

3.22 ORAUT-OTIB-0051: EFFECT OF THRESHOLD ENERGY AND ANGULAR RESPONSE OF NTA FILM ON MISSED NEUTRON DOSE AT THE OAK RIDGE Y-12 FACILITY

The review of ORAUT-OTIB-0051, Rev. 00, dated May 15, 2006, was prepared by Ron Buchanan, PhD, CHP.

3.22.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0051 is to provide definitive documentation of the effects of threshold energy and angular response of nuclear track emulsion, type A (NTA) film on missed neutron dose at the Oak Ridge Y-12 Plant.

3.22.2 Review Protocol

SC&A's evaluation of OTIB-0051 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the OTIB adequately supports the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.22-1: ORAUT-OTIB-0051 Review Outline/Checklist

Document No.: ORAUT-OTIB-0051, Rev. 00	**Effective Date:** 05/15/2006
Document Title: Effect of Threshold Energy and Angular Response of NTA Film on Missed Neutron Dose at the Oak Ridge Y-12 Facility	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	4	See Review Comments
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	

Table 3.22-1: ORAUT-OTIB-0051 Review Outline/Checklist

Document No.: ORAUT-OTIB-0051, Rev. 00	**Effective Date:** 05/15/2006
Document Title: Effect of Threshold Energy and Angular Response of NTA Film on Missed Neutron Dose at the Oak Ridge Y-12 Facility	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.22.3 Review Comments

Review Objective 1.3

Generally, the OTIB is complete in that it contains the data and tables required by the dose reconstructor to follow the recommendations in the OTIB. However, there are two areas that lack some technical details and clarity. The Critical Experiments Facility (CEF) is mentioned in several places in this OTIB and on pages 7 and 11 it is stated that the mean missed neutron dose (because of the energy threshold of NTA film) is 55% as determined in 1960 by measurements at

the CEF and reference is made to RPRT-0033 (ORAU 2005). There are areas that need addressed in more details:

- **Lack of complete CEF analysis -** The OTIB introduces the CEF at the beginning and lists the final recommendations in Table 8-1 for the CEF. However, the facility is left out of the analysis in between these two sections, such as the series of figures in Section 4 and Figure 6-1. The reader is left to read the RPRT-0033 (ORAUT 2005) report and fill in the data for OTIB-0051 to get a complete picture. For dose reconstruction, it is not clear if this OTIB will be used for the Critical Experiments Facility workers, or if RPRT-0033 is to be used for those workers (which mainly makes use of n/p ratios to compensate for the NTA film under response). Additionally, it has not been stated if there were, or were not, any criticality experiments conducted at Y-12 in the early days before the CEF was constructed that may have exposed workers to neutrons below the NTA threshold.

- **Fast and thermal neutron measurements at CEF -** OTIB-0051 uses the fact that on pages 20 and 21 of the RPRT-0033 (ORAUT 2005) it is stated that, "Fast neutrons" and "Thermal neutrons" were measured during the experiment at different locations at the CEF, and a mean missed-neutron dose of 55% was determined for the CEF. However, because OTIB-0051 is specifically concerned with the response of NTA film to neutrons of different energies, it is imperative that there be a detailed understanding of the neutron spectra and measurement methods involved in obtaining this data. No information is provided in RPRT-0033 as to the methodology used and therefore the implied energy spectra of Fast and Thermal neutrons in this case (i.e., Fast most likely does not refer to mono-energetic 4.00 MeV neutrons, or Thermal to only 0.025 eV neutrons). Considering the incompleteness of information, OTIB-0051 should not make use of the RPRT-0033 data in its present form as a basis for making DR recommendations concerning NTA film response at the CEF.

Review Objective 3.2.1

Use of personal dosimeters - See Section 7.3 concerning use of NTA film data.

Review Objective 5.2

The OTIB was generally claimant favorable in instances of unknown parameters affecting dose estimates. However, there are three situations where uncertain parameters could lead to an underestimate of neutron dose that were not identified in the OTIB; these are:

- **Moderated (alpha,n) neutrons –** Chemical operations are mentioned several times in the OTIB. However, the analyses in Section 4, Section 6, and the final results in Table 8-1 only deal with UF_4 and UO_3 in containers and in storage. OTIB-0051, Table 8-1, provides correction factors for fairly energetic neutrons from unmoderated (alpha,n) reactions, but do not provide for any correction factors for NTA results for workers that were potentially exposed to lower-energy neutrons from moderated (alpha,n) reaction neutrons. From the information provided in the OTIB, it would appear that the correction factors obtained from measurements made were for neutrons coming from (alpha,n) reactions taking place in metal containers, and not from wet chemical

processes where the water would act as a neutron moderator and quickly degrade the neutron energy below the 700 keV threshold of the NTA film. This could occur when workers were directly exposed to moderated neutrons while working on wet chemical processes (especially around recycled uranium operations), or near-by workers not directly involved in the process, but who received doses from moderated neutrons because of the material between them and the main operation(s). Therefore, the OTIB needs to develop and recommend a correction factor in Table 8-1, for highly moderated neutron exposure from (alpha,n) reactions.

- **Third parameter needs to be considered –** The OTIB, page 18, states that:

  The potential for neutron exposure depends on both the total activity of the uranium (which is a function of enrichment) and the chemical compound in question (the mixing of uranium and fluorine or other low-Z atoms).

  However, a third variable should be included in the contents of analyzing the response of NTA film to (alpha,n) neutrons; that is the amount of moderator (mainly hydrogenous material) present because the presence of moderating material increases the fraction of missed neutron dose when measured using NTA film.

- **Angular Response –** The short treatment and recommendations concerning the angular response of NTA film in Section 7 of this OTIB was compared to the recommendation of several other articles (such as Hine and Brownell 1956 and Kathren et al. 1965) and found that the use of 1.3x as an angular dependence factor is reasonable, although not necessarily overly conservative, i.e., compare to 1.39x or 1.54x for rotational geometry, which would be expected to be somewhat different. Therefore, it should only be used to compensate for frontal angular dependence in the anterior hemisphere of exposure. Anterior/Posterior (AP) versus Posterior/Anterior (PA) must also be considered in addition to angular dependence for the decrease in response in NTA film from neutrons from posterior exposure.

Review Objective 7.3

Most of this OTIB employed scientifically valid protocols for reconstructing doses. However, some areas of technical comparison/validation were not analyzed or were incomplete. These consisted of:

(1) OTIB-0051 missed dose vs. IAEA results for NTA film: An IAEA report, page 31, (IAEA 1990) list the computed NTA film response (mounted on a phantom) in Table 3-IX as a function of neutron-energy interval. Comparing the relative response of NTA film to neutrons of different energies and that of a calibration source can provide information to calculate missed neutron doses. Missed neutron doses at several important neutron energies/sources listed in OTIB-0051 were calculated using the IAEA information, and they were then compared to the results shown in Figure 6-1 of OTIB-0051. A summary of this comparison is shown in the following table.

Table 3.22-2: Comparison of % Missed Neutron Dose: IAEA Data vs. OTIB-0051

Source of Neutrons	Mean Neutron energy (MeV)	IAEA calc. NTA response	IAEA response @ E Compared to IAEA response @ 3.98 MeV	IAEA % missed dose	OTIB Fig. 6.1 % missed dose	Ratio of missed dose (IAEA)/(OTIB)
AmBe	3.98	6.12E-04	1.00	0	13	0
Cf-252	2.51	4.70E-04	0.77	23	21	1.1
86" Cyclo.	1.00	2.87E-04	0.47	53	28	1.9
Calib UF4	0.63	1.37E-04	0.22	78	51	1.5
CEF	0.45	1.76E--5	0.03	97	55	1.8

It appears that the information in IAEA provides for a larger missed dose than the OTIB-0051 claimant-favorable recommendations in Figure 6-1 for the same locations; this ranges from 1.1x for Cf-252 sources to 1.9x for the 86" cyclotron. This comparison can only be used as an indicator because the NTA response values listed in Table 3-IX of the IAEA report are for a narrow band of neutron energies (for example, 3.98 MeV represents neutrons from 3.16 MeV to 3.98 MeV). A source of neutrons as listed in Table 7.3-1 above would contain a broader energy spectra and the NTA film would respond with higher efficiency to neutrons with energies greater than 3.98 MeV, and with lower efficiency to neutrons with energies less than 3.98 MeV. However, this comparison does serve to illustrate the fact that the OTIB-0051 recommended correction factors for NTA film's lack of response to lower energy neutrons is not overly conservative and most likely represents the 50th percentile values and not the 95th percentile values.

(2) Situations where most, or all, of the neutrons are below the threshold: This OTIB does not recommend how the DR is to handle neutron exposure situations where the majority of the neutron flux ranges from the neutron threshold of the NTA film down to thermal energies. In these situations, there is not a significant number of higher-energy neutrons registered on the NTA film to use to calculate missed dose, regardless of the energy threshold used. These situations need to be identified and addressed.

(3) Y-12 worker at X-10 and rovers: The issue of Y-12 workers who worked on X-10 projects involving neutron fields, either at Y-12 or at X-10, is not addressed. Clarification has not been made if these workers' DR will be covered under Y-12 or X-10. Additionally, workers that were "rovers" who worked at many different locations at Y-12, and perhaps X-10, may have been exposed to a variety of neutron fields. It would be difficult to categorize these workers to a known neutron field as listed in the OTIB. The present OTIB does not recommend to the DR how to handle the NTA film's lack of response to lower energy neutrons in these cases.

(4) Selection of neutron energies for the 86" cyclotron: It is stated on page 11 of the OTIB that the average neutron energy for the 86" cyclotron was 1.05 MeV, and 4.0 MeV for 241-AmBe neutron sources. On page 15, last paragraph, of the OTIB it is stated that a Po-Be or Am-Be source used to calibrate NTA film is a good match to the neutron spectra found in the workplace at Y-12 facility, particularly the stray neutron field about the 86" cyclotron.

However, Po-Be and Am-Be sources have average energies around 4 MeV whereas the average energy of the neutron field at the cyclotron is around 1.05 MeV. Figure 3-1, page 10 of the OTIB, shows that the relative response of NTA film is approximately 1.5 at 1 MeV, compared to a relative response of approximately 4.1 at 4 MeV. This does not appear to be a good match and could create a dose assignment of only (1.5/4) = 38% of the true neutron dose, because of the decreased NTA film response to lower energy neutrons. Approximately the same results are obtained when using the IAEA data in Table 3-IX (IAEA 1990), i.e., (2.87E-4)/(6.12/E-4) = 47 %.

Summary. OTIB-0051 is a good start for NIOSH to attempt to correct for the under response of NTA film to lower-energy neutrons. It refers to IAEA for calculated NTA track response vs. neutron energy and Kathren et al. 1965 for angular dependence. The OTIB does not appear to apply (especially in the summary table on page 18) to chemical process workers who might have been exposed to moderated neutrons in process lines from (alpha,n) reactions (especially in early days of operations and/or around recycled uranium processes), but only to (alpha,n) reaction neutron exposures around the uranium storage areas. Situations where the majority of the neutron flux is below the effective threshold of NTA film are not addressed. Additionally, neutron doses to rovers and Y-12 workers on X-10 projects have not been addressed/clarified.

The final recommendations to the DR are contained in Table, which is a reproduction of Table 8-1 of OTIB-0051:

Table 3.22-3: Recommended Correction for Missed Neutron Dose due to Threshold Energy and Angular Response of NTA Film

Neutron source[a]	Correction factor for threshold energy	Correction factor for angular response	Total correction factor
Unshielded radionuclide sources	1.0	1.3	1.3
Cf-252 fission neutron source	1.3	1.3	1.7
86 Inch Cyclotron	1.4	1.3	1.8
Shielded radionuclide sources[b]	2.0	1.3	2.7
Enriched uranium storage containers	2.2	1.3	2.9
CEF[c]	2.2	1.3	2.9

a. See Section 2.0 and Table 2-1.
b. Health Physics Calibration Laboratory.
c. Normally inhabited locations inside CEF.
Source: OTIB-0051, Table 8.1

Overall, this is a good start and provides reasonable results. The methods need to be developed in more detail, other thresholds energies need to be considered, and perhaps a few example calculations provided to allow it to be evaluated for technical soundness and clamant favorability.

3.22.4 Workbooks

There are no workbooks directly involved in developing this OTIB. However, the following two workbooks could make use of the correction factors recommended in this OTIB:

(1) Y-12_Calculation Workbook 1.12.
(2) Y-12_Workbook CB_1951–1960 and CF After 1960 1.14.

3.22.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

Hine, G., and Brownell, G. 1956. Radiation Dosimetry. Academic Press, Inc.: New York, New York.

IAEA (International Atomic Energy Agency) 1990. *Compendium of Neutron Spectra and Detector Responses for Radiation Protection Purposes*, Technical Report Series No. 318, Vienna, Austria.

Kathren, R., Prevo, C., and Block, S. 1965. "Angular Dependence of Eastman Type A (NTA) Personnel Monitoring Film," Health Physics, Volume 11, pp. 1067–1069.

ORAUT-OTIB-0051. 2006. *Technical Information Bulletin: Effect of Threshold Energy and Angular Respons*, Rev. 00, May 15, 2006. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-RPRT-0033. 2005, *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 – Neutron Radiation*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. April 13, 2005.

3.23 ORAUT-OTIB-0052: PARAMETERS FOR PROCESSING CLAIMS FOR CONSTRUCT. WORKERS

The review of ORAUT-OTIB-0052 was performed as a separate subtask under this task order, and a draft report was delivered to NIOSH and the Board on July 3, 2007, with report number SCA-TR-TASK3-0004.

3.24 ORAUT-OTIB-0055: TECHNICAL BASIS FOR CONVERSION FROM NCRP REPORT 38 NEUTRON QUALITY FACTORS TO ICRP PUBLICATION 60 RADIATION WEIGHTING FACTORS FOR RESPECTIVE IREP INPUT NEUTRON ENERGY RANGES

This review of ORAUT-OTIB-0055, *Technical Basis for Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Publication 60 Radiation Weighting Factors for Respective IREP Input Neutron Energy Ranges*, Rev. 00, dated June 5, 2006, was prepared by William R. Hoey.

3.24.1 Purpose of the Technical Information Bulletin

The stated purpose of OTIB-0055 is to present the technical basis and methodology for converting from recorded neutron dose to neutron dose equivalent using the ICRP 60 radiation

weighting factors. This conversion has already taken place in many of the site TBDs; however, the basis for the conversion was not always clearly presented in the TBDs.

3.24.2 Review Protocol

SC&A's evaluation of OTIB-0055 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 3.24-1: ORAUT-OTIB-0055 Review Outline/Checklist

Document No.: ORAUT-OTIB-0055, Rev. 00	**Date:** 06/05/2006
Document Title: Technical Basis for Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Publication 60 Radiation Weighting Factors for Respective IREP Input Neutron Energy Ranges	
Auditor: William R. Hoey	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether procedures provide adequate guidance to be efficient in select instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	"For suspected high cumulative exposures," does the procedure provide clear guidance as to the magnitude of dose for any given tissue/organ that will exceed the 50% PC value?	N/A	
2.2	"In instances of suspected cumulative low doses," does the procedure provide clear guidance in defining worst-case assumptions?	N/A	

Table 3.24-1: ORAUT-OTIB-0055 Review Outline/Checklist

Document No.: ORAUT-OTIB-0055, Rev. 00	**Date:** 06/05/2006
Document Title: Technical Basis for Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Publication 60 Radiation Weighting Factors for Respective IREP Input Neutron Energy Ranges	
Auditor: William R. Hoey	

No.	Description of Objective	Rating 1-5*	Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	----	
3.1.1	Scope of information	N/A	
3.1.2	Level of detail sought and relevance to dose reconstruction	N/A	
3.1.3	Objectivity and lack of bias	N/A	
3.1.4	Sensitivity to the claimant	N/A	
3.1.5	Protection of information required under Privacy Act	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	No distributions are developed.

Table 3.24-1: ORAUT-OTIB-0055 Review Outline/Checklist

Document No.: ORAUT-OTIB-0055, Rev. 00	**Date:** 06/05/2006
Document Title: Technical Basis for Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Publication 60 Radiation Weighting Factors for Respective IREP Input Neutron Energy Ranges	
Auditor: William R. Hoey	

No.	Description of Objective	Rating 1-5*	Comments
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that cannot reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure require levels of detail that may have limited significance to the precision of the final dose estimate?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.24.3 General Comments

This procedure does a commendable job in presenting the technical basis for the conversion of individual neutron doses recorded at the various sites to the neutron dose to be used as part of an individual's dose reconstruction that is based on the most current scientific publication, ICRP Publication 60 (ICRP 1991), concerning the calculation of personnel neutron doses.

According to information presented in the procedure, this procedure was prepared largely in response to questions from technical personnel at some sites concerning the presentation and use of the ICRP Publication 60 neutron radiation weighting factors in that site's TBD. It was determined that the various TBDs did not always present a clear description of the methodology and basis for the methodology to be used to convert recorded personnel neutron doses to the neutron doses to be used as part of the dose reconstruction for these personnel.

In addition to providing a detailed discussion of the technical basis for the neutron dose conversion process, the procedure also presents an example of how a dose conversion would be performed.

3.24.4 Review Comments

SC&A's review of this procedure produced no comments, and SC&A agrees with its contents.

3.24.5 References

ICRP (International Commission on Radiological Protection) 1991. *1990 Recommendations of the International Commission on Radiological Protection,* Publication 60, Pergamon Press, Oxford, England.

ORAUT-OTIB-0055, *Technical Basis for Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Publication 60 Radiation Weighting Factors for Respective IREP Input Neutron Energy Ranges,* Rev. 00, Oak Ridge Associated Universities, Cincinnati, Ohio. June 5, 2006.

3.25 ORAUT-OTIB-0057: EXTERNAL RADIATION DOSE ESTIMATES FOR INDIVIDUALS NEAR THE 1958 CRITICALITY ACCIDENT AT THE OAK RIDGE Y-12 PLANT

The review of ORAUT-OTIB-0057, Rev. 00, dated May 15, 2006, was prepared by Ron Buchanan, PhD, CHP.

3.25.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0057 is to review the available dosimetric data and its potential application in dose reconstruction for Y-12 workers who were near the nuclear criticality accident in Building 9212 of the Y-12 Plant in Oak Ridge, Tennessee, in 1958. The accident occurred on Monday, June 16, at approximately 2:05 p.m. (UCNC 1958; Callihan and Thomas 1959). Additional data relevant to individuals described in this OTIB of a personal nature can be found in *Y-12 1958 Criticality Accident Roster* (ORAUT 2006), which is available to dose reconstructors as needed.

3.25.2 Review Protocol

SC&A's evaluation of OTIB-0057 is summarized below in Table. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 3.25-1: ORAUT-OTIB-0057 Review Outline/Checklist

Document No.: ORAUT-OTIB-0057, Rev. 00	**Effective Date:** 05/15/2006
Document Title: External Radiation Dose Estimates for Individuals Near the 1958 Criticality Accident at the Oak Ridge Y-12 Plant	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	

Table 3.25-1: ORAUT-OTIB-0057 Review Outline/Checklist

Document No.: ORAUT-OTIB-0057, Rev. 00	**Effective Date:** 05/15/2006
Document Title: External Radiation Dose Estimates for Individuals Near the 1958 Criticality Accident at the Oak Ridge Y-12 Plant	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	5	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	

Table 3.25-1: ORAUT-OTIB-0057 Review Outline/Checklist

Document No.: ORAUT-OTIB-0057, Rev. 00	**Effective Date:** 05/15/2006
Document Title: External Radiation Dose Estimates for Individuals Near the 1958 Criticality Accident at the Oak Ridge Y-12 Plant	
Auditor: Ron Buchanan, PhD, CHP	

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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.25.3 Review Comments

Review Objective 1.1

Generally, the OTIB was written in a fairly clear and unambiguous manner. However, some wording and errors contained in the text create confusion and require several rereads, and/or assumptions to be made, to clarify the issues. The following are the areas identified:

- The last paragraph on page 7 lists the whole-body limit as **15 mrem/yr***;* this should read **15 rem/yr.**

- The last sentence of the second paragraph on page 12 states, "The last column of Table 5-1 lists the doses of record for these eight individuals (UCNC 1958)." The meaning of this should be qualified by rewording it to read, "The last column of Table 5-1 lists the original doses of record for these eight individuals using an RBE of 2.0 (UCNC 1958)."

- Towards the end of the first sentence in the first paragraph on page 16, the words "**greater** than" should be changed to "**less** than;" i.e., it should read, "For the first IREP neutron energy interval (less than 10 keV), all of the first two energy intervals in Table 7-1 were combined and the total percentage of the absorbed dose at energies **less** than 10 keV was 13.5%."

Review Objective 5.2

The OTIB was generally claimant favorable in instances of unknown parameters affecting dose estimates. However, one area that lacked sufficient detailed analysis was the uncertainty associated with the dose assignments. In the footnote of Table 5-1 on page 13, it is mentioned that the estimated uncertainty for both neutrons and gamma doses is 20% for the eight workers listed in the table. In the last sentence of the second paragraph on page 18, the following is stated:

> *The estimated uncertainties of 10% by Mole and 20% by Hurst, Ritchie, and Emerson (1958) suggest an overall uncertainty of approximately 25% in the estimated dose to workers from the accident.* [Note: *(1958)* should read *(1959)*]

This does not provide a complete analysis of the uncertainty of the estimated doses, especially for this accident where there are a number of unknown and assumed parameters for both the 31 workers involved and any other workers that may have been exposed and DR becomes necessary. The 20% factor comes from AP versus lateral exposure mentioned on page 12, and the 10% factor comes from the difference in serum content of sodium between the burro and humans, as mentioned on page 13. These are only two of the many uncertainties in this accident situation. In the next section, **Review Objective 7.3** provides some details concerning the unknowns, assumptions, and uncertainties in this case. As can be seen from that analysis, the suggested uncertainty of $\pm$25% does not bound the uncertainties found in the actual results.

OTIB-0057 presents a solid reconstruction of the accident and associated doses. However, further analysis of the unknowns/assumptions, and a more realistic uncertainty, are needed. In this accident situation, an uncertainty in the range of at least $\pm$50% is needed to encompass the feasible doses and to ensure claimant favorability.

Review Objective 7.3

Most of this OTIB employed scientifically valid protocols for reconstructing doses. However, one area of technical comparison/validation was not analyzed and considered. This consists of comparing the neutron dose results obtained by sodium analysis at various distances to those obtained by inverse-square of the distance for the two workers (F and G) at 25 ft, which were used to estimate the dose to other workers further away from the accident. If the dose versus distance of the data in Table 6-1 for workers #8 and #10 - 31 (which are based on the sodium analysis of workers F and G) are plotted on a log-log scale, as shown in Figure, a straight line can be drawn connecting these data points and extended to smaller and larger distances. If the individual doses obtained from the sodium activation analysis of workers A - H are then plotted as a function of distance on the same graph, Figure shows that the latter data points do not fall on the predicted dose line as a function of distance.

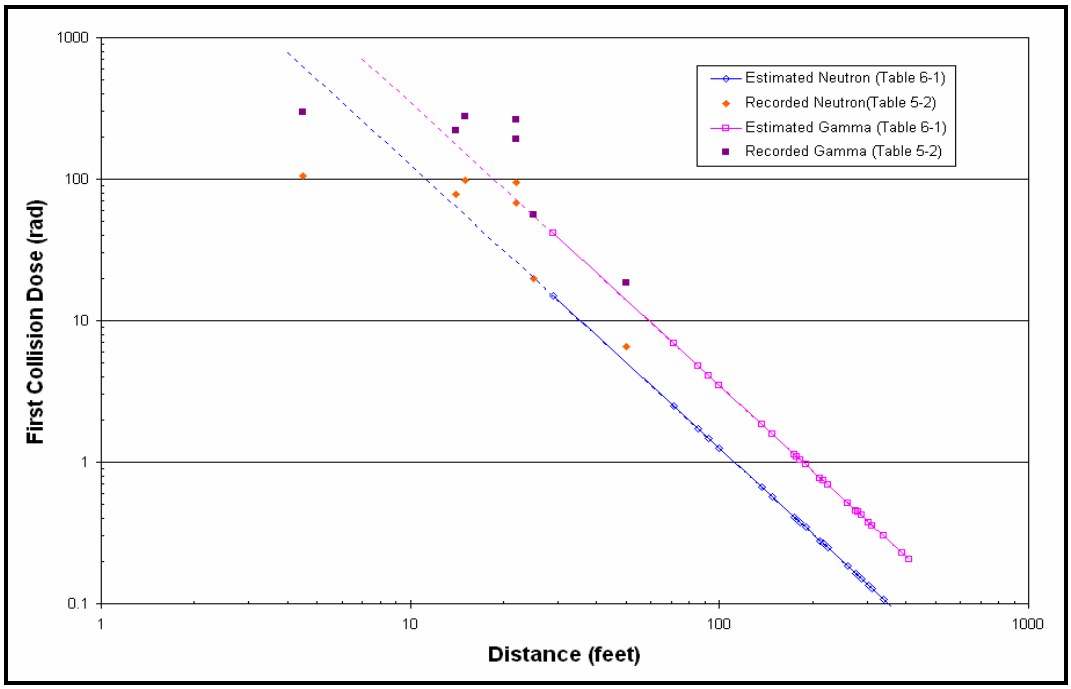


Figure 3.25-1: Comparison of Recorded to Estimated Doses

Furthermore, as shown by Table, workers' B, C, D, and E predicted neutron doses (by the results of workers F and G; 20 rem at 25 ft.) are all significantly less than the actual measured dose by sodium activation analysis. The predicted dose for worker A dose is significantly more than that which was measured, but the uncertainty in distance and geometry (i.e., 3–6 ft) associated with this close of distance precludes the use of this data point for comparison.

Table 3.25-2: Comparison of Predicted vs. Measured Neutron Doses

Worker	Distance (ft)	Meas. neutron dose (rad) by Na act.	Predicted dose by $1/r^2$	Difference Predicted/measured
B	14	78	63.8	-18.2%
C	17	98	43.3	-55.8%
D	22	95	25.8	-72.8%
E	22	68	25.8	-62.1%
F	25	20	Benchmark	-
G	25	20	Benchmark	-
H	50	6.6	5.00	-24.2%

From the results shown in Table and Figure, it can be seen that the actual measured dose exceeded the predicted dose in all the comparisons; in 3 out of 5 cases the difference was greater than the ±25% uncertainty suggested in Section 8.0, page 18.

This analysis leads to the conclusion that the unknown factors, assumptions, and uncertainties in this accident situation and its recreation are greater than anticipated. Some possible unknowns/uncertainties are as follows:

- Source geometry
- Radiation energy spectra
- Knowledge of distances
- Knowledge of exposure times and exposure conditions
- Dose measurement errors
- Differences between mock up experiment and accident
- Differences between burro and humans
- Others

The main concern with this OTIB is that if the doses predicted by use of the inverse-square of the distance method are less than those measured dose, then the doses assigned workers that were not measured could be underestimates of the actual doses they received.

3.25.4 Workbooks

There were no notebooks associated with this OTIB.

3.25.5 References

42 CFR Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule*, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

Callihan, D., and J. T. Thomas. 1959. *Accidental Radiation Excursion at the Oak Ridge Y-12 Plant–I, Description and Physics of the Accident*, Health Physics, Vol. 1, No. 4, pp. 363-372.

Hurst, G. S., R. H. Ritchie, and L. C. Emerson, 1959, *Accidental Radiation Excursion at the Oak Ridge Y-12 Plant—III, Determination of Radiation Doses*, Health Physics, Volume 2, pp. 121–133.

Mole, R. H., 1984, *Sodium in Man and the Assessment of Radiation Dose After Critical Accidents*, Physics in Medicine and Biology, Volume 29, pp. 1307–1327.

ORAUT-OTIB-0057. 2006. *External Radiation Dose Estimates For Individuals Near The 1958 Criticality Accident At The Oak Ridge Y-12 Plant*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 15, 2006.

ORAUT 2006. *Y-12 1958 Criticality Accident Roster*, Rev. 00 (Official Use Only), Oak Ridge Associated Universities Team, Cincinnati, Ohio.

UCNC 1958. *Accidental Radiation Excursion at the Y-12 Plant*, June 16, 1958, Final Report, Y-1234, Y-12 Plant, Union Carbide Nuclear Company, Oak Ridge, Tennessee.

3.26 ORAUT-OTIB-0058: EXTERNAL COWORKER DOSIMETRY DATA FOR ROCKY FLATS

The review of ORAUT-OTIB-0058, *External Coworker Dosimetry Data for Rocky Flats*, Rev. 01 PC-1, dated March 29, 2007, was prepared by Ron Buchanan, PhD, CHP.

3.26.1 Purpose of the Technical Information Bulletin

The purpose of OTIB-0058 is to provide information to allow dose reconstructors to assign doses based on site coworker data to Rocky Flats Plant (RFP) workers who have no or limited monitoring data. In addition, the data in this OTIB should be used to assign dose for gaps in the dosimetry record. The data are to be used in conjunction with ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Dose Assignment* (ORAUT 2005b).

3.26.2 Review Protocol

SC&A's evaluation of OTIB-0058 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 3.26-1: ORAUT-OTIB-0058 Review Outline/Checklist

Document No.: ORAUT-OTIB-0058, Rev. 01 PC-1	**Effective Date:** 03/29/2007
Document Title: External Coworker Dosimetry Data for Rocky Flats	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	

Table 3.26-1: ORAUT-OTIB-0058 Review Outline/Checklist

Document No.: ORAUT-OTIB-0058, Rev. 01 PC-1	**Effective Date:** 03/29/2007
Document Title: External Coworker Dosimetry Data for Rocky Flats	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	4	See Review Comments
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	3	See Review Comments
3.2.4	Unmonitored periods of exposure	4	See Review Comments
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	See Review 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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	

Table 3.26-1: ORAUT-OTIB-0058 Review Outline/Checklist

Document No.: ORAUT-OTIB-0058, Rev. 01 PC-1	**Effective Date:** 03/29/2007
Document Title: External Coworker Dosimetry Data for Rocky Flats	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	4	See Review Comments
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.26.3 Review Comments

Review Objectives 1.1

Generally, the OTIB was written in a style that is clear and unambiguous. However, in several areas information was inconsistent or its application was not clear. These areas were:

- **Mixed versions of the OTIB-0058:** Page 8 of OTIB-0058 states, "Inclusion of NDRP data in the HIS20 database led to the development of tables of data for penetrating and nonpenetrating dose that include and exclude the NDRP values." This is apparently a carryover from the earlier editions that contained Tables 7-3 and 7-5, which excluded NDRP data. These tables no longer appear in the March 29, 2007, version of OTIB-0058. Additionally, the heading on pages 4, 8, and 16 of Rev. 01 PC-1 contain the older date and version numbers.

- **Inconsistent dates for n/p values:** The third bullet point on page 8 of OTIB-0058 instructs the dose reconstructor (DR) to use the n/p values in OTIB-0050 (ORAUT 2005d) for 1977–2005. However, OTIB-0050, page 8, Table 4-1 only lists annual n/p ratios for 1977 to 2000. It is not clear to the DR if NIOSH intends for the DR to use the average n/p value of 0.42 (obtained from 1977–2000 TLD data) for all years during 1977–2005, or if the results for each specific year are to be used (if so, what is to be used for 2001–2005?). Additionally, if the average n/p value of 0.42 is to be applied to all years during 1977–2005, there is no mention of the justification for this recommendation.

When one-half maximum potential annual missed dose is added is not clear: Step 1 on page 9 describes how the coworker doses contained in HIS20 database were normalized to 1 year. Step 2 states that one-half the maximum potential annual missed dose values were added to the reported annual doses from the HIS-20 database. Then Step 3 states that the dose data from Step 2 were ranked according to percentile. If the procedure were performed in the order stated,

then there would be no zeros in the ranked data because all would at least contain some contribution from the one-half the maximum potential annual missed dose added. However, the coworker data file [O-drive ->AB Doc ->RFP -> Co-worker data -> RRFP Coworker Stats (NDRP Included HIS 20 Data)] that Table 7-1 of OTIB-0058 was derived from contains some zero, or very low dose, entries for the 50th percentile penetrating dose for some years; e.g., 1978, 1980, 1981, 1982, 1989, 2000–2004, etc., indicating that the missing dose values were not added in before ranking. The OTIB needs to clarify this sequence of steps concerning how and when the one-half the maximum potential annual missed dose was added.

Review Objective 1.3

As the RFP dose reconstruction system has evolved, it has come to encompass many procedures and documents. Some of these are listed in the reference section of this report; i.e., ORAUT-OTIB-0017, ORAUT-OTIB-0020, ORAUT-OTIB-0027, ORAUT-OTIB-0050, and ORAUT-OTIB-0052; the NDRP report; numerous workbooks; and the regular list of generic procedures and OTIBs. OTIB-0058 does contain some of the coworker specific data tables for use by the DR. However, the overall RFP dose reconstruction system has grown to the point where there is a potential for incorrect assignment of dose during the dose reconstruction process because of the complexity of the process. This is not directly the fault of OTIB-0058, but the resulting complex system of dose reconstruction for RFP that has been developed.

Review Objective 1.4

The procedures in OTIB-0058 were consistent with other procedures, with one exception. This involves the selection of coworker data if there are zeros present. As described in Step 2, page 9, of OTIB-0058, the zero entries were modified by one-half the maximum potential annual missed dose. However, for some years and percentiles it is claimant favorable to not use the zero entries and not add the one-half the maximum potential annual missed dose, as is described in ORAUT-OTIB-0021 (ORAUT 2006a), page 6, Section 7.0, Step 3. This is discussed in more detail in the Review Objective 3.2.3 of this report.

Review Objective 3.2.1

OTIB-0058 did not always address site-specific dosimetry data adequately. For example, there are problems with calculated neutron dose entries during 1969-1970, as stated on page 10 of the OTIB:

> *Also, for the 1969–1970 time period, the data from the HIS-20 database were analyzed without consideration of the zero readings in the database due to issues regarding the accurate recording of "zero" dose readings during that period.*

This was a claimant-favorable analysis. However, what was not considered was the fact that many of the neutron NTA films during the period 1967–1970 were not read, because it was decided that it was necessary to read fewer, high-exposure potential, NTA film with more accuracy than had been done in the past; this left a lot of NTA films unread. For some of these unread NTA films, a neutron dose was calculated from photon dose × (n/p) values and entered in the worker's dose of record. This makes some of the coworker composite dose data consist of

photon plus neutron dose derived by using the (photon dose) × (n/p) method, not separately measured photon and neutron doses. Unfortunately, during this same time period, it was also decided that the NTA film did not need to be archived; therefore, they were not available for reread by the NDRP. Although the zero entries during 1969–1970 have been compensated for, the problem of potentially incorrect neutron dose entries in the workers' composite dose of records makes the database questionable for constructing a coworker model for that time period.

Review Objective 3.2.3

In some dose assignment procedures, OTIB-0058 adequately addressed missing dosimetry data. However, two areas that were not claimant favorable are:

(1) ***Use of zero data entries:*** A process is described in Step 2, page 9, of OTIB-0058 where data for Table 7-1 are derived using zero entries, modified by one-half the maximum potential annual missed dose. However, for some years and percentiles it is claimant favorable to not use the zero entries and not add the one-half the maximum potential annual missed dose as is described in OTIB-0021 (ORAUT 2006a), page 6, Section 7.0, Step 3. Preliminary calculations show that about 40% of the penetrating 95th percentile doses in Table 7-1 would be greater if the coworker doses were used without zeros and no addition was made for one-half the maximum potential annual missed dose. For example, the HIS-20 penetrating dose [O-drive ->AB Doc ->RFP -> Co-worker data -> RRFP Coworker Stats (NDRP Included HIS 20 Data)] for the 95th percentile for 1980 was 0.633 rem from the data table, which included zeros, and 1.001 rem without zeros. The corresponding entry in Table 7-1 of OTIB-0058 consists of 0.633 + 0.120 = 0.743 mrem, which is about 25% less than if the non-zero data had been used. This does not usually apply to the 50th percentile dose, because the dose values are lower in this category and the one-half the maximum potential annual missed dose overrides these lower values. OTIB-0058 should follow the guidance of OTIB-0021 (ORAUT 2006a) and use the most claimant-favorable method of calculating the coworker data in Table 7-1 for each year.

(2) ***No missed-dose adjustments made for neutron doses:*** The reason for not including any missed dose for neutron dosimetry is stated on page 10, Step 5 of OTIB-0058:

> *The NDRP data include an estimate of missed neutron dose (addressed as notional dose by the NDRP (project); therefore, no adjustments are needed for missed neutron dose for 1952 to 1969. Similarly, for 1970 to 2005, missed neutron dose is accounted for when the applicable neutron-to-photon ratio is applied to the data in Table 7-1.*

1952–1969 NTA film: There must be a distinction made between *missed* neutron dose (due to the LOD of the dosimetry system) and a *gap* in neutron monitoring (because there was no recorded neutron dose). The NDRP report (ORISE 2005) only used notional doses to fill in *gaps* if, and only if, there were positive photon doses on record for that period and the worker was known have potentially been exposed to neutrons. The notional doses were based on a combination of (photon dose) × (n/p) and the worker's measured neutron doses for that year (in the 1950s, the notional dose consisted of only

the (photon dose) × (n/p)). There were no missed doses assigned resulting from the LOD of the neutron dosimeter by the NDRP. If a zero NTA film result was recorded (either from an original reading or from a reread during the NDRP project), then it remained that way; no adjustment was made for the LOD of the neutron dosimeter by the NDRP process.

1970–2005 TLDs: Generally, if a zero TLD neutron result was measured then it remained that way, no adjustment was made for the LOD of the neutron dosimeter in the records.

The data in Tables 7-1 and 7-2 of OTIB-0058 contain adjustment for missed dose due to the LOD of the photon dosimetry system only. As illustrated above, the NDRP did not include missed dose, due to the LOD of the neutron dosimetry system, and neither does the n/p method compensate for missed dose when TLDs were used. Therefore, the data entries in Tables 7-1 and 7-2 consider only the LOD for photons and do not include an LOD adjustment for neutrons. To illustrate this concept, consider the following:

- Table 1 of OTIB-0058 lists a penetrating composite (photon + neutron) dose of 2.505 rem for the 50th percentile for 1952. This value was derived from the HIS-20 coworker database of 2.045 rem composite dose + ½(24 × 0.040 – 0.40) LOD of the *photon* dosimetry system = 2.505 rem. Note that the composite dose in the HIS-20 database consists of both photon plus neutron doses and the total dose could have consisted of zero neutron readings as well as zero photon readings, yet the only adjustment made was for the photon LOD.

- Table 2 of OTIB-0058 lists a photon dose of 1.390 rem for the 50th percentile for 1952. This value was derived from the HIS-20 coworker database of 2.045 rem composite dose by using an NDRP specified n/p value of 1.2 plus a photon LOD of + ½(24 × 0.040 – 0.40) = 0.460 rem; i.e., 2.045 rem /(1+1.2) + 0.460 rem = 1.330 rem.

- Table 2 of OTIB-0058 lists a neutron dose of 1.115 rem for the 50th percentile for 1952. This value was derived from the HIS-20 coworker database of 2.045 rem composite dose by using an NDRP specified n/p value of 1.2; i.e., [2.045 rem /(1+1.2)] × 1.2 = 1.115 rem. Note that there was no missing dose added to the neutron dose as there was for the photon dose. But the composite dose could have contained zero entries for neutron reading. This is generally true for TLD readings as well as NTA film reading.

Analyzing the file *tblNDRPData* [located at O-drive ->AB Doc ->RFP -> NDRP -> Copy of NDRP_BE_20070319 -> tblNDRPData] shows that out of 23,563 entries, the final NDRP neutron dose was blank for 87 entries (0.4%), ≤15 mrem for 2742 entries (11.6%) and ≤30 mrem for 3594 entries (15.1%). This indicates that there were a significant number of final NDRP neutron doses under the LOD of NTA film, especially in view of the neutron LODs values listed in NIOSH's workbook entitled "RFP Missed Zero Cal WB 1.44" of September 8, 2006. Column 15 of that table lists Neutron LOD/2 values ranging from 0.010 to 0.200 rem per exchange cycle. Comparing these values to the LOD values for photons listed in Column 11 of that table (ranging from 0.010 to 0.020

rem) results in potential missed neutron doses that are up to 10 times greater than missed photon doses.

Considering this information, it cannot be stated that OTIB-0058 is always claimant favorable in instances of missing dosimetry data.

Review Objective 3.2.4

Generally, OTIB-0058 adequately addressed unmonitored periods of exposure. However, there are two areas of concern:

(1) An incorrect assumption may be implied by the statement made on page 10, Step 5, of OTIB-0058, that the NDRP assigned a notional dose. Assignment of notional dose should not be interpreted as meaning that it corrects for all gaps in neutron monitoring and all missed dose due to the LOD of the neutron dosimetry systems. The fact that the LOD of the neutron dosimetry systems is not included in the NDRP data was discussed previously in Review Objective 3.2.3. The only gaps in neutron dose records that the NDRP bridges are periods of time when there were positive photon doses of record and the worker was known to be potentially exposed to neutrons. A review of several of the individual DOE claimants' files show that the NDRP does not generally apply to all years of photon monitoring, or to all years of employment. Therefore, the NDRP should not be considered to compensate all missed and unmonitored neutron dose for 1952–1969.

(2) OTIB-0058 incorporated OTIB-0052's (ORAUT 2006b) recommendation of multiplying the coworkers' dose by 1.4 to arrive at a dose assignment for unmonitored construction workers directly into Tables 7-3 and 7-4. However, OTIB-0058 used different methodologies for the time period of 1952–1969 compared to 1970–2005; the DR is not informed of this change in methods by OTIB-0058. An evaluation of the use of one adjustment factor of 1.4 for all construction workers for the entire period of 1952–2005 is beyond the scope of this review; SC&A has performed a review of OTIB-0052 in a separate report. OTIB-0058 did not discuss the appropriateness of using the recommendation of OTIB-0052 for RFP constructions workers, nor did it contain supportive evidence for it use.

Review Objective 5.2

OTIB-0058 is not always claimant favorable in instances of unknown parameters. One example is the assignment of n/p values for 1952–2005. The third bullet point on page 8 of OTIB-0058 provides the n/p values used to determine neutron doses in Table 7-2:

> *To determine neutron dose for the period from 1952 to 1969, neutron-to-photon ratios defined in the NDRP study* [ORISE 2005] *were used. Neutron-to-photon ratios for the period from 1970 to 1976 are defined in this document (see Table 6-2). For 1977 to 2005, values from ORAUT-OTIB-0050 were used (ORAUT 2005*[d]*).*

During these three major time periods and the many different locations/operations that took place at RFP, the n/p values could have ranged from <0.1 to 10, or more. According to OTIB-0058, the appropriate n/p values for all unmonitored workers potentially exposed to neutrons are as follows:

- 1952–1958: n/p = 1.2, which was derived from the average of all the buildings for 1959.
- 1959–1969: The appropriate n/p value for all unmonitored workers ranges from 0.5 to 3.0 depending on the year as listed in Table 11.1 of the NDRP (ORISE 2005); these values were derived from the average of all the buildings each year.
- 1970–1976: Table 6-2 of OTIB-0058 lists the average coworkers' n/p value for each year derived from some years of measured data (5 years out of 7 years). The n/p values ranged from 0.67 to 1.61.
- 1977–2005: An average n/p value of 0.42 from OTIB-0050 is used. The n/p values ranged from 0.26 to 0.61. These values were derived from TLD data obtained during 1977–2000.

As can be seen from this brief summary, there are no job-specific (or even category of jobs specific) or even building-specific n/p values recommended. Additionally, for 1952–1958 and 1977–2005, one n/p value covers multiple years. The assumptions that would have to be made to justify assigning these few n/p values to cover over 50 years of changes and all building, operations, and job types would not be considered claimant favorable in view of the many unknowns in neutron exposures and dosimetry.

Review Objective 5.3

The purpose of OTIB-0058 is to provide claimant-favorable dose reconstruction procedures in instances where the claimant was not monitored. Therefore, the overall evaluation of OTIB-0058 is relevant to this review objective. OTIB-0058 is sometime (but not always, as is discussed in the various sections of this report) claimant favorable; therefore, it is rated as 3 (*sometimes* fulfills the requirements) in the rating system of 1 to 5.

Review Objective 7.2

Generally, the level of detail in this procedure was reasonable. However, in some areas there were not sufficient details concerning the origin of the data, or how the data were derived, to allow the DR to make technically sound decisions involving individual cases or in non-standard circumstances. This mainly applies to the data contained in Tables 7-1 through 7-4. The data in these tables were not derived in an obvious manner and it requires some analysis to understand their origin and appropriate application. Additionally, the methodology is different for the period 1952–1969 as compared to 1970–2005. This difference is not noted in the text of the OITB. It would assist the DR in better understanding the dose being assigned if a brief description of the derivation of the data and/or several short examples were illustrated, as contained in Review Objective 3.2.3, Item 2 of this report. A basic understanding of the data being used may enable the DR to perform better, and more consistent, dose reconstructions.

Review Objective 7.3

For the most part, the procedure employed scientifically valid protocols. However, one area could have been made more scientifically correct, as noted below:

Prorating dose leads to uneven weighting of actual measured data: Pages 6 and 9 of OTIB-0058 describe the procedure used to normalize each worker's dose to a full year, so yearly percentile values could be computed. In the data file *RRFP Coworker Stats (NDRP Included HIS 20 Data)* [located at O-drive ->AB Doc ->RFP -> Co-Worker data -> RRFP Coworker Stats (NDRP Included HIS 20 Data)], this is accomplished by using a fractional function in which the original dose is divided by the fraction of a year that the dose record is for; i.e., if the worker's dose of 400 mrem was acquired in 6 months, the normalized annual dose would be 400 mrem/0.5 = 800 mrem. The problem with this methodology is that is gives equal weight to all annualized yearly doses. For example, if Worker A had one month of dose data and Worker B had 12 months of dose data, there are actually only 13 data points that should be used in analyzing the coworker data. However, using the HIS-20 method, there would appear to be 24 months of dose data, all with equal weight when normalized. The number of prorated-dose values is not always negligible in the HIS-20 database; e.g., 19% of the dose entries for 1966 are prorated (561 out of 2,921). The correct method would be to use only the recorded data values and then normalize them using the lowest common denominator, in this case dose per day. The annual doses would then be obtained by multiplying the resulting dose per day by 365 (or the appropriate number of days per year). Then analyses, such as percentile ranking, averages, etc., could be performed on these annual values. The difference between the two methods does not have a large impact on the results of percentile ranking, but is important if the normalized annual data in the HIS-20 database are used for other purposes, such as calculating average doses or n/p values.

3.26.4 Ramification of Developments since Issuance of OTIB-0058, Rev. 01 PC-1, March 29, 2007

Up to this point, OTIB-0058 has been reviewed according to the information and dose reconstruction protocol available as of March 29, 2007. However, significant changes have taken place since that time that will impact the implementation of OTIB-0058. These proposed changes are as follows:

(1) On May 4, 2007, the Advisory Board recommended that SEC status be granted for workers who were or should have been monitored for neutrons at the RFP during the period of 1952–1958.

(2) On June 12, 2007, the Advisory Board recommended that SEC status be granted for workers who were or should have been monitored for neutrons at the RFP during the period of 1959–1966.

(3) On May 17, 2007, at the Advisory Board's request, NIOSH provided alternate neutron dose reconstruction procedures for the period 1959–1970 (NIOSH 2007).

The alternate neutron dose reconstruction procedures for the period 1959–1970 proposed by NIOSH would:

- Eliminate the previous n/p method of estimating an unmonitored worker's neutron dose. That method consisted of multiplying the worker's recorded photon dose by an n/p value; this n/p value was derived for a specific building for a given year.

- Replace the previous method with one that uses a given percentile (i.e., 50^{th} or 95^{th}) of the neutron dose results that were obtained from workers badged for neutrons for a specific building for a given year. These badge results are on a badge-exchange basis, as opposed to an annual average, to better reflect the variations in neutron doses with job types and time dependence.

- Remove the use of the reading bias correction factor of 1.99 for Building 71 and 1.13 for all other buildings for unaffected (i.e., non-reread) Original Neutron Dose when using NDRP dose records.

- Replace the previous reading bias correction factor with a 50^{th} percentile value of 1.640 or 95^{th} percentile value of 6.950 (derived from 1959–1969 reread vs. unaffected data analysis) for workers with NDRP unaffected neutron doses greater than zero. If the NDRP unaffected neutron dose was recorded as zero, then the worker will be assigned a claimant-favorable neutron dose of 73 mrem/d (50^{th} percentile value) or 183 mrem/d (95^{th} percentile value).

- Notional doses in the worker's NDRP dose records (part of which were derived from n/p values) would be replaced by coworker data, as described in the second bullet point above. At this time, it appears that NIOSH would only replace the n/p derived portion of the notional dose and leave the dose derived from the worker's adjacent neutron dose readings as they presently are.

Because OTIB-0058 covers photon, beta, and neutron exposures for 1952–2005, the recent proposed changes will only affect part of the procedures/data in OTIB-0058; those concerned with neutron exposures (or procedures using the n/p method to derive photon doses from composite doses) during 1952 through 1970. This includes the 95^{th} and 50^{th} percentile photon and neutron dose data for 1952–1970 in Tables 7-2 and 7-4. Additionally, Section 8.0 concerning justification for extrapolation of n/p values from 1959 to the 1952 to 1958 period will not be needed if the n/p method is not used.

At this time, it is not obvious how the photon dose will be calculated from the composite doses records for the period 1952–1970, for unmonitored workers that were not exposed to neutrons. Presently, the values for photon dose in Table 7-2 and 7-4 of OTIB-0058 are derived by using n/p values, as discussed in Review Objective 3.2.3 Item 2 of this report. However, this method depends on use of n/p values, which is not used in NIOSH's alternate neutron dose reconstruction procedures (NIOSH 2007). Also, it is not certain if the alternate neutron procedure will extend back to cover the period 1952–1958 (if it is accepted) as a means to separate out the photon doses from the composite doses.

The proposed changes most likely will require the revision of some RFP dose reconstruction documents, such as TBDs and OTIBs. Some of these documents are:

(1) TKBS-0011-6 (Langsted 2007), especially parts 6.7.3.4 and 6.7.3.5 concerning NTA film reading bias factors and the use of the NDRP n/p data.

(2) OTIB-0027 (ORAUT 2005c), Section 3.0 and Tables 4-1 and 4-2.

(3) OTIB-0050 (ORAUT 2005d), Sections 3 and 4 will have to be rewritten concerning notional doses.

(4) OTIB-0058 (ORAUT 2007), as previously described in this section of this report.

3.26.5 Workbooks

Seven RFP workbooks use the data generated by OTIB-0058. Following are the titles of these seven workbooks, along with comments concerning their dependence on recent changes made in OTIB-0058 as of March 29, 2007, and proposed changes since March 29, 2007:

(1) ***Complex Wide CoWorker Data 1.10:*** The data for RFP in this workbook is outdated because it was taken from Table 7-2 of older versions of OTIB-0058 and that table has been deleted in recent versions of OTIB-0058.

(2) ***RFP_OTIB-0058 Implementation Guidance_6-13-06:*** This guide is outdated because of the recent changes in OTIB-0058, and it will also be affected by the proposed SECs and NIOSH alternate neuron dose reconstruction procedures.

(3) ***RFP_OTIB-0058 Co-worker data Tool 1.00:*** This tool is outdated because of the recent changes in OTIB-0058, and it will also be affected by the proposed SECs and NIOSH alternate neuron dose reconstruction procedures.

(4) ***RFP-Missed Zero Calculation Workbook 1.14:*** The columns concerned with neutron dose for the period 1951–1970 will need to be modified accordingly.

(5) ***RFP Calculation Workbook 2.24:*** No apparent changes because of the revised OTIB-0058 were identified for this workbook. Changes to this workbook will be required because of the SECs and the NIOSH's alternate neutron dose reconstruction procedure, if these are approved.

(6) ***RFP_BE words for DRs_5-16-06:*** No apparent changes to this workbook because of the revised OTIB-0058. Changes to this workbook will be required because of the SECs and the NIOSH's alternate neutron dose reconstruction procedure, if these are approved.

(7) ***RFP Basic Guidelines for RFP Version 1.10, 4-5-06:*** Changes in the recent OTIB-0058 will require changes in this guide, i.e., page 9 of the guide refers to the use of the n/p value of 1.42 for the period 1971–1976; this has since been replaced by Table 6-2 in the new OTIB-0058. Additionally, if the proposed SEC's and NIOSH's alternate neutron dose reconstruction procedures are accepted, the NDRP and other neutron dose issues discussed on pages 8–18 of the guide will need to be revised.

3.26.6 Summary

This review of the OTIB-0058, Rev. 01 PC-1, March 29, 2007, provides an evaluation of the latest OTIB concerned with assigning coworker dose to unmonitored RFP workers for the period 1952–2005. Additionally, it incorporates recent proposed changes and their major impacts to provide a view of the current status of the external dose reconstruction procedures for unmonitored RFP workers. This can serve as a starting point when the RFP dose reconstruction process begins to be finalized.

3.26.7 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

NIOSH (National Institute for Occupational Safety and Health) 2007. NIOSH's response entitled *III ABRWH Request 3, "Neutron Doses 1959 to 1970,"* May 17, 2007.

ORAUT-OTIB-0017. 2005a. *Technical Information Bulletin: Interpretation of Dosimetry Data for Assignment of Shallow Dose*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 11, 2005.

ORAUT-OTIB-0020. 2005b. *Technical Information Bulletin: Use of Coworker Dosimetry Data for External Dose Assignment*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 7, 2005.

ORAUT-OTIB-0027. 2005c. *Technical Information Bulletin: Supplementary External Dose Information for Rocky Flats Plant*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 19, 2005.

ORAUT-OTIB-0050. 2005d. *Technical Information Bulletin: Use of Rocky Flats Neutron Dose Reconstruction Project Data in Dose Reconstructions*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 13, 2005.

ORAUT-OTIB-0021. 2006a. *Technical Information Bulletin: External Coworker Dosimetry Data for the X-10 Site*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. Oak Ridge, Tennessee. November 7, 2006.

ORAUT-OTIB-0052. 2006b. *Technical Information Bulletin: Parameters to Consider When Processing Claims for Construction Trade Workers*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. August 31, 2006.

ORAUT-OTIB-0058. 2007. *Technical Information Bulletin: External Coworker Dosimetry Data For The Rocky Flats Plant*, Rev. 01 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. March 29, 2007.

ORAUT-TKBS-0011-6, 2007. *Technical Basis Document: Rocky Flats Plant – Occupational External Dose*, Rev. 0, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 8, 2007.

ORISE (Oak Ridge Institute of Science and Education) 2005. *Technical Basis Document for the Neutron Dose Reconstruction Project*, ORISE 05-0199, Oak Ridge, Tennessee. February 7, 2005.

3.27 ORAUT-OTIB-0060: INTERNAL DOSE RECONSTRUCTION

The review of ORAUT-OTIB-0060, *Internal Dose Reconstruction*, Rev. 00, dated February 6, 2007, was prepared by Doug Farver, CHP, CSP.

3.27.1 Purpose of the Technical Information Bulletin

This document supersedes PROC-0003 and provides information and guidance for reconstructing internal dose and to document the rationale for selection of certain default parameters.

3.27.2 Review Protocol

As part of the first set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated ORAUT-PROC-0003 *Internal Dose Reconstruction*, Rev. 0 (May 1, 2003). Our findings were published in *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, dated January 2005 (SCA-TR-Task3). Following the submission of this report and its findings, an expanded review and issues-resolution process was initiated. The process began by NIOSH providing written responses to each of SC&A's findings. Under the direction of a Board-appointed work group, a series of meetings was held between representatives of NIOSH and SC&A auditors to discuss and resolve each finding. This process resulted in the preparation of an issues-tracking matrix, whereby the closeout status of each finding is tracked.

As indicated in the issues-tracking matrix, PROC-0003 was replaced with ORAUT-OTIB-0060, and the resolution of many findings identified during our review of PROC-0003, Rev. 0 were to be addressed with the issuance of OTIB-0060. The PROC-0003 findings were also assigned a resolution priority ranking of high, medium, or low by the Advisory Board. Our evaluation of OTIB-0060, Revision 0, therefore, was designed to ensure that (1) the findings identified for PROC-0003 were adequately resolved, and (2) the document adequately supports the dose reconstruction process. Table provides a list of applicable PROC-0003, Rev. 0 findings, the Board-recommended resolution ranking, and our evaluation to assess whether those findings were adequately addressed.

SC&A's evaluation of OTIB-0060 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 3.27-1: Evaluation of Findings Identified in the Review of ORAUT-PROC-0003

Review Objective	ORAUT-PROC-0003, Rev. 0 Finding Description	Resolution Ranking	Corrected in ORAUT-OTIB-0060?	Comments
1.3	Guidance in procedure incomplete since it does not include references for ICRP 30, 56, 67, 69, 71, 72, and 78, which are necessary to understand Table 1. (PROC-0003-01)	Low	Partially	ICRP 30, 66, 71, and 78 are currently referenced, but ICRP 67, 69, and 72 are not.
2.1/2.2	Table 1, Absorption Types for Selected Radionuclides, page 10, Column "deposition sites" should be changed to "systemic deposition sites." (PROC-0003-03)	Low	Not Applicable	PROC-0003, Table 1 'Absorption Types for Selected Radionuclides' has not been carried forward into OTIB-0060. Rather than assigning specific absorption types for radionuclides, OTIB-0060, Section 5.2.3 states "an assessment of each type to which the element is assigned in ICRP 68 (…) shall be made, and that which results in the largest dose to the organ of interest shall be selected".
2.1/2.2	Table 1, Absorption Types for Selected Radionuclides, page 10, soft tissue compartments are present in new physiologically based biokinetic models (Sr, Ra, U, Th, Np, Pu, Am, Cm) and represent body compartments that are not considered the main ones. (PROC-0003-04)	Low	Not Applicable	
2.1/2.2	Table 1, Absorption Types for Selected Radionuclides, page 10, does not consider the introduction of compartments produced by decay product nuclides (i.e., kidneys/spleen for Ra-226). (PROC-0003-05)	Low	Not Applicable	
2.1/2.2	Table 1, Absorption Types for Selected Radionuclides, page 10, contains deposition site errors: (1) Ra should include liver, (2) Th should include kidneys, (3) Np, Pu, and Am should include kidneys and red bone marrow, and (4) Cm should include gonads, kidneys, and red bone marrow. (PROC-0003-06)	Low	Not Applicable	

Table 3.27-2: ORAUT-OTIB-0060 Review Outline/Checklist

Document No.: ORAUT-OTIB-0060, Rev. 00	**Effective Date:** 02/06/2007
Document Title: Internal Dose Reconstruction	
Auditor: Doug Farver, CHP, CSP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	The guide references NIOSH and ORAUT documents and should be revised to reference IMBA documentation for additional guidance.
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	2	See Review Comments
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	5	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	

Table 3.27-2: ORAUT-OTIB-0060 Review Outline/Checklist

Document No.: ORAUT-OTIB-0060, Rev. 00	**Effective Date:** 02/06/2007
Document Title: Internal Dose Reconstruction	
Auditor: Doug Farver, CHP, CSP	

No.	Description of Objective	Rating 1-5*	Comments
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?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	3	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.27.3 General Comments

ORAUT-OTIB-0060 describes the parameters and methodology used to reconstruct the internal dose of workers who had the potential for internal exposure to radionuclides. The document provides guidance for instances where the worker was monitored, by fitting the bioassay data or assigning a missed dose; where the worker was not monitored, by assigning an unmonitored dose or using coworker information; and practices to improve the case processing efficiency, such as calculating over or under estimates of a worker's dose.

NIOSH uses the Integrated Modules for Bioassay Assessment (IMBA) computer code to estimate single or multiple intakes of various radionuclides, and to calculate the resulting doses

from measurements of activity in the body and/or excreta, based on a worker's bioassay measurements and site-specific information.

The approach of assigning actual, missed, unmonitored, and/or coworker internal dose and using a standardized computer code provides a certain amount of consistency and reproducibility. However, some specific areas of the internal dose reconstruction process would benefit from including additional details and technical justifications. These areas include discussion of the bioassay measurement error, error distribution, and the process of fitting positive bioassay results.

Measurement Error

In Section 5.2.5.2 of the guide, NIOSH states the following:

> *If there are no errors reported with the results, Measurement Error should be calculated using the Uniform Relative option, with k = 0.3 as a starting point. Note that in this instance the value of k is somewhat arbitrary; the same intake will result from any percentage, given the same percentage for all results. This might not be a reasonable estimate if there are some reasonably well-defined peaks or results vary by more than 1 order of magnitude. Larger values will have more precise statistics and might need to be assigned relatively smaller errors to obtain a better fit. Alternative values for the error should be tried if a reasonable fit is not obtained (e.g., the majority of results appear to be underpredicted, or the larger results are underpredicted). Application of a 10% error to the largest results while retaining a 30% error on the smaller results might improve the fit. Other values can be tried if this does not provide a satisfactory fit. Use of the Uniform Absolute option, with the same value entered for all results, will yield an unweighted fit (i.e., all results are weighted equally). If you cannot obtain a reasonable fit, contact the Principal Internal Dosimetrist for assistance.*

The first comment related to this section and the guide in general concerns the use of terms like "better fit," "satisfactory fit," and "reasonable fit," without providing a method to measure the "goodness of fit." As shown below, the fit of the data can be very dependent on other parameters. The IMBA code as used by NIOSH applies the maximum likelihood method to find the "best estimate" of intake from a given set of bioassay measurement data. IMBA allows the user to select the method used to calculate measurement error for bioassay results reports without errors. The user may choose Uniform Absolute, Uniform Relative, Square Root, and Logarithmic error assumptions (James 2004a). Briefly, Uniform Absolute error assumes the errors on each data point are the same; Uniform Relative error assumes the error on each data point are relative to the magnitude of the data point (i.e., measurement results may have been quoted as ± 10%); Square Root errors are proportional to the square root of measurement result (i.e., errors primarily from counting statistics); and Logarithmic errors assume the errors on each measurement are lognormally distributed with a given geometric standard deviation, instead of being normally distributed. The effect of the different error assumptions is illustrated in the IMBA Technical Basis document (James 2004b) using a $^{239}PuO_2$ inhalation as an example.

Table, from the IMBA TBD, Table A.37, shows how the "best estimate" of intake can vary widely, depending on the type of errors assumed.

Table 3.27-3: Effect of Error Assumption on Best Estimate of Intake

Error assumption	Best estimate of intake, Bq
Uniform absolute	4,169
Uniform relative	904.2
Square root	2,444
Logarithmic	1,413

Source: IMBA TBD, Table A.37

Assuming uniform absolute error gives the best visual fit on a linear scale as shown in Figure (James 2004b, Figure A-21).

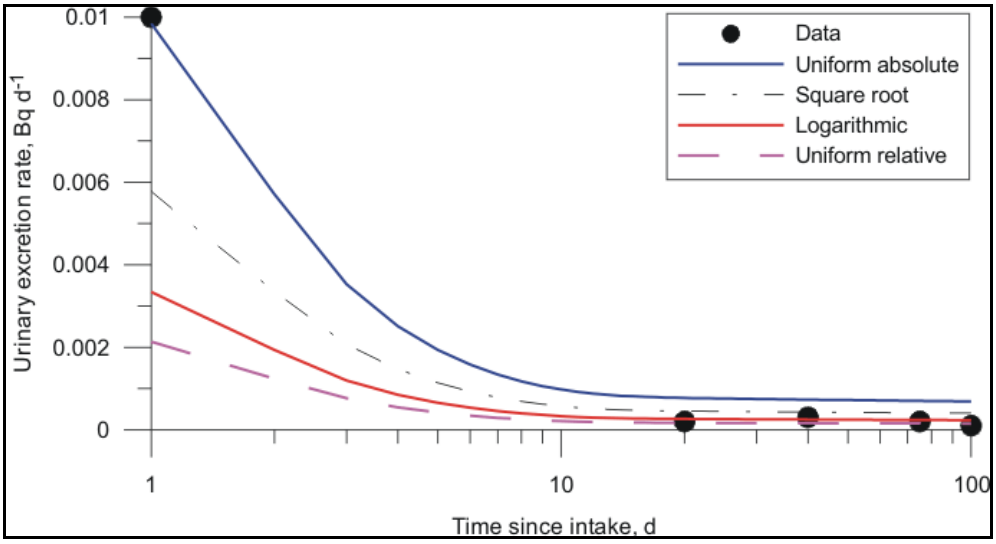


Figure 3.27-1: Linear Plot of Plutonium Oxide Excretion Rate for Various Fits

Reproduced from the IMBA TBD:

> *The "uniform absolute" error assumption appears to give the best by eye fit to the data because this is the only fit that comes close to the first data point, while still not appearing too far from the last four data points. The other fits are much closer to the last four data points, because the errors associated with these data are much smaller than that associated with the first point. Consequently, since the shape of the curve is fixed (by the ICRP Publication 67 plutonium biokinetic model), these other fits cannot represent the first data point as well.*

Before jumping to the conclusion that the assumption of uniform absolute error is "best," it is instructive to view the data and fits plotted on a logarithmic scale. [Figure below].

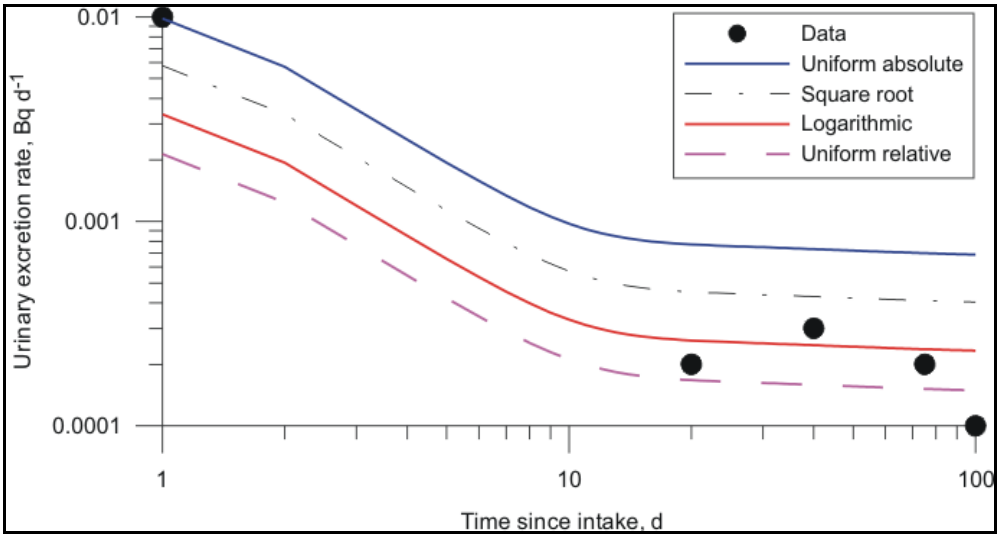


Figure 3.27-2: Logarithmic Plot of Fits of Plutonium Oxide Data

The IMBA TBD also recommends:

As a general guide one can consider the following criteria for selecting the most appropriate error assumption in the absence of specific estimates for any (or all) data points.

Data criterion	***Appropriate error assumption***
1. Error dominated by counting statistics	*Square-root errors*
2. Data are believed to be distributed lognormally	*Lognormal errors*
3. Excretion data varying over a large range	*Lognormal errors*
4. In-vivo data	*Uniform relative errors*
5. No information whatsoever	*Test all assumptions*[(a)]

[(a)] *The assumption selected must satisfy the requirements of your regulatory authority.*

Assuming the errors on each in-vitro bioassay measurement are lognormally distributed, with a given geometric standard deviation (GSD), *ICRP Draft Guidance on Interpretation of Bioassay Data, Annex E, "Data Fitting"* (ICRP 2006) provides several ranges of GSDs. Table E-2 from Annex E is reproduced in Table, below. The scattering factor for Type B uncertainties (SF_B) is the GSD of the lognormal Type B uncertainty distribution.

Table 3.27-4: Default Values for the Lognormal Scattering Factor (SF) for Various Types of Measurement from Different Studies (Type B Errors)

Ranges are given in Parentheses

Quantity	Log. normal scattering factor SF_B
True 24-hr urine	1.1[a]
Simulated 24-hr urine, creatinine or specific gravity normalized.	1.6[b] (1.3[c] - 1.8[d])
Spot urine sample	2.0[a]
Fecal 24-hr sample	3 (2 - 5)[b]
Fecal 72-hr sample	2 (1.5–2.5)[e]
Chest count (see Table E.1)	1.2 to 2.1

(a) Value given by Moss et al., 1969 based on plutonium in urine measurements of workers at Los Alamos.

(b) Value based on judgment and experience.

(c) At Los Alamos, Type B uncertainties, in terms of the coefficient of variation, for urine samples normalized using volume and specific gravity has been found to be 30% (i.e., an SF of 1.3).

(d) Value given by Riddell et al., 1994 based on plutonium in urine measurements of Sellafield workers. Because sampling procedures and measurements techniques have improved over the years recent measurements are likely to have a SF less than 1.8.

(e) SF values for 72-hr fecal samples are consistent with 24-hr fecal samples.

Source: ICRP 2006 Annex E, Table E-2

In summary, NIOSH's guidance on using a Uniform Relative error may be applicable for in-vivo measurements. However, it may not be applicable or claimant favorable for modeling in-vitro measurement results. After a review of proposed ICRP guidance, NIOSH may decide that using a logarithmic error assumption for in-vitro measurement results and selecting specific GSD values (i.e., 1.5 for 24-hr urine, 2.0 for spot urine, and 1.6 for chest counts) would reduce the arbitrary k-value selection and improve the overall consistency of the internal dose assessments.

Error Distribution

Section 5.2.5.3 of the guide simply states:

> *Individual bioassay results are assumed to be normally distributed*

As discussed above, this may not be true in all cases. NIOSH may wish to review ICRP guidance and possibly revise or elaborate on the technical justification supporting this statement.

Fitting Positive Bioassay Results

Section 5.3 of the guide provides the general philosophy and guidelines for fitting positive bioassay results. The guide uses the following terms and definitions for the discussion of fitting positive bioassay results:

- Positive – means a result greater than the reporting level (i.e., MDA, detection level)
- Negative – means a result that is less than or equal to the reporting level.

The second bullet of Section 5.3.2 of the guide states:

> *In IMBA, for results < MDA, Measurement Result = MDA value, Data Type = "<LOD." Include the first negative (<MDA) result following each set of positive results. If there are multiple positive results, include no more than two negative results. For fewer than five consecutive positive results, include only one negative result. Use of additional "<LOD" results, particularly for chronic exposures, frequently yields a fit that appears to underestimate the general trend of the data. Note that the presence of a result less than the MDA does not mean that a new intake must be assigned for the next result greater than the MDA.*

NIOSH provides the guidance to "include no more than two negative results" for data with multiple positive bioassay results and to "include only one negative result" for data with fewer than five consecutive positive results. The justification given is that "additional '<LOD' results, particularly for chronic exposures, frequently yield a fit that appears to underestimate the general trend of the data." This position seems to contradict IMBA's Technical Basis document (James 2004b), which specifically states the following:

> *A major benefit of the maximum likelihood method is that it enables measurements that are "less than the limit of detection" (< LOD) to be considered in an unbiased manner in the estimation of intake.*
>
> *The unbiased estimation of intake by the maximum likelihood method in the case of a dataset with a large proportion of values "< LOD" has been validated (by Monte Carlo calculations) by Marsh et al. In press.* (Marsh et al. 2002)

If, indeed, a large proportion of < LOD values result in an underestimate of intake using the maximum likelihood fitting method, then NIOSH should document the technical justification and may wish to consult with the IMBA designers as to why IMBA is not performing as described in the technical documentation.

3.27.4 Review Comments

Review Objectives 1.5 and 4.1

Though the OTIB is prescriptive, it makes use of several subjective terms that could be interpreted differently by different dose reconstructors. Terms such as "better fit," "reasonable fit," or "satisfactory fit" would benefit by some type of quantification guidance (i.e., intake quantity ± 10% defined as satisfactory fit). Section 5.4 discusses "long-lived/retained" and "short-lived/retained" radionuclides and provides a few examples, but does not specify a boundary. It may be beneficial, to avoid potential confusion, to either specify time ranges for the two radionuclide groups or provide a table with all the radionuclides used by IMBA list with the appropriate time range. Section 5.4.1 "Missed Dose Determination" lists the following as decision criteria:

If the detection threshold decreases over time and the radionuclide/absorption type reaches equilibrium slowly in the compartment of interest (e.g., in urine: Type M or S plutonium/transuranics or Type S uranium), perform the fit using the date of the last sample and half of the associated detection threshold, assuming a single chronic intake for the entire potential exposure period.

- *If the detection threshold decreases over time for radionuclide/absorption types that reach equilibrium rapidly, or if the detection threshold increases over time, use IMBA to determine chronic intakes applicable to each period (note that this is applicable only if there is a bioassay result in the period).*

These statements rely on the dose reconstructor to determine if the radionuclide/absorption type reaches equilibrium slowly or rapidly, with no quantification of what is slow or rapid. Again, a table listing the radionuclides and equilibrium rate would eliminate the ambiguity.

Review Objective 6.1

As discussed in the General Comments, the OTIB prescribes certain distributions to be used (i.e., Section 5.3.2 lists Set Error Distribution = Normal). However, NIOSH's prescriptions may not be valid in all cases. For example, ICRP guidance (ICRP 2006) considers bioassay data to be lognormally distributed. The OTIB does not provide the technical basis for the decision of a normal distribution.

Review Objective 7.3

The OTIB would benefit from more thorough explanations of the bases for the guidance prescribed in Section 5.3, "Fitting Positive Bioassay Results," Section 5.4, "Assignment of Missed and Unmonitored Dose," and Section 5.5, "Assessment Methods."

3.27.5 References

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ICRP (International Commission on Radiological Protection) 1990. *Age-Dependent Doses to Members of the Public from Intake of Radionuclides: Part 1*, Publication 56, Pergamon Press, Oxford, England.

ICRP (International Commission on Radiological Protection) 1994. *Age-Dependent Doses to Members of the Public from Intake of Radionuclides: Part 2 Ingestion Dose Coefficients,"* ICRP Publication 67, Annals of the ICRP, Volume 23/3-4, August 1994.

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Moss, W.D., Campbell, E.E., Schulte H.F. and Tietjen, G. L. 1969. *A Study of the Variations Found in Plutonium Urinary Data.* Health Phys. 17, 571–578.

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3.28 ORAUT-OTIB-0063: LOS ALAMOS NATIONAL LABORATORY BIOASSAY DATA PROJECT

This document has not been issued by ORAUT. It is suggested that review of this document be deferred until next fiscal year, after the document has been issued by NIOSH.

4.0 OAK RIDGE ASSOCIATED UNIVERSITIES TEAM (ORAUT) PROCEDURES

4.1 ORAUT-PROC-0006: EXTERNAL DOSE RECONSTRUCTION

The review of ORAUT-PROC-0006, *External Dose Reconstruction*, Rev. 01, dated June 5, 2006, was prepared by Kathleen Behling.

4.1.1 Purpose of the Procedure

The stated purpose of this procedure is to provide instructions on the performance of external dose reconstructions:

> *This procedure specifies steps taken to incorporate direction from the National Institute for Occupational Safety and Health (NIOSH) Office of Compensation Analysis and Support (OCAS) in the performance of external dose reconstructions (DRs) as contained in the External Dose Reconstruction Implementation Guideline (OCAS-IG-001), Technical Information Bulletins (TIBs), approved site Technical Basis Documents (TBDs), and Oak Ridge Associated University Team (ORAUT) procedures (PROCs).*

4.1.2 Review Protocol

As part of the first set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated Revision 00 of the procedure *External Dose Reconstruction* (June 2003). Our findings were published in *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, dated January 2005 (SCA-TR-Task3). Following the submission of this report and its findings, an expanded review and issues-resolution process was initiated. The process began by NIOSH providing written responses to each of SC&A's findings. Under the direction of a Board-appointed work group, a series of meetings was held between representatives of NIOSH and SC&A auditors to discuss and resolve each finding. This process resulted in the preparation of an issues-tracking matrix, whereby the closeout status of each finding is tracked.

The resolution of many findings identified during our review of Revision 00 of the external dose reconstruction procedure required NIOSH to incorporate appropriate changes in a future revision of ORAUT-PROC-0006. These findings were also assigned a resolution priority ranking of high, medium, or low by the Advisory Board. Our evaluation of ORAUT-PROC-0006, Revision 01, therefore, was designed to ensure that (1) the findings identified in Revision 00 were adequately resolved, and (2) the document adequately supports the dose reconstruction process.

Table provides a list of applicable ORAUT-PROC-0006, Rev. 00 findings, the Board-recommended resolution ranking, and our evaluation to assess whether those findings were adequately addressed in Revision 01. It should be noted that the issues-tracking matrix for the first set of procedures did not specifically list all of the ORAUT-PROC-0006, Rev. 00 findings, but simply indicated that, "Due to the similarities between OCAS-IG-001 and ORAUT-PROC-0006, review comments considered relevant to OCAS-IG-001 also apply to ORAUT-PROC-

0006." However, many of the OCAS-IG-001 findings are not applicable to PROC-0006, due to the differences in document structures and the fact that PROC-006 was designed to provide a step-by-step approach to external dose reconstruction, rather than the more general guidance provided in OCAS-IG-001. As a result of these differences in document style and purpose, only 6 of the 15 unresolved findings from OCAS-IG-001, Rev. 00, apply to PROC-0006; and in some cases, the wording of the findings was slightly modified to make them more applicable, as shown in Table.

Table is a checklist containing SC&A's evaluation of procedural objectives, as described in the introduction to this report.

Table 4.1-1: Evaluation of Findings Identified in the Review of ORAUT-PROC-0006, Rev. 00

Review Objective	OCAS-IG-001, Rev. 1 Finding Description	Resolution Ranking	Corrected in Rev. 1?	Comments
1.1	Deficiencies with procedure layout include (1) excessive amount of useless data and/or historical background in main body, and (2) critical data for dose reconstruction found in Appendices rather than main body.	Low	Yes	Revision 01 of the ORAUT-PROC-0006 constitutes a total rewrite of the document. This revision is written in a clear, concise, and structured manner. Critical dose reconstruction data that were previously contained in Attachments have now been incorporated into the main body of the procedure.
1.3	Guidance for deriving film and TLD dosimeter uncertainty requires data and resources that are not available to the dose reconstructor.	Medium	Yes	ORAUT-PROC-0006, Rev. 01, provides specific guidance and instructions regarding dosimeter uncertainty. It also identifies site-specific documentation that is available to the dose reconstructor and calculational tools that can be used for determining uncertainty.
5.0	PROC-0006, Appendix B, DCFs for bone surface and red marrow are underestimated.	Medium	Yes	Revision 01 of the external dose procedure has eliminated the attachment containing the photon and neutron DCFs and refers the dose reconstructor to OCAS-IG-001, *External Dose Reconstruction Implementation Guideline*, for these values. This issue, which was also a finding in OCAS-IG-001, has been appropriately addressed in Revision 2 of the implementation guide.
6.0	PROC-0006, Appendix B, PA geometry DCFs are in error and underestimate dose.	High	No	ORAUT-PROC-0006, Revision 01, has eliminated the attachment containing the photon and neutron DCFs and refers the dose reconstructor to OCAS-IG-001 External Dose Reconstruction Implementation Guideline for the DCF values. (It should be noted however, that this issue, which was also a finding in OCAS-IG-001, has not been addressed in Revision 2 of the implementation guide.)

Table 4.1-1: Evaluation of Findings Identified in the Review of ORAUT-PROC-0006, Rev. 00

Review Objective	OCAS-IG-001, Rev. 1 Finding Description	Resolution Ranking	Corrected in Rev. 1?	Comments
6.0	PROC-0006, Appendix B, rotational and isotropic geometry DCFs are in error and underestimate dose.	High	Yes	Revision 01 of PROC-0006 has eliminated the attachment containing DCF values and refers the dose reconstructor to OCAS-IG-001, *External Dose Reconstruction Implementation Guideline*, for these values. This issue, which was also a finding in IG-001, has been appropriately addressed in Revision 2 of the implementation guide.
6.0	Guidance for the selection of uncertainty distributions for total organ dose raises question of consistency and requires professional judgment.	Medium	Yes	Attachment C of PROC-0006, Rev. 00, contained guidance for assessing annual organ dose and its distribution. This attachment has been eliminated and instructions for assessing total dose uncertainty are provided in the main section of the procedure. These modified instructions provide a more clear and consistent approach to determining uncertainty distributions and direct the dose reconstructor to applicable calculational tools and technical documentation for such determinations.

Table 4.1-2: ORAUT-PROC-0006 Review Outline/Checklist

Document No.: ORAUT-PROC-0006, Rev. 01	**Effective Date:** 06/05/2006
Document Title: External Dose Reconstruction Implementation Guideline	
Auditor: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
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?	5	

Table 4.1-2: ORAUT-PROC-0006 Review Outline/Checklist

Document No.: ORAUT-PROC-0006, Rev. 01	**Effective Date:** 06/05/2006
Document Title: External Dose Reconstruction Implementation Guideline	
Auditor: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	5	

Table 4.1-2: ORAUT-PROC-0006 Review Outline/Checklist

Document No.: ORAUT-PROC-0006, Rev. 01	**Effective Date:** 06/05/2006
Document Title: External Dose Reconstruction Implementation Guideline	
Auditor: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.1.3 Review Comments

Review Objective 1.4

SC&A's review of ORAUT-PROC-0006, Rev. 01, identified only one minor inconsistency with other procedures employed by NIOSH for dose reconstruction. Section 5.3 of PROC-0006, Rev. 01, contains the following statement: "Appendix A of OCAS-IG-001 lists the basic ICD-9 codes and general information on the corresponding organ for which the external dose should be calculated." Two months after the release of Rev. 01 of PROC-0006, NIOSH issued Revision 2 of OCAS-IG-001, which no longer contains the list of ICD-9 codes in Appendix A. Appendix A of OCAS-IG-001, Rev. 2, provides the photon and neutron DCFs and the list of ICD-9 codes has been removed from the implementation guide.

SC&A realizes that at the time Rev. 01 of PROC-0006 was released, this statement was appropriate. However, since Appendix A of OCAS-IG-001 no longer contains the list of ICD-9 codes, this statement should be removed in a future revision.

It should also be noted that Rev. 01 of PROC-0006, Section 5.3, contains the following statement: "Detailed information on ICD-9 codes and the appropriate external organ is provided in ORAUT-OTIB-0005." This statement, along with more detailed instructions that are provided in Section 6.0 of PROC-0006, should direct the dose reconstructor to the appropriate technical documents for assignment of ICD-9 code and surrogate external organs.

4.1.4 Conclusions

Revision 01 of ORAUT-PROC-0006 has appropriately addressed all of SC&A's findings associated with Revision 00. In addition, this revised procedure has introduced current information and updated external dose reconstruction practices. The procedure is written in a clear and concise style. The dose reconstructor is directed to applicable technical and site-

specific documentation and calculation tools, when available. Lastly, instructions for the reconstruction of external doses are sufficiently comprehensive and provide appropriate levels of detail to maximize consistency in the dose reconstruction process and minimize data interpretations.

4.1.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

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SC&A 2005. *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-Task3, S. Cohen and Associates, McLean, Virginia. January 2005.

4.2 ORAUT-PROC-0042: ACCOUNTING FOR INCOMPLETE PERSONAL MONITORING DATA ON PENETRATING GAMMA-RAY DOSES TO WORKERS IN RADIATION AREAS AT THE OAK RIDGE Y-12 PLANT PRIOR TO 1961

The review of ORAUT-PROC-0042, Rev. 00, dated September 9, 2004, was prepared by Ron Buchanan, PhD, CHP.

4.2.1 Purpose of the Procedure

The purpose of ORAUT-PROC-0042 is to provide ORAUT dose reconstructors with a procedure they can use to account for incomplete personal monitoring of penetrating gamma-ray doses to workers in radiation areas at the Oak Ridge Y-12 Plant prior to 1961.

4.2.2 Review Protocol

SC&A's evaluation of ORAUT-PROC-0042 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether OTIBs adequately support the dose reconstruction process, as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 4.2-1: ORAUT-PROC-0042 Review Outline/Checklist

Document No.: ORAUT-PROC-0042, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant Prior to 1961	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

Table 4.2-1: ORAUT-PROC-0042 Review Outline/Checklist

Document No.: ORAUT-PROC-0042, Rev. 00	**Effective Date:** 09/09/2004
Document Title: Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant Prior to 1961	
Auditor: Ron Buchanan, PhD, CHP	

No.	Description of Objective	Rating 1-5*	Comments
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	4	See Review Comments
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	See Review 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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.2.3 Review Comments

Review Objective 1.1

Generally, the OTIB was written in a fairly clear and logical manner. However, there are several areas that could be improved to assist the DR in understanding the different stages of development of the DR instructions. Additionally, some wording and errors contained in the text create confusion and require several rereads, and/or assumptions to be made, to clarify the issues. The following areas were identified:

- It should be made clear at the beginning that this procedure only applies to certain workers during a given time period exposed to penetrating gamma radiation, and not to ***Y-12 workers in general. Specifically, it applies only to unbadged workers who worked in areas at Y-12 that had the potential for penetrating gamma radiation exposures during the period of 1947–1960.*** They may or may not have been employed at Y-12 after 1960.

- The format of the procedure appears to not match those of other procedures and OTIBs. For example, the references are listed in the front rather than at the end of the document. Also, Section 4.0, RESPONSIBILITES, page 3, does not appear in other documents reviewed to date. If this procedure is revised, a current, uniform, format is suggested.

- The wording of the titles and the sequence of some of the subsections in Section 6.0 could be improved to help guide and inform the DR of the purpose and flow of the procedure.

- In Section 6, the procedure starts the text in most subsections with words that end with "s", i.e., Uses, Obtains, and Extracts. This is somewhat confusing to the reader. It would be clearer if the instruction is definite, such as, "Use the data in Table 5.2…"

- It would provide a clearer meaning if the word, "obtain," in the main paragraph of Section 6.5, page 11, was replaced with the word, "extract," because this is what the title instructs the DR to do. For example:

  > *Uses the following steps to **extract** the annual organ doses and their uncertainty parameters for a worker of interest and for all years of interest.*

- Section 6.1, page 7, uses the term "censored doses" without defining what the term means.

Review Objective 1.5

The OTIB was generally written in a prescriptive manner. However, several areas could be improved. They are as follows:

(1) In Section 5, page 4, it is stated:

> *In addition, dose reconstructors must evaluate monitoring data from the 1940s and 1950s cautiously because the purpose of monitoring programs at that time was to ensure compliance with exposure limits that were much higher than the current standard of 5 rem per year for dose to the whole body.*

In this section, the DR is not provided with definite instructions on how to evaluate the monitoring data from the 1940s and 1950s. Reference to problems during this era and appropriate OTIBs would be helpful.

(2) Section 6.3, page 9, instructs the DR to use the "Microsoft® Excel® computer program and Crystal Ball®," and Section 6.4, page 10, instructs the DR to perform steps to calculate the scaled annual distributions for organ doses. Both instructions are without a definite reference to the name of the programs and/or workbooks to be used. This could cause incorrect dose reconstruction results if the wrong programs and/or workbooks were used, or inconsistencies between different dose reconstructors.

Review Objective 3.2.1

It is not stated in this document that the dose data for the years 1947–1956 (3rd quarter) in Table 5.1, page 5, is not actually from badged workers' dose records. In fact, these values are inferred doses from regression analyses of 147 badged workers at Y-12 for the period of 1956–1965. Document ORAUT-RPRT-0032 must be analyzed to understand the development of this data. This may be an acceptable method to use in view of the lack of actual, reliable, recorded dose data for 1947–1956, but it should be clearly stated in the procedure that this is the case and not presented as actual dose of record. The second paragraph on page 4 of the procedure only refers to "the estimated parameters for lognormal distributions derived for each calendar quarter for July 1947 to December 1965 (ORAUT-OTIB-0013)," but not to the origin of the dose data.

Review Objective 5.3

For this procedure to be considered claimant favorable in instances where claimants were not monitored, there are number of assumptions/limitations that have to be accepted. These assumptions/limitations are not necessarily explicitly pointed out in detail in the procedure, and links/references to other documents must sometimes be followed to fully evaluate the applicability and technical soundness of this document. Some of these assumptions/limitations are listed below.

(1) The worker's routine duties and work location must have remained essentially the same during the 1950s and early 1960s (p. 4) and this information must be documented/verified.

(2) To adjust for a worker that had above average exposures during 1947–1960, the worker must have 5 or more quarters of recorded dose data during 1961–1965 on file and remained in the same exposure situation during the 1950s and early 1960s (p. 4).

(3) If the worker did not have 5 or more quarters of recorded dose data during 1961–1965, or did not work at Y-12 during 1961–1965, then the worker can only be assigned a dose derived from the average badged worker during 1956–1965 without any adjustments for above average exposure jobs during this period.

(4) It must be assumed that the workers that were badged during 1956–1960 were the highest exposed workers at Y-12 (pg. 6).

(5) It must be assumed that the dose records for the 147 workers analyzed from the fourth quarter of 1956–1965 correctly represents the trend of increasing dose as they extrapolate back in time from 1956 to 1947, because there are no reliable dose records (RPRT-0032) that can be used to verify the time period of 1947–1956.

(6) It must be assumed that the mean dose (not the upper percentile) of the badged workers is sufficient to calculate the assigned dose to unbadged workers.

Some workers would fit into this category and the dose assigned would be claimant favorable. However, if a worker was not monitored for at least 5 quarters during 1961–1965, a scaling factor of 1.0 will be applied; if the exposure conditions did not remain constant, then a scaling factor of 1.0 would be applied and average coworker data would be assigned. This procedure may not be claimant favorable to some workers who were exposed to radiation fields prior to 1961; especially to uncharacterized or unrecognized sources at the time. Although PROC-0042, page 6, states that the recommended approach is claimant favorable, because workers who had the potential for exposure above 10% of the radiation protection guidelines were monitored, at other DOE sites it has been found that some workers who were exposed may not have been those who were monitored, especially in the early years. It is not technically sound to assume that a worker received a dose below a certain limit because the worker was not monitored; there is no quantitative data to support such an assumption.

Review Objective 7.3

Most of this procedure employed scientifically valid protocols for reconstructing doses. However, the following technical errors were found in the text that could lead to errors in the assigned dose errors, if used as stated in the procedure:

The procedure appears to contain a technical error in applying the scaling factor. This error would not result in an underestimate of a worker's dose, but could result in a worker that had average, or below average, recorded doses during 1961–1965 being assigned a higher dose during 1947–1960 than another worker that has greater than average recorded doses during 1961–1965. To correct this error, the last paragraph on Page 6 should be changed from "…assume a scaling factor of unity (one) and use…" to "…assume a scaling factor of **zero (0)** and use…." Also, change the second paragraph on page 8 from:

> *…assume a scaling factor of unity (one) and use the "population dose distributions for monitored workers" in Table 5.1 as a reasonable but necessary claimant favorable procedure to generate data for input to the NIOSH-IREP*

Program. If a scaling factor is assumed to be unity (one) or a scaling factor for a monitored worker is calculated to be equal to or less than unity (one),…

to:

*…assume a scaling factor of **zero (0)** and use the "population dose distributions for monitored workers" in Table 5.1 as a reasonable but necessary claimant-favorable procedure to generate data for input to the NIOSH-IREP Program. If a scaling factor is assumed to be **zero (0)** or a scaling factor for a monitored worker is calculated to be equal to or less than **zero (0)**,…*

Additionally, change the title of Section 6.2, page 8, from:

Use of calculated scaling factors greater than unity

to:

*Use of calculated scaling factors greater than **zero***

This is needed because the scaling factor appears in the exponent ($GM^* = e^{u+\varphi}$) in calculating the scaled value of the geometric mean. Therefore, it must be zero to apply a multiplication factor of 1.0 to the dose. These paragraphs, and the associated errors, do not appear in the other related OTIBs and RPRT.

4.2.4 Workbooks

The following two workbooks are designed for use with this procedure:

(1) Y-12_Calculation Workbook 1.12. - This workbook is currently undergoing revision and will be evaluated by SC&A in the future.

(2) Y-12_Workbook CB_1951–1960 and CF After 1960 1.14. - A review of this workbook in conjunction with its use with PROC-0042 did not reveal any obvious errors or incorrect data.

4.2.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0013. 2004. *Technical Information Bulletin: Individual Dose Adjustment Procedure for Y-12 Dose Reconstruction,* Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. September 9, 2004.

ORAUT-PROC-0042. 2004. *Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant*

Prior to 1961, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. September 9, 2004.

ORAUT-RPRT-0032. 2005. *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee*: *Part 1 – Gamma Radiation*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. April 13, 2005.

4.3 ORAUT-PROC-0044: SPECIAL EXPOSURE COHORT

It was not possible for SC&A to review this document in time for this deliverable and SC&A plans to deliver this review as an addendum to this report.

4.4 ORAUT-PROC-0060: OCCUPATIONAL ONSITE AMBIENT DOSE RECONSTRUCTION

The review of ORAUT-PROC-0060, *Occupational Onsite Ambient Dose Reconstruction*, Rev. 01, dated June 28, 2006, was prepared by Stephen F. Marschke.

4.4.1 Purpose of the Procedure

The stated purpose of this procedure "is to provide direction … for the assignment of external dose from onsite ambient radiation …"

4.4.2 Review Protocol

As part of the first set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated ORAUT-OTIB-0007 *Occupational Dose from Elevated Ambient Levels of External Radiation*, Revision 0 (November 12, 2003). Our findings were published in *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, dated January 2005 (SCA-TR-Task3). Following the submission of this report and its findings, an expanded review and issues-resolution process was initiated. The process began by NIOSH providing written responses to each of SC&A's findings. Under the direction of a Board-appointed work group, a series of meetings was held between representatives of NIOSH and SC&A auditors to discuss and resolve each finding. This process resulted in the preparation of an issues-tracking matrix, whereby the closeout status of each finding is tracked.

As indicated in the issues tracking matrix, OTIB-0007 was replaced with ORAUT-PROC-0060, and the resolution of many findings identified during our review of OTIB-0007, Revision 0 were to be addressed with the issuance of PROC-0060. Our evaluation of PROC-0060, Revision 1, therefore, was designed to ensure that (1) the findings identified for OTIB-0007 were adequately resolved, and (2) the document adequately supports the dose reconstruction process. Table provides a list of applicable PROC-0003, Rev. 0 findings, the Board-recommended resolution ranking, and our evaluation to assess whether those findings were adequately addressed.

Table 4.4-1: Evaluation of Findings Identified in the Review of ORAUT-OTIB-0007

Review Objective	ORAUT-OTIB-0007, Rev. 00 Finding Description	Corrected in ORAUT-PROC-0060, Rev. 01?	Comments
1.0	Guidance in its current form is incomplete and does not provide sufficient data to account for EALER missed doses, as acknowledged in procedure. (OTIB-0007-01)	Yes	A workbook has been developed to assist the dose reconstructor in determining EALER doses. That workbook was reviewed by SC&A in the Task 3, Supplement 2 report.
4.1	Guidance provides no specific instruction on processing EALER missed dose for amending a claimant's exposure record (e.g., should EALER dose be assumed to be chronic or episodic). (OTIB-0007-02)	Yes	Attachment B provides site-specific EALER dose information.
4.1	OTIB provides no guidance for assessing shallow dose in cases involving skin cancer or surficial tissues such as the eye, testes, etc. (OTIB-0007-03)	No	PROC-0060 does not provide any information on EALER doses to the skin, eyes, testes, etc.
7.0	Amending OTIB to include necessary site-specific data is time consuming and undermines the efficiency process; the use of claimant-favorable default values may be more efficient method of accounting for EALER. (OTIB-0007-04)	Yes	Attachment B provides site specific EALER dose information.

As part of the second set of procedures/guidance documents selected by the Advisory Board for review, SC&A evaluated Revision 00 of ORAUT-PROC-0060 (March 7, 2005)[1]. Our single finding was published in *Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction, Supplement 1*, June 8, 2006. The finding from that first SC&A review is repeated below:

> *The method for maximum doses should address what the analyst should do when there is no data in the table in Attachment B. For example, what should the analyst do for someone who was at the Nevada Test Site (NTS) prior to 1963? The table has no doses listed for this site for the years prior to 1963. Should the analyst use the best-estimate approach?* (SC&A 2006, page 150)

SC&A's evaluation of PROC-0060 is summarized in Table, below. Table is a checklist containing the objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

[1] ORAUT-PROC-0060 was misidentified as ORAUT-OTIB-0060 in the Section 3.11 heading in SC&A's *Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction, Supplement 1*, June 8, 2006.

Table 4.4-2: ORAUT-PROC-0060 Review Outline/Checklist

Document No.: ORAUT-PROC-0060, Rev. 01	**Effective Date:** 06/28/2006
Document Title: Occupational Onsite Ambient Dose Reconstruction	
Auditor: Stephen F. Marschke	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	5	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	

Table 4.4-2: ORAUT-PROC-0060 Review Outline/Checklist

Document No.: ORAUT-PROC-0060, Rev. 01	**Effective Date:** 06/28/2006
Document Title: Occupational Onsite Ambient Dose Reconstruction	
Auditor: Stephen F. Marschke	

No.	Description of Objective	Rating 1-5*	Comments
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.4.3 Review Comments

Review Objective 1.5

The revision to PROC-0060 did not address the previous SC&A comment on this document, namely; "The method for maximum doses should address what the analyst should do when there is no data in the table in Attachment B."

Review Objective 7.3

A check of the Appendix B data produced the following results:

ANL-W — no problems identified.

Fernald — (1) a dose of 0.000 rem is reported for 1979; the correct value should be 0.338 rem, and (2) notes refer to TBD, Table 4-17, which is an error, should refer to TBD, Table B-1.

Hanford — (1) was able to reproduce the doses for years 1944 through 1981 and 1998 through 2003, by assuming a radiation measuring device under-response factor of 1.0, **not** 1.3 as specified in Section 6.2, and (2) was not able to reproduce the doses for years 1982 through 1997.

INEEL — Incorrect values for 1983–1997 (listed below), source of error unknown:

Year	Correct Value	Attachment B Value
1983	0.062	0.127
1984	0.073	0.027
1985	0.073	0.025
1986	0.073	0.027
1987	0.073	0.027
1988	0.073	0.027
1989	0.073	0.03
1990	0.028	0.027
1991	0.028	0.035
1992	0.028	0.031
1993	0.027	0.03
1994	0.025	0.036
1995	0.032	0.026
1996	0.019	0.026
1997	0.016	0.026

K-25 — All values listed as 0.130 Rem/y in document; this is rounded down from the calculated value of 0.13305 Rem/y (off by a factor of ~1.024)

LLNL — There is no Table 4-9 listed in the Occupational External Dose ORAUT-TKBS-0035-4; values are apparently calculated using Table 4-7 and simply multiplying by 1.3 without any correction for 2,600 hours per year. For 1976, the table lists the value of 0.121 Rem/y, which would be based on a TBD value of ~93; however, the TBD lists the value at 293 for 1976—the correct value should be .381

LANL — The treatment states that for the years 1943–1964, the highest value from 2001 should be used; however, these spaces are left blank in the table. Incorrect values were listed for the following years: 1974 should be 0.041 rem/y, 1976 should be .071 rem/y, 1995 should be 0.048 rem/y, and 2002 should be 0.046 rem/y

Mound — The value listed for 2003 is in Attachment B (same value as the previous 12 years); however, no value is given in Mound's Occupational Environmental Dose TBD (ORAUT-TKBS-0016-4) for that 2003. Value of 2.5 listed for 1944, correct value is 2.4.

In the TBD, in order to calculate a geometric standard deviation, the upper limit dose of 15 rem/yr is assigned to 1945–1948 as the 95th percentile dose (page 16). PROC-0060 then uses this 95th percentile dose as the maximizing external ambient dose. This is not consistent with 42 CFR 82.10(k)(3), which states, "Worst-case assumptions will be employed … only for claims

for which it is evident that further research and analysis will not produce a compensable level of radiation dose …?"

NTS — No problems identified.

PNNL — See Hanford.

PADGDP — No problems identified.

Pantex — No problems identified.

Pinellas — Utilizes the value of .001 rem based on the expected exposure to the general public of 77 mrem (36 mrem from rocks and soil, 40 mrem from cosmic radiation, 1 mrem from weapons testing).

PORGDP — 1994 value reads .061 rem, the correct value for 1994 is .047 rem, a value is listed in Attachment B for 2003, though no value exists in the TBD for this year

RFP — (1) TBD, Table 4-3 has a column titled '2σ' and a second column titled 'Recommended Value (1σ).' The TBD is not very clear as to what these two columns represent. A Table 4-3 footnote to one of the values in the '2σ' column identifies it as the '95% confidence limits' (which agrees with normal convention), while Section 4.4.2 refers to the 'Recommended Value (1σ)' column as the 'annual recommended values of uncertainty.' The Attachment B notes utilize the 'Recommended Value (1σ)' as if it were the standard deviation, and adds 2 times it to the mean to determine the 95th-percentile dose. This cannot be a correct interpretation of the 'Recommended Value (1σ)', because if it were, then the standard deviation would be greater than twice the standard deviation (e.g., σ = 39 versus 2σ = 5 for 1989). If the 'Recommended Value (1σ)' is actually a conservative (at 1σ) estimate of the dose received by a worker, then for 1989 it would be calculated via (2,000/8,760) × (Mean$_{1989}$ + 2σ$_{1989}$/2) = 0.228 × (167 + 5/2) = 39. Although for most (i.e., 13) of the years in TBD, Table 4-6, this equation can be used to reproduce the 'Recommended Value (1σ)', it does not produce the correct value for some of the years (i.e., 7).

(2) Similar to other sites that were evaluated at the 95th percentile (i.e., K-25 and Y-12), the equation given in the notes does <u>not</u> include the TLD under-response factor of 1.3, as specified in Section 6.2. No basis is provided for not using the ambient radiation measurement device under-response multiplication factor at the 95th percentile.

Weldon Spring — No problems identified.

ORNL (X-10) — Values are based on the correction factor of 1.3 and a 2,600-hour work year NOT the 2,500-hour work year stated in the "best estimates" section on X-10.

Y-12 — Correct value based on a 2,600-hour work year should be .335 Rem not .315 Rem.

SRS — The doses are given in TBD, Table 3.4-1, rather than in Appendix B. (1) The Table 3.4-1 doses were calculated from TBD, Table C-19, by adjusting from 40 to 50 hours per week (i.e., multiplying by 1.25). TBD, page 60, states that the Table C-19 values are based on 2,000 hr/yr.

Therefore, the adjustment factor should be (2,600/2,000 =) 1.3. (2) The Table 3.4-1 doses do not include the TLD under-response factor of 1.3, as specified in ORAUT-PROC-0060, Section 6.2, nor does it include a reason for not including the factor.

4.4.4 Workbooks

The External Ambient Dose Workbook 0.20 is a straightforward tool to retrieve the maximizing external ambient doses from PROC-0060, Attachment B. It prompts the user for inputs such as the work site, beginning and ending year of work, and the number of hours worked per year. The tool then retrieves the appropriate ambient external doses as prescribed by Attachment B, and formats them for entry into the IREP computer code. SC&A performed a review of the External Ambient Dose Workbook 0.20, and the results of that review have been included in the draft report, *Review of Nine General Dose Reconstruction Tools* (SCA-TR-TASK3, Supplement 2, April 2007).

4.4.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-OTIB-0007. 2003. *Occupational Dose from Elevated Ambient Levels of External Radiation*, Revision 0, Oak Ridge Associated Universities Team, Cincinnati, Ohio. November 12, 2003.

ORAUT-PROC-0003. 2003. *Internal Dose Reconstruction*, Rev. 0, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 1, 2003.

ORAUT-PROC-0060. 2006. *Occupational Onsite Ambient Dose Reconstruction*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. June 28, 2006.

ORAUT-TKBS-0035-4. 2005. *Lawrence Livermore National Laboratory – Occupational Environmental Dose*, Rev. 00, Oak Ridge Associated Universities, Cincinnati, Ohio. November 18, 2005.

ORAUT-TKBS-0016-04. 2004. *Technical Basis Document for the Mound Site – Occupational Environmental Dose*, Rev. 00. Oak Ridge Associated Universities, Cincinnati, Ohio. October 6, 2004.

ORAUT-TKBS-0011-4. 2004. *Rocky Flats Plant – Occupational Environmental Dose, Rev*. 01. Oak Ridge Associated Universities, Cincinnati, Ohio. June 29, 2004.

ORAUT-TKBS-0003. 2005. *Savannah River Site*, Rev. 03. Oak Ridge Associated Universities, Cincinnati, Ohio. April 5, 2005.

SC&A 2005. *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-Task3, S. Cohen and Associates, McLean, Virginia. January 2005.

SC&A 2006. *Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-TASK3 Supplement 1, Rev. 0, Draft Report, S. Cohen and Associates, Vienna, Virginia. June 8, 2006.

SC&A 2007. *Review of Nine General Dose Reconstruction Tools*, SCA-TR-TASK3, Supplement 2, S. Cohen and Associates, Vienna, Virginia. April 2007.

4.5 ORAUT-PROC-0086: CASE PREPARATION – COMPLEX INTERNAL DOSIMETRY CLAIMS

The review of ORAUT-PROC-0086, *Case Preparation – Complex Internal Dosimetry Claims*, Rev. 0, dated December 7, 2005, was prepared by Doug Farver, CHP, CSP.

4.5.1 Purpose of the Procedure

The procedure applies to Claim Preparers who examine the DOE Response file submitted by DOE sites, summarize, and record on spreadsheets the relevant radiological data.

4.5.2 Review Protocol

SC&A's evaluation of PROC-0086 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 4.5-1: ORAUT-PROC-0086 Review Outline/Checklist

Document No.: ORAUT-PROC-0086, Rev. 00	**Effective Date:** 12/07/2005
Document Title: Case Preparation – Complex Internal Dosimetry Claims	
Auditor: Doug Farver, CHP, CSP	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	

Table 4.5-1: ORAUT-PROC-0086 Review Outline/Checklist

Document No.: ORAUT-PROC-0086, Rev. 00	**Effective Date:** 12/07/2005
Document Title: Case Preparation – Complex Internal Dosimetry Claims	
Auditor: Doug Farver, CHP, CSP	

No.	Description of Objective	Rating 1-5*	Comments
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?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
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?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
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?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	

Table 4.5-1: ORAUT-PROC-0086 Review Outline/Checklist

Document No.: ORAUT-PROC-0086, Rev. 00	**Effective Date:** 12/07/2005
Document Title: Case Preparation – Complex Internal Dosimetry Claims	
Auditor: Doug Farver, CHP, CSP	

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)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.5.3 General Comments

PROC-0086 describes steps of the claim preparation process as it relates to the review of the EE's radiological data provided by DOE and contained in the CATI. The procedure applies primarily to the Claim Preparers and, to a lesser extent, the Dose Reconstructor Group Managers. Overall, the procedure provides a very systematic method to summarize and record the EE's radiological information on Excel spreadsheets. The six spreadsheets, Attachment A to the procedure, are easy to read and should provide a good overview of the EE's radiological work history.

4.5.4 Review Comments

Review Objective 1.1

The purpose of this procedure is stated as, "to define the methodology for reviewing Energy Employee (EE) records submitted by U.S. Department of Energy (DOE) sites for Dose Reconstructors to determine the most efficient approach to process claims filed by EEs." This is misleading since the procedure does not discuss efficient claims process approaches and the role of the Dose Reconstructor is very minimal in this procedure. This procedure strictly applies to the review and summary of the EE's records. NIOSH may wish to revise the purpose statement to more clearly describe the contents of the procedure. For example, a revised purpose statement might read:

> *The purpose of this procedure is to define the methodology for reviewing, summarizing, and consolidating Energy Employee (EE) information from records submitted by U.S. Department of Energy (DOE) sites.*

In fact, efficiency is only mentioned in the procedure scope and in Section 6.2.1.1 of the procedure, which mentions "Efficiency Tips" when describing information contained in the Excel spreadsheets. Also, neither the procedure nor any of the six spreadsheets contained in Attachment A of the procedure describe what is meant by "Efficiency Tips." NIOSH may wish to clarify what is meant by "Efficiency Tips" or simply delete the reference, since the term is not used any other place in the procedure.

One final observation concerns the note to Section 6.3.12.1 concerning the review of DOE incident investigation reports. In the note, NIOSH gives examples of what is and what is not considered to be an incident and should or shouldn't be entered into the spreadsheet. From the procedure:

> *Incidents that should be noted in the appropriate area on the spreadsheet include clothing and skin contaminations, any report of incident or investigation noted in the DOE Response file, and any inhalation exposure.*

It would be prudent to include any mention, medical, or operations report, related to a wound. It is quite common for an employee to work at several different site locations during a day, week, month, etc. So the employee could sustain a wound (i.e., lacerated finger) a in non-radiological location in the morning and may be working in a radiological location that afternoon or the next day. Documenting the wound information could help the Dose Reconstructor determine work location or intake date.

4.5.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

ORAUT-PROC-0086. 2005. *Case Preparation – Complex Internal Dosimetry Claims*, Rev. 0, Oak Ridge Associated Universities Team, Cincinnati, Ohio. December 7, 2005.

4.6 ORAUT-PROC-0094: VERIFICATION AND VALIDATION PROCESS FOR TOOLS DEVELOPMENT GROUP

This review of ORAUT-PROC-0094, *Verification and Validation Process for the Tools Development Group*, Rev. 00, January 5, 2006, was prepared by Stephen L. Ostrow, PhD.

4.6.1 Purpose of the Procedure

The stated purpose of this procedure is as follows:

> *…to establish the verification and validation (V&V) process for software tools created by the Tools Development Group (TDG) of the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH) for the purpose of conducting dose reconstruction* (Section 1.0).

As also noted, the "V&V process applies to all software tools used in the dose reconstruction (DR) process and developed by the TDG, or software tools developed by individuals outside the TDG that ask the TDG to sanction a tool for general use" (Section 2.0). Furthermore, "Implementation of this procedure shall constitute a quality review process as that terminology is defined by ORAUT-PLAN-0001, Quality Assurance Program (QAP)" (Section 2.0).

4.6.2 Review Protocol

The subject procedure lists the ORAU Quality Assurance Program (ORAUT-PLAN-0001) as a driver (Section 8.1); hence the procedure (which is administrative rather than technical) is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review, Section 3.0 provides general comments on the document, and Section 4.0 presents specific comments.

4.6.3 General Comments

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure. Several attachments are also appended to the procedure. Notably, Attachment D is a detailed flowchart of the entire V&V process for different integrity levels (0–4) of software.

Table 4.6-1: ORAUT-PROC-0094 QA-Document Compliance Checklist

Document No.: ORAUT-PROC-0094, Rev. 00	**Effective Date:** January 5, 2006
Document Title: Verification and Validation Process for the Tools Development Group	
Reviewer: Stephen L. Ostrow, PhD	

No.	Question	Y/N	Comments
1.0	**Quality Assurance Program Plan (QAPP)**		
1.1	Have the organizations originating the procedures and related documents established a QA program appearing in a Quality Assurance Program Plan (QAPP), and do the implementing documents reflect higher-level regulatory and project requirements and nuclear industry good practices?	N/A	

Table 4.6-1: ORAUT-PROC-0094 QA-Document Compliance Checklist

Document No.: ORAUT-PROC-0094, Rev. 00	**Effective Date:** January 5, 2006
Document Title: Verification and Validation Process for the Tools Development Group	
Reviewer: Stephen L. Ostrow, PhD	

No.	Question	Y/N	Comments
1.2	When more than one organization is involved in the execution of activities, are the responsibilities and authorities of each organization clearly established in the QAPP to the extent necessary to smoothly perform the activities?	N/A	
1.3	Does the QAPP identify the management position responsible for QA development, implementation, assessment, and improvement?	N/A	
1.3.1	Are there adequate procedures for assuring that personnel performing project tasks have proper levels of experience and education?	N/A	
1.4	Are there adequate procedures for training of project personnel?	N/A	
1.4.1	Have staff training requirements been identified?	N/A	
1.4.2	Has staff received general orientation training?	N/A	
1.4.3	Has staff received training in the requirements of the Privacy Act of 1974 and the Freedom of Information Act?	N/A	
1.4.4	Has staff received training in the provisions of the QAPP?	N/A	
1.4.5	Is a master record of staff training maintained in project files?	N/A	
1.5	Are there adequate procedures for Management and QA surveillance, inspection, and audit of work products and processes to achieve continuous quality improvement?	N/A	
1.6	Do procedures provide for adequate corrective action for identified deficiencies and non-conformances in work products and processes?	N/A	
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?	N/A	
1.8	Are there procedures covering all work activities of the project?	N/A	
2.0	**Individual Procedures and Documents**		
2.1	Is the procedure or document properly identified by title, document number, revision number, and date?	Y	

Table 4.6-1: ORAUT-PROC-0094 QA-Document Compliance Checklist

Document No.: ORAUT-PROC-0094, Rev. 00	**Effective Date:** January 5, 2006
Document Title: Verification and Validation Process for the Tools Development Group	
Reviewer: Stephen L. Ostrow, PhD	

No.	Question	Y/N	Comments
2.2	Do the title, document number, revision number, page number, and date appear on each page?	N	Title appears only on the first page; however, the other items appear on each page and unambiguously identify the document.
2.3	Has the procedure been reviewed and approved by an independent reviewer familiar with the subject matter?	Y	Written by the Task 5 Manager and reviewed and approved by the Tools Development Group Leader and the Project Director
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	
2.5	Are revisions clearly indicated on affected pages?	N/A	This is Rev. 00
2.6	Are all abbreviations, acronyms, and technical terms, which may not be generally known by the average reader, adequately defined in the text or in a separate section?	Y	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
2.7	Are all scientific and engineering constants, values, equations, and assumptions, which may not be known by the average reader, clearly presented and referenced?	N/A	The procedure is "administrative," not "technical."

4.6.4 Review Comments

The Dose Reconstruction Submittal procedure provides adequate guidance to ORAU to conduct and document V&V of software tools. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) The procedure considers software categorized into five different integrity levels, ranging from minor cosmetic changes to existing software (Level 0) to development of complex technical programs (Level 4) and, appropriately requires different degrees of V&V for each level. This categorization allows application of the appropriate level of V&V to a software tool and is consistent with taking a "graded approach" to QA.

(2) Section 5.1 reiterates the statement of Section 2.0, by saying that "All computer tool V&V tests performed under this procedure shall constitute quality reviews pursuant to

ORAUT-PLAN-0001, Quality Assurance Program" and lists eight attributes of a quality review. The subject procedure successfully covers all eight attributes.

(3) The ORAUT Quality Assurance Program Plan (QAPP) states: "All Project-designed algorithms and databases shall be developed, tested, and controlled in accordance with ORAUT-PLAN-0003, Information Systems Quality Assurance Plan ..." (ORAUT-PLAN-0001, Rev. 1, January 31, 2005, Section 6.11.2). It appears that ORAUT-PLAN-0003 applies to ORAUT-PROC-0094 (since the QAPP uses "all"), but the latter neither references nor indicates how it complies with the applicable requirements of the former. If ORAUT does not intend the software tools covered in the subject procedure to be covered by ORAUT-PLAN-0003, then it should state its reasoning to avoid possible confusion.

(4) The subject procedure is inconsistent in its references to the title of ORAUT-PLAN-0001, sometimes calling it the Quality Assurance Program and sometimes the Quality Assurance Program Plan. It should be noted that ORAUT-PLAN-0001 is entitled Quality Assurance Program, but also refers to itself as the Quality Assurance Program Plan (QAPP). This is a minor inconsistency since the use of the alternative forms does not result in any confusion or ambiguity.

(5) Attachment D, Verification and Validation Process for the Tools Development Group, is a very useful, multi-page flowchart that can guide the user of the subject procedure through the many V&V steps and branches. Unfortunately, the flowchart does not appear to be referenced in the body of the text where it would be most beneficial. It should be referenced in the beginning of Section 6.0, Procedure.

(6) While the Attachment D flowchart and the text of Section 6.2.2.3 clearly show a branch point in the subject procedure, depending on whether the Tools Development Group Manager determines that a software tool in integrity level 2 requires ORAUT-FORM-0054 (go to Section 6.4) or a test plan (go to Section 6.10), Sections 6.4 and 6.10 do not mention this distinction. Section 6.4 states: "NOTE: This is the beginning of the steps for verifying and validating a software integrity level of 1 or 2." The note should also say that it applies to level 2 only, if it has been determined that ORAUT-FORM-0054 is required rather than a test plan. Section 6.10 states: "NOTE: This is the beginning of the steps for verifying and validating software integrity levels of 2, 3, or 4." This note should also say that it applies to level 2 only, if it has been determined that a test plan rather than ORAUT-FORM-0054 is required.

(7) Section 5.3.1, for software under integrity level 2, states that "the test plan [if required] for future revisions will test only the additions/changes made to the lookups and will reference prior test plans," and Section 5.3.2, for software under Integrity Levels 3 or 4, states that "test plans for future revisions need only test the items that the change in the software affected." The requirement to test only changes made is not good practice, since, not infrequently, software development adheres to the "rule of unintended consequences," whereby a change in one part of the program inadvertently affects seemingly unrelated parts of the code. Hence, ORAU should at least spot check the performance of the entire software tool whenever any changes are made; this requirement should be in the procedure.

4.6.5 References

ORAUT-FORM-0054. 2007. *Lower Integrity Level Review.* Rev. 02. Oak Ridge Associated Universities, Cincinnati, Ohio. January 31, 2007.

ORAUT-PLAN-0001. 2007. *Quality Assurance Program Plan.* Rev. 03. Oak Ridge Associated Universities, Cincinnati, Ohio. July 31, 2007.

ORAUT-PLAN-0003. 2005. *Information Systems Quality Assurance Plan*, Rev. 00. PC-1. Oak Ridge Associated Universities, Cincinnati, Ohio. November 18, 2005.

ORAUT-PROC-0094. 2006. *Verification and Validation Process for the Tools Development Group,* Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 5, 2006.

SC&A 2004. *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures*, Rev. 0, Draft, S. Cohen and Associates, McLean, Virginia. April 12, 2004.

4.7 ORAUT-PROC-0095: GENERATING SUMMARY STATISTICS FOR COWORKER BIOASSAY DATA

The review of ORAUT-PROC-0095, *Generating Summary Statistics for Coworker Bioassay Data*, Rev. 00, dated June 5, 2006, was prepared by Harry Chmelynski, PhD.

4.7.1 Purpose of the Procedure

This procedure describes the processes for converting coworker bioassay data into a usable analytical format, calculating statistics on the data, and validating the analyses for subsequent intake modeler use and, ultimately, for internal dose reconstruction use. The procedure applies only to bioassay data from coworkers and does not address coworker external dosimetry data. More detailed descriptions of the recommended statistical procedures are found in ORAUT-OTIB-0019, which is incorporated by reference in the scope of this procedure.

4.7.2 Review Protocol

SC&A's evaluation of PROC-0095 is summarized in Table, below. Table is a checklist containing objectives that SC&A developed to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 4.7-1: ORAUT-PROC-0095 Review Outline/Checklist

Document No.: ORAUT-PROC-0095, Rev. 00	**Effective Date:** 06/05/2006
Document Title: Generating Summary Statistics for Coworker Bioassay Data	
Auditor: Harry Chmelynski, PhD	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
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?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data.**		
3.1	Assess quality of data collected via interviews:	-----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Adequacy and use of site-specific data pertaining to:	-----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In-vivo/In-vitro bioassays	5	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	

Table 4.7-1: ORAUT-PROC-0095 Review Outline/Checklist

Document No.: ORAUT-PROC-0095, Rev. 00	**Effective Date:** 06/05/2006
Document Title: Generating Summary Statistics for Coworker Bioassay Data	
Auditor: Harry Chmelynski, PhD	

No.	Description of Objective	Rating 1-5*	Comments
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?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
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)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	5	
7.0	**Assess procedures for striking a balance between technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	4	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.7.3 General Comments

The purpose of ORAUT-PROC-0095 is to provide guidance for converting coworker bioassay data into a usable format, calculating summary statistics on the data, and validating the data for use by the intake modeler. The recommended statistical methods are designed to provide estimates of lognormal distribution parameters based on available coworker data. This procedure assumes site bioassay data are available in readable format. The product of the procedure is a series of validated statistical results for use in intake modeling. Individuals responsible for performing the analyses include (1) Site Team Leader, (2) Subject Matter Expert, (3) Coworker Bioassay Statistics Team Leader, (4) Statistics Analyst, and (5) Statistics Validator. The procedure requires that the roles of Statistical Analyst and the Statistics Validator be performed by different individuals.

The proposed procedure provides detailed instructions for three data analysis steps: (1) preparing the data in a usable format for subsequent analysis; (2) generating estimates of the 50^{th} and 84^{th} percentiles, geometric mean (GM) and the geometric standard deviation (GSD) from the available data; and (3) validating the analysis. After data preparation, which includes

treatment of censored data and outliers, two statistical methodologies are recommended in the procedure for determining the 50th and 84th percentiles of the data. The first method is based on a simple ranking of the data. The second method is a regression method based on assumption of a lognormal distribution. The regression approach provides a second set of estimates of the 50th and 84th percentiles, as well as estimates of the GM and GSD of the fitted lognormal distribution.

In this application, censored data refers to measurements below the Minimum Detection Limit (MDL) established for the laboratory analytical procedure used for collecting the data. Many of these data sets include data entries recorded as below the MDL, or data entries that are recorded as zero, or "less than x." The estimation of lognormal distribution parameters is complicated by the common occurrence of missing data and/or censored data. Several alternatives are suggested in Section 6.2.1.2 of the procedure for handling censored data. The suggested procedures are reviewed in more detail in the following section of this review.

4.7.4 Review Comments

Review Objective 1.5

The procedure addresses the problem of "outliers," although the term outlier is not used explicitly by the authors. Section 6.2.1.3 of the procedure suggests that the analyst:

> *Deletes, as the Site Team Leader directs, abnormal data such as known errors or results that have been determined to be nonrepresentative of the exposure conditions (e.g., a sample contaminated in the laboratory).*

No additional guidance is provided for performing the very subjective task of identifying known errors and/or nonrepresentative data points. The procedure does require in Section 6.2.1.4 that all deletions or modifications of the data be documented in the OTIB. Specific procedures for identifying and handling erroneous and/or nonrepresentative data should be identified in the procedure.

Review Objective 6.1

The regression method proposed in the procedure for a data set of size *n* is written as follows:[2]

$$\ln(y_i) = m\, x_i + b$$

The symbols y_i (i = 1, ... , r n) denote the *r* data values above the MDA (i.e., not including the "less than" values) with corresponding normal scores $x_i = \Phi^{-1}[\,(R_i - 0.5)/n]$ for i = 1, ... , r n. The symbols *b* and *m* denote the y-intercept and slope of the regression line, respectively. Here $\Phi^{-1}[\bullet]$ denotes the inverse of the cumulative normal distribution function, and R_i is the rank of the data y_i when all *n* data values are included in the ranking and the *(n-r)* values below the MDA are assigned the lowest *(n-r)* ranks. If the data fit a lognormal distribution where the logs have mean μ and standard deviation σ, then a scatter plot of the *r* points $(x_i , \ln(y_i))$ will lie on a

[2] It is far more common to use the symbol z_i for the normal score variate, but the use of x_i as the explanatory variable in a regression takes priority in this discussion.

straight line with slope $m = \sigma$ and a y-intercept $b = \mu$. It is easily shown that the geometric mean of the lognormal distribution is e^{μ} and the GSD is e^{σ}.

The regression method may be used not only to verify that the data follow a lognormal distribution, but also to provide alternative estimates for the parameters of the lognormal distribution when there are values in the data set below the MDA. Since the regression estimates are based on the entire set of data above the MDA, they may be preferred over estimates obtained by ranking the data. This is particularly true for the estimate of the GSD, which is based on the ratio of the 84^{th} to the 50^{th} percentiles when using the minimal information method.

A determination of the goodness-of-fit of a lognormal distribution to a data set of size n is to be based on regression analysis. Specifically, the following recommendations are made in Section 3.4 of ORAUT-OTIB-0019:

> *Calculate the associated R^2 fit parameter. A value greater than 0.9 indicates a very good fit; however, values as low as 0.7 are acceptable, and even lower values may be acceptable if no better equation seems appropriate.*

It is difficult to determine the source and applicability of the OTIB recommendations regarding goodness of fit. Our concerns are based on the known dependencies that exist in the regression estimates derived from ranked data.

When the points in the scatterplot do not all lie on a straight line, it is recommended that the R^2 of the regression be examined to determine if the data are fitted approximately by a lognormal distribution. However, ORAUT-OTIB-0019 fails to warn the investigator that the R^2 of this regression should be interpreted with care. The data values in the scatterplot are not independent observations. Indeed, if it is known that $x_i \leq x_j$, then it is also known that $y_i \leq y_j$. This dependence among the observations violates the usual assumption of conditional independence of the y values in the regression, given the set of x values.

In general, the interpretation of R^2 when there is known conditional dependence and censored data is not a simple matter. As a result of the dependency, the observed R^2 value may be seriously over-inflated. The subject was explored by Looney and Gulledge (1985). Using a very similar scatterplot and regression-model approach to estimate the parameters of a normal distribution, they provide tables based on simulation studies that may be used to adjust the observed R^2 values to account for conditional dependence (with no censored data). Extrapolation to the censored data case does not appear to be a straightforward extension of their results and is deserving of further study.

The recommendations quoted above from Section 3.4 of ORAUT-OTIB-0019 for interpreting the regression R^2 do not appear to take this serious deviation from the standard regression model assumptions into account. Note that the conditional dependence does not result in biased regression parameter estimates for μ and σ, only the interpretation of the R^2 value as a goodness-of-fit statistic. Hence, the regression estimates remain as a valid "reality check" for the minimal information parameter estimates currently recommended.

Review Objective 7.3

The procedure does not address the use of well-known maximum likelihood method (Cohen 1959 and Cohen 1961) for estimating the parameters of the lognormal distribution using censored data. The proposed regression procedure is not the most efficient methods for estimating lognormal parameters (Aitchison and Brown 1957), but is designed to provide valid parameter estimates over a relatively large number of disparate data sets. The regression method recommended in the procedure for estimating lognormal parameters is much easier to implement than the maximum likelihood method, and provides approximate parameter estimates when fitting the lognormal distribution to a large number of censored data sets. With relatively large data sets, the parameter estimates generated using the recommended regression method should differ only slightly from the maximum likelihood method.

The regression method proposed in the procedure for estimating lognormal parameters does not require that specific values be assigned for missing values and/or "less than" data. However, the procedure does provide the following recommendation for the development of replacement values for censored data:

> *6.2.1.2 Determines if the data have been censored (by consulting the Site Team Leader's instructions) and follows the Team Leader's instructions for handling such data.*
>
> > *NOTE: If the data are censored, rank all the data, but fit only the uncensored data unless directed to substitute a linear distribution (or another approved distribution) of values for the censored data. Methods for handling censored data may include deleting the data, using the data as presented, replacing the data with an appropriate distribution, or some other action that allows the full data set to be used. One method for handling censored data includes substituting a linear distribution as described here. The linear distribution is of the form, 1*C/n, 2*C/n, …, n*C/n, where C is the cutoff value for the censored data and n is the number of censored values. This linear distribution has an average equal to one-half the censored value. Other distributions or data substitutions may be used with the approval of the Site Team Leader and the Subject Matter Expert. In some cases, it might not be possible to determine the censoring value and, therefore, it might not be possible to substitute a distribution. In such cases, zeros or less-than values in the database may be used as the Site Team Leader directs.*

The use of a linearly spaced distribution of values as substitute values for measurements below the MDL is illustrated for a hypothetical case in Figure, below. The blue symbols represent a sample of 50 data points from a lognormal(0,1) distribution. For this illustration, the lowest 11 data points are considered censored (i.e., below the MDL). The open circles at the lower left of Figure represent 11 substitute values developed using the linearly spaced distribution. Note that the substitute values fall below the original data points, indicating that use of the linearly spaced substitute values is not claimant favorable. This recommendation should be removed from the procedure.

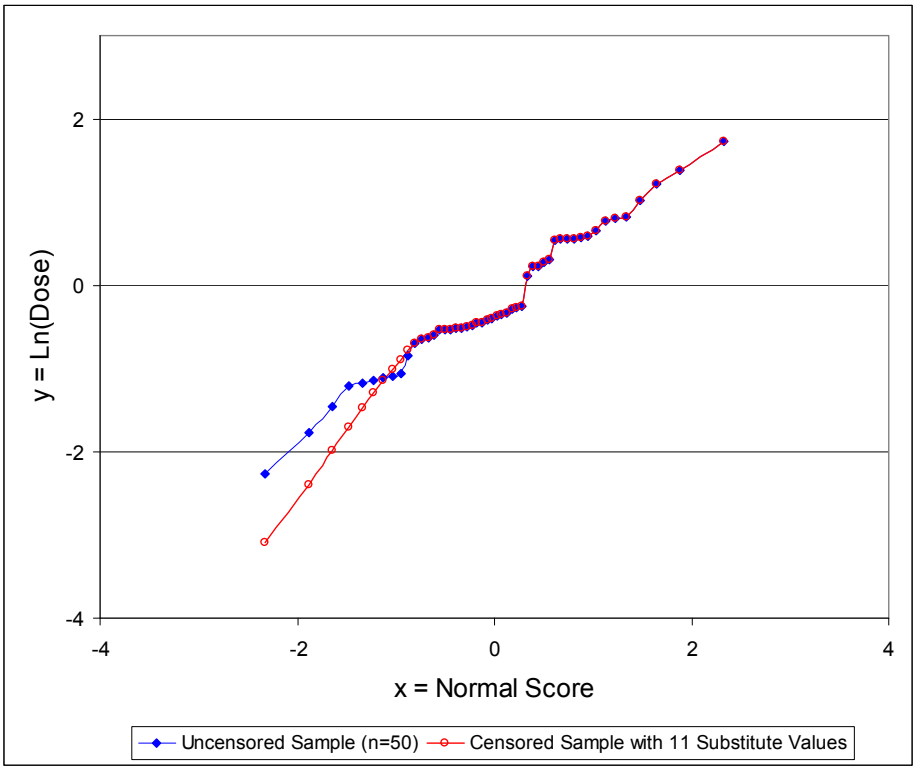

Figure 4.7-1: Comparison of Uncensored Data from a Lognormal(0,1) Distribution versus Censored Distribution with a Linear Distribution of Values Substituted for Censored Data

4.7.5 References

42 CFR 82. 2002. *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002.

Aitchison, J., and J. A. C. Brown, 1957. *The Lognormal Distribution*, Cambridge University Press, Cambridge, U.K., p..91.

Cohen, A. Clifford, Jr., 1959. "Simplified Estimators for the Normal Distribution When Samples are Singly Censored or Truncated," Technometrics, Vol. 1, No. 3 (August), pp. 217–237.

Cohen, A. Clifford, Jr., 1961. "Tables for Maximum Likelihood Estimates: Singly Truncated and Singly Censored Samples," Technometrics, Vol. 3, No. 4 (November), pp. 535–541.

Looney, Stephen W., and Thomas R. Gulledge, Jr., 1985. "Use of the Correlation Coefficient with Normal Probability Plots," American Statistician, Vol. 39, No. 1 (Feb.), pp. 75–79.

ORAUT-OTIB-0019. 2005. *Technical Information Bulletin: Analysis of Coworker Bioassay Data for Internal Dose Assignment*, Rev. 00, October 7, 2005. Oak Ridge Associated Universities Team, Cincinnati, Ohio.

ORAUT-PROC-0095. 2006. *Generating Summary Statistics for Coworker Bioassay Data*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. June 5, 2006.

4.8 ORAUT-PROC-0096: CLAIMANT COMMUNICATIONS QUALITY CONTROL PROCESS

This review of ORAUT-PROC-0096, *Claimant Communications Quality Control Process*, Rev. 00, March 3, 2006, was prepared by Stephen L. Ostrow, PhD.

4.8.1 Purpose of the Procedure

The stated purpose of this procedure is as follows:

> *… to provide instruction for performing quality control (QC) checks for the various Task 4 claimant communications functions of the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute of Occupational Safety and Health (NIOSH) to ensure timely transfer, completeness, and accuracy of data"* (Section 1.0).

As also noted, the "procedure applies to Project personnel involved in Task 4 claimant communications functions" (Section 2.0).

4.8.2 Review Protocol

The subject procedure lists the ORAU Quality Assurance Program (ORAUT-PLAN-0001) as a driver (Section 8.1); hence the procedure (which is administrative rather than technical) is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review, Section 3.0 provides general comments on the document, and Section 4.0 presents specific comments.

Table 4.8-1: ORAUT-PROC-0096 QA-Document Compliance Checklist

Document No.: ORAUT-PROC-0096, Rev. 0	**Effective Date:** March 3, 2006
Document Title: Claimant Communications Quality Control Process	
Reviewer: Stephen L. Ostrow, PhD	

No.	Question	Y/N	Comments
1.0	**Quality Assurance Program Plan (QAPP)**		
1.1	Have the organizations originating the procedures and related documents established a QA program appearing in a Quality Assurance Program Plan (QAPP), and do the implementing documents reflect higher-level regulatory and project requirements and nuclear industry good practices?	N/A	

Table 4.8-1: ORAUT-PROC-0096 QA-Document Compliance Checklist

Document No.: ORAUT-PROC-0096, Rev. 0	**Effective Date:** March 3, 2006
Document Title: Claimant Communications Quality Control Process	
Reviewer: Stephen L. Ostrow, PhD	

No.	Question	Y/N	Comments
1.2	When more than one organization is involved in the execution of activities, are the responsibilities and authorities of each organization clearly established in the QAPP to the extent necessary to smoothly perform the activities?	N/A	
1.3	Does the QAPP identify the management position responsible for QA development, implementation, assessment, and improvement?	N/A	
1.3.1	Are there adequate procedures for assuring that personnel performing project tasks have proper levels of experience and education?	N/A	
1.4	Are there adequate procedures for training of project personnel?	N/A	
1.4.1	Have staff training requirements been identified?	N/A	
1.4.2	Has staff received general orientation training?	N/A	
1.4.3	Has staff received training in the requirements of the Privacy Act of 1974 and the Freedom of Information Act?	N/A	
1.4.4	Has staff received training in the provisions of the QAPP?	N/A	
1.4.5	Is a master record of staff training maintained in project files?	N/A	
1.5	Are there adequate procedures for Management and QA surveillance, inspection, and audit of work products and processes to achieve continuous quality improvement?	N/A	
1.6	Do procedures provide for adequate corrective action for identified deficiencies and non-conformances in work products and processes?	N/A	
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?	N/A	
1.8	Are there procedures covering all work activities of the project?	N/A	
2.0	**Individual Procedures and Documents**		
2.1	Is the procedure or document properly identified by title, document number, revision number, and date?	Y	

Table 4.8-1: ORAUT-PROC-0096 QA-Document Compliance Checklist

Document No.: ORAUT-PROC-0096, Rev. 0	**Effective Date:** March 3, 2006
Document Title: Claimant Communications Quality Control Process	
Reviewer: Stephen L. Ostrow, PhD	

No.	Question	Y/N	Comments
2.2	Do the title, document number, revision number, page number, and date appear on each page?	N	Title appears only on the first page; however, the other items appear on each page and unambiguously identify the document.
2.3	Has the procedure been reviewed and approved by an independent reviewer familiar with the subject matter?	Y	Written by the Task 4 Manager and reviewed and approved by the Project Director and the Health Science Administrator.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	
2.5	Are revisions clearly indicated on affected pages?	N/A	This is Rev. 00.
2.6	Are all abbreviations, acronyms, and technical terms, which may not be generally known by the average reader, adequately defined in the text or in a separate section?	Y	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
2.7	Are all scientific and engineering constants, values, equations, and assumptions, which may not be known by the average reader, clearly presented and referenced?	N/A	The procedure is "administrative," not "technical."

4.8.3 General Comments

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure for performing QC checks, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure.

4.8.4 Review Comments

The subject procedure provides adequate instructions to ORAU to perform QC checks of Task 4 claimant communications functions, including CATI, close-out interviews, and dose reconstruction submittals. Responsibilities are clearly delineated and the reader is taken through the various processes step-by-step. Many useful graphics (computer screen shots) are included

to illustrate what the user of a computer system should see. The procedure also references ORAUT-PROC-0079 for proper handling of records covered by the Privacy Act.

4.8.5 References

ORAUT-PLAN-0001. 2007. *Quality Assurance Program Plan,* Rev. 03, Oak Ridge Associated Universities, Cincinnati, Ohio. July 31, 2007.

ORAUT-PROC-0096. 2006. *Claimant Communications Quality Control Process,* Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. March 3, 2006.

ORAUT-PROC-0079. 2004. *Protecting Privacy Act Data,* Rev. 00,

SC&A 2004. *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures*, Rev. 0, Draft, S. Cohen and Associates, McLean, Virginia. April 12, 2004.

4.9 ORAUT-PROC-0097: CONDUCT OF WORKER OUTREACH PROGRAM

It was not possible for SC&A to review this document in time for this deliverable and SC&A plans to deliver this review as an addendum to this report.